

**Date and Time:** Tuesday 1 October 2024 00:13:00 CEST

**Job Number:** 234830415

**Documents (28)**

1. [*The Moral Voice of Corporate America*](https://advance.lexis.com/api/document?id=urn:contentItem:5P93-HGC1-DYR7-C363-00000-00&idtype=PID&context=1516831)

**Client/Matter:** -None-

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| News | Tijdlijn: jun 01, 2017 tot jun 01, 2018; Locatie: International; Plaats van publicatie: Europe; Taal: English; Taal: English |

2. [*Anti-system Contentions and Authoritarian Response in China: Evolution and Mechanisms*](https://advance.lexis.com/api/document?id=urn:contentItem:6BH2-VXY1-JBMY-H41T-00000-00&idtype=PID&context=1516831)

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3. [*Washington: EXECUTIVE CALENDAR*](https://advance.lexis.com/api/document?id=urn:contentItem:5RCR-XKM1-F0YC-N05V-00000-00&idtype=PID&context=1516831)

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4. [*Pat Kane: Here's why we ALL need to fight to protect Brand Scotland*](https://advance.lexis.com/api/document?id=urn:contentItem:5PW7-5P11-JD39-X0HF-00000-00&idtype=PID&context=1516831)

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5. [*TOP NEWS SUMMARY: Standard Life Profit Rises Ahead Of Aberdeen Merger*](https://advance.lexis.com/api/document?id=urn:contentItem:5P6G-PPT1-DXW0-C00C-00000-00&idtype=PID&context=1516831)

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6. [*Summary of Russian press for Friday 13 April 2018*](https://advance.lexis.com/api/document?id=urn:contentItem:5S64-BR71-DYRV-34GT-00000-00&idtype=PID&context=1516831)

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7. [*Social climbers SOCIAL MEDIA TECHNOLOGY ; The recent Facebook scandal over illicitly distributed personal data has thrust social media into the spotlight, but banking is a sector that faces stringent compliance over privacy. So how are US banks using social media channels to best engage customers and promote their business? Jane Monahan reports.*](https://advance.lexis.com/api/document?id=urn:contentItem:5S7T-YHR1-DY9P-N2V0-00000-00&idtype=PID&context=1516831)

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8. [*BRIEF NEWS BULLETIN NO. 10275*](https://advance.lexis.com/api/document?id=urn:contentItem:5R5C-3PM1-JDKJ-10XD-00000-00&idtype=PID&context=1516831)

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| News | Tijdlijn: jun 01, 2017 tot jun 01, 2018; Locatie: International; Plaats van publicatie: Europe; Taal: English; Taal: English |

9. [*Summary of Russian press for Friday 2 June 2017*](https://advance.lexis.com/api/document?id=urn:contentItem:5NP6-0651-JC8S-C2GJ-00000-00&idtype=PID&context=1516831)

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10. [*Brand tribalism in technology and sport: determinants and outcomes*](https://advance.lexis.com/api/document?id=urn:contentItem:673K-K021-JCWX-C02X-00000-00&idtype=PID&context=1516831)

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11. [*Acquirer-to-target relatedness and target country unfamiliarity in acquisitions*](https://advance.lexis.com/api/document?id=urn:contentItem:5V6X-0HW1-JB00-310G-00000-00&idtype=PID&context=1516831)

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12. [*P8\_TA(2015)0410 Prevention of radicalisation and recruitment of European citizens by terrorist organisations European Parliament resolution of 25 November 2015 on the prevention of radicalisation and recruitment of European citizens by terrorist organisations (2015/2063(INI))*](https://advance.lexis.com/api/document?id=urn:contentItem:5PX3-MST1-JDG9-Y281-00000-00&idtype=PID&context=1516831)

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13. [*Managing menu innovation in a saturated market: An empirical evidence from the Chain restaurants in Malaysia*](https://advance.lexis.com/api/document?id=urn:contentItem:6BM4-FYP1-JBMY-H00M-00000-00&idtype=PID&context=1516831)

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14. [*Doing Politics in the Recent Arab Uprisings: Towards a Political Discourse Analysis of the Arab Spring Slogans*](https://advance.lexis.com/api/document?id=urn:contentItem:6BH2-VXY1-JBMY-H3YR-00000-00&idtype=PID&context=1516831)

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15. [*MPs discuss huge scale of Grenfell Tower inquiry - Politics live Rolling coverage of the day's political developments as they happenDowning Street lobby briefing - SummaryLunchtime summaryEarly evening summary*](https://advance.lexis.com/api/document?id=urn:contentItem:5SB0-95P1-JCJY-G3VN-00000-00&idtype=PID&context=1516831)

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16. [*Council of the European Union: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the internal market for electricity (recast) ST 10681 2017 INIT*](https://advance.lexis.com/api/document?id=urn:contentItem:5R18-T1B1-JDG9-Y33X-00000-00&idtype=PID&context=1516831)

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17. [*BRIEF NEWS BULLETIN NO. 10398*](https://advance.lexis.com/api/document?id=urn:contentItem:5S3D-P111-F12K-R0HR-00000-00&idtype=PID&context=1516831)

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18. [*The Human Conditioning: International Law and Science-Fiction*](https://advance.lexis.com/api/document?id=urn:contentItem:6BNK-CF41-DY41-72F3-00000-00&idtype=PID&context=1516831)

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19. [*FEDERAL REGISTER: Assessment and Collection of Regulatory Fees for Fiscal Year 2017 Pages 26019 - 26041 [FR DOC # 2017-11578]*](https://advance.lexis.com/api/document?id=urn:contentItem:5P52-B0C1-JDG9-Y3CB-00000-00&idtype=PID&context=1516831)

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20. [*Register of Commission documents: Proposal for a Regulation of the European Parliament and of the Council on ENISA, the "EU Cybersecurity Agency", and repealing Regulation (EU) 526/2013, and on Information and Communication Technology cybersecurity certification (''Cybersecurity Act'') Document date: 2017-09-13 COM\_COM(2017)0477 COM documents*](https://advance.lexis.com/api/document?id=urn:contentItem:5PX4-DD71-JDG9-Y3CC-00000-00&idtype=PID&context=1516831)

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21. [*Cambridge Analytica : How the scandal unfolded*](https://advance.lexis.com/api/document?id=urn:contentItem:5RXR-0TD1-JCJY-G15B-00000-00&idtype=PID&context=1516831)

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22. [*European Union (Withdrawal) Bill.*](https://advance.lexis.com/api/document?id=urn:contentItem:5RS0-CGM1-JDG9-Y429-00000-00&idtype=PID&context=1516831)

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23. [*FEDERAL REGISTER: Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S Navy Marine Structure Maintenance and Pile Replacement in Washington*](https://advance.lexis.com/api/document?id=urn:contentItem:5RTH-M8K1-JDG9-Y076-00000-00&idtype=PID&context=1516831)

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24. [*Australia legalises same-sex marriage - politics live MPs agree to legalise same-sex marriage after marathon campaign. Follow here for all the day's events*](https://advance.lexis.com/api/document?id=urn:contentItem:5R44-XW11-JCJY-G4WP-00000-00&idtype=PID&context=1516831)

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25. [*Tower Hamlets final council to declare - as it happened Electoral Reform Society releases figure as local elections in England bring mixed results for main partiesLocal council election results 2018 - in fullEarly morning summaryHow the night unfolded in key races*](https://advance.lexis.com/api/document?id=urn:contentItem:5S7P-GBT1-F021-63DD-00000-00&idtype=PID&context=1516831)

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26. [*Federal budget and dual citizenship: four MPs quit after high court ruling - as it happened Labor grills government over tax plan, while reeling over resignations sparked by Katy Gallagher being ruled ineligible. Follow all the day's events, liveSign up to receive the latest news in Australian politics every weekday*](https://advance.lexis.com/api/document?id=urn:contentItem:5S8S-GW71-F021-653W-00000-00&idtype=PID&context=1516831)

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27. [*FEDERAL REGISTER: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Pages 56336 - 56527 [FR DOC # 2017-25068]*](https://advance.lexis.com/api/document?id=urn:contentItem:5R2J-NC51-F0YC-N49J-00000-00&idtype=PID&context=1516831)

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28. [*FEDERAL REGISTER: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Pages 56336 - 56527 [FR DOC # 2017-25068]*](https://advance.lexis.com/api/document?id=urn:contentItem:5R2J-NC51-F0YC-N4F5-00000-00&idtype=PID&context=1516831)

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# [***Cambridge Analytica: How the scandal unfolded***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5RXR-0TD1-JCJY-G15B-00000-00&context=1516831)

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**Section:** NEWS; Version:1

**Length:** 2461 words

**Body**

Cambridge Analytica, the British data analytics company, is accused of exploiting data taken from Facebook and of using dirty tricks to manipulate elections across the world.

Investigations into their practices have warranted reactions from Facebook, MPs and the prime minister but what exactly has the firm been accused of and how did these allegations surface?How have these claims come to light?

Christopher Wylie, a former Cambridge Analytica contractor, was the whistleblower. He told The Observer newspaper that the British company had used ill-gotten Facebook data to build personality profiles of voters during the US presidential election.

He claimed that the data was collected by Aleksandr Kogan, an academic at the University of Cambridge, through his company Global Science Research (GSR). It was then sold to Cambridge Analytica for between $700,000 and $800,000.

GSR gathered the information through a personality quiz "app" through which users authorised the collection of selected data from their profiles. The app was authorised by only 270,000 users but Facebook gave him access to limited data on each user's friends, with the full package consisting of between 30 million and 50 million profiles.Was this a breach of user data?

Facebook says that it is not, on the basis that Global Science Research had its permission to obtain the data of survey participants and their friends. But they say GSR then went on to share that data in contravention of Facebook's policies, so the net effect was a leak of data to third parties without users' consent.Who is Christopher Wylie?

Mr Wylie, 28, a Canadian, joined Cambridge Analytica's parent company, the ***Strategic*** Communication Laboratories Group (SCL), in 2013. He acted as Cambridge Analytica's research director until 2014, where he worked to "harvest Facebook users" and "create sophisticated psychological and political profiles" using personal information.

According to The Guardian, he submitted a dossier of evidence to the Information Commissioner's Office and the National Crime Agency's cybercrime unit early in March, allowing him to go on the record.What other accusations have been made of Cambridge Analytica?

In an undercover investigation by Channel 4, the company's chief executive, Alexander Nix, was filmed saying that he would offer bribes to smear a client's political opponents as corrupt and that Cambridge Analytics campaigned secretly in elections by operating through front companies or by using subcontractors.

Speaking to an undercover reporterwho posed as a fixer for a rich Sri Lankan hoping to get candidates elected, Mr Nix said: "We'll offer a large amount of money to the candidate, to finance his campaign in exchange for land for instance. We'll have the whole thing recorded, we'll blank out the face of our guy and we post it on the internet."

Channel 4 also filmed incognito meetings with Mark Turnbull, managing director of Cambridge Analytica's political division, and Alex Tayler, its chief data officer. Mr Turnbull explained how the company's business model centred on using data from social media to understand and then exploit voters' most "deep-seated underlying fears".Who are the people under fire?Alexander Nix, 42, has been suspended as chief executive of Cambridge Analytica.

A graduate of the University of Manchester, he began his career in finance in Mexico before returning to Britain and co-founding SCL Group.

At a parliamentary select committee inquiry into fake news in February Mr Nix told MPs that Cambridge Analytica did not work with Facebook data and that the company did not hold any Facebook data.

In undercover footage released by Channel 4, Mr Nix, when asked about digging up material on political opponents, suggested that the company could "send some girls around to the candidate's house". He added that Ukrainian women "are very beautiful, I find that works very well".

Mr Nix claims to have worked on 40 political campaigns in the US, South America, the Caribbean, Europe, Asia and Africa. He has denied using entrapment or bribes and says that he was simply humouring the reporters. He has since been suspended from the company.Mark Turnbull, managing director of Cambridge Analytica's political division

Mr Turnbull, a Cambridge philosophy graduate, started his career as a journalist in Canada before switching to public relations. He worked for companies including Bell Pottinger, the lobbyists, in South Africa and London before joining Cambridge Analytica in May 2016.

He was filmed, alongside Mr Nix and the company's chief data officer, Alex Tayler, claiming that Cambridge Analytica used "unattributable" methods to share negative messages about ***opposition*** candidates during the 2016 US presidential election.

Mr Turnbull said that in addition to sending positive messages under the banner of the official Trump campaign the company used "proxies", including charities and activist groups, to send out negative material on rivals.

He said: "We just put information into the bloodstream to the internet and then watch it grow, give it a little push every now and again over time to watch it take shape. And so this stuff infiltrates the online community and expands but with no branding, so it's unattributable, untrackable."Aleksandr Kogan, 37, founder of Global Science Research

Dr Kogan, a psychologist at the University of Cambridge, was introduced to Cambridge Analytica by a PhD student in his department and initially provided consultancy on survey data. By 2014 he was working through GSR to create a personality quiz app which gathered information on American Facebook users.

Dr Kogan said that he was unaware of how his data was used. He says that he is prepared to appear before MPs or congressional committees in the United States if summoned to do so.

The University of Cambridge said that he was "continuing with his academic research" and would remain in his post.What links Cambridge Analytica to the Trump campaign?

The company was built partly by people who later rose to prominence in Donald Trump's campaign, including conservative donor Robert Mercer and the future White House chief strategist Steve Bannon, who is said to have chosen the company's name.

Cambridge Analytica was hired by the Trump campaign in the summer before the US election, having originally working for Ted Cruz, a rival for the Republican nomination.

Mr Trump's campaign paid $350,000 for Cambridge Analytica to use its "psychographics" technology to target voters likely to be most receptive to his message.

In footage filmed by Channel 4 News Mr Nix said that he met Mr Trump "many times" and that his company "did all the research, all the data, all the analytics, all the targeting" for his presidential campaign.

Julian Assange, the founder of Wikileaks, claims that Mr Nix asked him for copies of 30,000 emails that had been ***deleted*** by the Democratic candidate Hillary Clinton. The communications, from when she was secretary of state in 2009 to 2013, were the subject of intense interest during the campaign.Who is Robert Mercer?

Mr Mercer is a billionaire computer scientist and one of President Trump's biggest backers. He invested $15 million in a joint venture with SCL Group in 2014. He drove the growth of Cambridge Analytica and his daughter Rebekah sat as a board member. There is no suggestion that they were aware of any wrongdoing by the company.

During 2016 US presidential campaign, Mercer publicly donated $22.5 million to Republican candidates and political-action committees.Does the company have any ties to Russia?

Hillary Clinton has suggested that Cambridge Analytica may have helped Russia to spread pro-Trump, anti-Clinton messages and misinformation during the election.

Cambridge Analytica denies any Russian connections but The Observer reported that it had seen correspondence indicating that in 2014 its executives met senior figures at Lukoil, an oil firm with links to the Kremlin, and discussed the micro-targeting of individuals in elections.

The Channel 4 report suggested that Cambridge Analytica may have broken US laws by working both for the official Trump campaign and independent campaigning committees that are not constrained by spending rules to spread "Crooked Hillary" messages. Coordination between an official campaign and outside groups is illegal but the company denies wrongdoing, saying that it maintained strict separation between its different teams.

Dr Kogan, who obtained the data cache later acquired by Cambridge Analytica, has been paid by the Russian state for research on the effects of social media and travelled several times to lecture at St Petersburg State University. In an email to Cambridge colleagues he denied being a "Russian spy".How has Cambridge Analytica operated during election campaigns in Kenya, the Caribbean, and beyond?

Cambridge Analytica was alleged to have stoked ethnic tensions and "demonised" ***opposition*** candidates during a "deadly" election campaign in Kenya last year.

Nic Cheeseman, professor of democracy at the University of Birmingham, said that Cambridge Analytica was "accused of designing a divisive campaign in Kenya that was intended to demonise Raila Odinga . . . and has yet to suffer any consequences".

The SCL Group also carried out a "sting" operation in St Kitts and Nevis. Lindsay Grant, leader of the ***opposition*** in the Caribbean country, who was running against the country's Labour Party - one of Cambridge Analytica's clients - was targeted by the firm in January 2010.

He was caught on video agreeing to sell land well under market value in exchange for a contribution of $1.7 million to his campaign.

Cambridge Analytica has also operated in Libya, Pakistan, Australia and India.Did Cambridge Analytica work on Brexit campaigns?

In February 2016 Mr Nix wrote that Cambridge Analytica had "teamed up with" Leave.EU, the Ukip-linked Brexit campaign group, and that it had "already helped supercharge Leave.EU's social media campaign".

Brittany Kaiser, a Cambridge Analytica executive, was on the panel at Leave.EU's press launch in October 2015. Leave.EU's communications director, Andy Wigmore, said that Cambridge Analytica had been "happy to help" Leave.EU.

Both Cambridge Analytica and Leave.EU have since changed their stories. The company now insists that it was never retained by Leave.EU, nor did it provide any services, paid or unpaid, to Leave.EU or any other of the Brexit campaigns.Who has responded to the revelations?The government. A spokesman for Theresa May said:

"The allegations are clearly very concerning. It's essential people can have confidence that their personal data can be protected and used in an appropriate way. So it is absolutely right the information commissioner is investigating this matter and we expect Facebook, Cambridge Analytica and all the organisations involved to cooperate fully."

The information commissioner, Elizabeth Denham, has said that she will seek a court warrant to examine Cambridge Analytica's databases and servers after it failed to provide access by her March 19 deadline.

She asked forensic auditors already in the company's offices on behalf of Facebook to "stand down" to make way for the official investigation, stressing the need for investigators to understand how data was processed or ***deleted*** by the company.Facebook

Before The Observer published Christopher Wylie's interview Facebook published a statement stating that it had suspended Cambridge Analytica and SCL Group and banned Aleksandr Kogan. The statement said: "In 2015 we learned that a psychology professor at the University of Cambridge named Dr Aleksandr Kogan lied to us and violated our platform policies by passing data from an app that was using Facebook Login."

Facebook has suspended SCL "pending further investigation", claiming that "contrary to the certificates we were given, not all data was ***deleted***".

The company is "looking into" claims that Joseph Chancellor, one of its researchers, was a director of Dr Kogan's company Global Science Research when it obtained the data for Cambridge Analytica.

Mark Zuckerberg, the founder of Facebook, released a statement on March 21 describing the incident as a "breach of trust". In a follow-up interview with CNN he apologised for the breach and said that he was willing to testify to US lawmakers if it was deemed necessary.Aleksandr Kogan

Dr Kogan told BBC Radio 4: "The events of the past week have been a total shell shock, and my view is that I'm being basically used as a scapegoat by both Facebook and Cambridge Analytica when we thought we were doing everything appropriately. We were assured by Cambridge Analytica that everything was perfectly legal and within the terms of service."

He said that neither he nor his firm, Global Science Research (GSR), had profited from the exercise, claiming that most of the money went to participants in the survey via a third party.

He also denied Cambridge Analytica's assertion that he had instigated the commercial harvesting of information. Kogan said he was unaware of how his data was used and would feel "absolutely horrible" if they had helped the Trump campaign. "I just didn't ask enough questions. I had never done a commercial project and I had no reason to doubt their sincerity."Alexander Nix

In response to the investigation, Mr Nix said that he believed that Cambridge Analytica was being targeted because of its work on the 2016 US presidential election. He said: "Fighting elections is polarising. You ***win*** an election for a candidate like Trump and you alienate 100 million people. Therefore by extension of that you are the devil."

He strenuously denied that the company used "entrapment, bribes or so-called honeytraps" and claimed that the company was moral, adding: "We only work for mainstream political parties in free and fair elections in free and fair democracies and we are proud of the work that we do."

Before he was suspended on March 20 he said that his future at the British data company was "a decision for the board". He told The Times: "If that is going to help the company that is the right thing to happen."Cambridge Analytica

The company states that it "fully complies with Facebook's terms of service and is currently in touch with Facebook following its recent statement that it had suspended the company from its platform, in order to resolve this matter as quickly as possible".

The company said that it was unaware that the data was obtained on its behalf without users' informed consent and in contravention of Facebook's terms. It said that it had destroyed all of the data in 2015 at Facebook's request.

It formally denies using Kogan's data to influence the US election, despite its bosses having been caught in an undercover investigation boasting about the information's pivotal role.

**Load-Date:** June 20, 2018

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[***TOP NEWS SUMMARY: Standard Life Profit Rises Ahead Of Aberdeen Merger***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5P6G-PPT1-DXW0-C00C-00000-00&context=1516831)

Alliance News

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**Length:** 2588 words

**Body**

LONDON (Alliance News) - The following is a summary of top news stories Tuesday.

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COMPANIES

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Standard Life reported that its first-half profit attributable to equity holders rose 29% to GBP292 million from GBP226 million a year earlier. Total revenue for the first half declined to GBP7.40 billion from last year's GBP7.70 billion. The insurer raised its dividend by 8.2% to 7.0 pence. Standard Life noted that its proposed merger with Aberdeen Asset Management is expected to be effective from next Monday. Looking ahead, Standard Life noted that the slowdown in gross inflows it saw in the first half of the year is expected to ease as the company progresses with the merger integration. The company also expects to benefit from strong demand for its retail platforms and improving investment performance.

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Betting firm Paddy Power Betfair reported a pretax profit of GBP102.3 million for the six months to June 30, swinging from a GBP45.9 million loss the prior year. Revenue rose 9% to GBP827.0 million from GBP708.8 million year-on-year. Paddy Power Betfair raised its interim dividend per share to 65.0 pence from 40.0p the prior year. The company said its full-year underlying earnings before interest, tax, depreciation and amortisation are expected to be between GBP445.0 million and GBP465.0 million. The results follow on from Monday's news that Chief Executive Breon Corcoran will step down in the near future and be replaced by WorldPay's Peter Jackson.

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Intercontinental Hotels Group reported growth in profit in the first half of 2017, as revenue grew across the business and it said it is confident about the full year after passing its landmark of over 1.0 million rooms. IHG - which owns hotel brands including Holiday Inn and Crowne Plaza - said pretax profit in the six months to June 30 rose to USD326.0 million from USD298.0 million in the first half of 2016, as revenue grew to USD857.0 million from USD838.0 million. Growth was driven by a 2.1% increase in revenue per available room and 3.7% increase in net system size, as the company passed its landmark of over 1.0 million open or pipeline rooms. Occupancy grew by 0.9 percentage points. ***Geographically***, Revenue per available room was up 1.1% in the Americas, 6.2% in Europe, 1.4% in Asia, the Middle East & Africa, and 4.1% in Greater China.

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Payment services company Worldpay Group said the deadline for Vantiv to make a firm takeover offer for the company has been extended for a second time by the UK Panel on Takeovers and Mergers. Worldpay and Vantiv agreed the merger in July, which will see Worldpay delisted from the London Stock Exchange. Under the deal, Worldpay shareholders will receive 55 pence in cash and 0.0672 new Vantiv shares for each share they own. Including a 5.0p per share planned dividend, the total value will be 385p per Worldpay share, or GBP7.70 billion for all of Worldpay's equity. The deal will leave Worldpay shareholders with approximately 41% of the combined company. Last week, the deadline for Vantiv to make a firm offer was extended to 1700 BST on Tuesday, but this has now been extended further to no later than 1700 BST on Friday.

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Pets at Home Group reported growth in revenue in the first quarter of its financial year and said it is on track to meet expectations for the full year. The pet products retailer and veterinary services provider said revenue in the 16 weeks ended July 20 rose by 5% year-on-year to GBP256.5 million, as Merchandise revenue grew by 2.8% to GBP216.4 million and revenue in the smaller Services business increased by 19% to GBP40.1 million. Like-for-like revenue was up 2.7%, reflecting strong growth in first opinion and specialist referral vet services, as well as continued positive momentum in Merchandise trading. On a like-for-like basis, Merchandise revenue grew by 1.5% and Services revenue rose by 11%. Pets at Home said its price investment and operational cost savings initiatives are in line with plan, while its full-year profit outlook is in line with expectations.

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Bellway said full year Housing revenue in the 12 months to the end of July is expected to be up 13% from the previous year at GBP2.50 billion, with volumes continuing to grow, up 11% to 9,644 completions from 8,721 the year before. The operating margin will be broadly flat. The forward sales position is strong and the order book at the end of July was 16% higher year-on-year at GBP1.29 billion.

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Rotork said pretax profit in the first half of 2017 was considerably higher than the year before, on higher revenue and the release of the contingent consideration relating to the Bifold acquisition, prompting a rise to the interim payout. The mid-cap manufacturer of electric, pneumatic and hydraulic valve actuators and gearboxes said its dividend for the first half of the year has been lifted 5.1% to 2.05 pence from the 1.95 pence payout the year before, after posting a 27% rise in pretax profit. Pretax profit climbed to GBP48.8 million from GBP38.3 million, driven by revenue rising to GBP299.8 million from GBP263.9 million, to push the gross profit up to GBP130.7 million from GBP117.3 million the year before.

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Synthomer said revenue soared in the first half of 2017 from a year earlier, but still reported a drop in profit because of the cost of restructuring, closing sites and amortisation charges. The mid-cap supplier of latices and specialty emulsion polymers said revenue in the first half of the year soared to GBP770.3 million from GBP446.2 million the year before, but operating profit still declined to GBP58.3 million from GBP61.2 million. The lower operating profit was due to a higher amount of exceptional items, totalling GBP18.2 million versus GBP3.7 million the year before, which was caused by charges related to restructuring, site closures, amortisation and acquisition costs.

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SIG cut its interim dividend after swinging to a loss in the first half of 2017, as it continues its ***strategic*** review of the business, although revenue rose thanks to sales growth in Europe and the UK. The building products supplier said it made a pretax loss of GBP10.7 million in the six months ended June 30, having made a GBP38.4 million pretax profit in the first half of 2016, as it booked GBP49.0 million in non-underlying items mostly relating to losses on sale, closure or review of businesses. SIG is currently conducting a comprehensive review of its strategy, use of capital and cost base. The aim of the review is to assess the potential profits and returns achievable by the group over the medium term and to identify the "key ***strategic*** levers that will drive a step change in performance". SIG cut its interim dividend to 1.25 pence from 1.83p the year before.

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Plastic piping systems manufacturer Polypipe Group said its has continued to perform in line with management expectations in the first half of 2017, but remains cautious over political and economic uncertainties in the UK. Polypipe reported pretax profit for the six months ended June 30 at GBP31.5 million, up from GBP29.9 million for the same period the year before, on revenue that rose 8.4% to GBP242.0 million from GBP223.3 million. Polypipe said the improvement in revenue was due to purely organic growth, with focus largely on ***strategic*** growth initiatives, such as legacy material substitution, the development of selected export markets and legislative progress in water management and carbon efficiency.

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MARKETS

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London shares were lower with Paddy Power, IHG and Standard Life weighing on the FTSE 100 after poorly received earnings. Commodity prices were higher due to dollar weakness. Wall Street was pointed to a flat to lower open with entertainment giant Walt Disney set to report second quarter earnings.

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FTSE 100: down 0.1% at 7,525.22

FTSE 250: down 0.1% at 19,970.67

AIM ALL-SHARE: up 0.3% at 1,005.03

GBP: flat at USD1.3030 (USD1.3026)

EUR: up at USD1.1810 (USD1.1788)

GOLD: up at USD1,260.70 per ounce (USD1,258.25)

OIL (Brent): up at USD52.62 a barrel (USD51.59)

(changes since previous London equities close)

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ECONOMICS AND GENERAL

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Permanent job placements in the UK grew at the fastest pace in more than two years in July, a report compiled by the Recruitment & Employment Confederation and IHS Markit showed. The number of people placed in permanent jobs increased notably in July and the rate of expansion was the fastest for twenty-seven months. Similarly, growth in temporary or contract staff placements improved to a near two-and-a-half year high in July. The availability of both permanent and temporary workers continued to fall sharply during July. As a result, starting salary for successful permanent candidates rose further in July, with the rate of inflation reaching a 20-month record.

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Like-for-like sales in the UK were up 0.9% on year in July, the British Retail Consortium said on Tuesday - in line with expectations and slowing from 1.2% in June. Overall retail sales in the UK were up 1.4% on year. For the three months ending in July, like food sales gained 2.3%, while non-food sales fell 0.7%. "We can expect food to continue making the running for sales growth for the time being, although driven more by price than volume, with non-food continuing to struggle," said Helen Dickinson, Chief Executive of the BRC.

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Social media firms will be required to ***delete*** information on children and adults when asked under new UK laws aimed at giving people a greater "right to be forgotten" online. The Data Protection Bill will make it simpler for people to control how companies use their personal details, with extra powers for the information watchdog to issue fines of up to GBP17 million, or 4% of a firm's global revenue, having previously been capped at just GBP500,000.The new powers will mean people can ask social media platforms to ***delete*** information they posted in their childhood. The bill will also require people to give explicit consent for their information to be collected online, rather than firms relying on pre-selected tick boxes. The legislation will bring the European Union's General Data Protection Regulation into domestic law, helping Britain prepare for Brexit because it will mean the systems are aligned when the UK leaves the bloc. The bill will be introduced in Parliament when MPs and peers return from the summer break in September.

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A report released by the Federal Reserve on Monday showed consumer credit in the US increased by less than expected in the month of June. The Fed said consumer credit rose by USD12.4 billion in June after jumping by USD18.3 billion in May. Economists had expected consumer credit to climb by USD15.5 billion. Non-revolving credit such as student loans and car loans increased by USD8.2 billion in June after climbing by USD11.5 billion in May. Revolving credit, which largely reflects credit card debt, edged up by USD4.1 billion in June after rising by USD6.9 billion in the previous month. The Fed said consumer credit increased by an annual rate of 3.9% in June, as revolving and non-revolving credit rose by 4.9% and 3.5%, respectively.

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US Secretary of State Rex Tillerson landed in Bangkok on Tuesday for his first official visit to Thailand. Tillerson is the highest ranking US official to visit Thailand since the country's May 2014 coup. Analysts see the trip as a signal of improved US-Thailand relations under US President Donald Trump's administration, following a previous downgrade of diplomatic and military relations in protest of the military regime. "The visit is a sign of our continued commitment to our enduring alliance with Thailand," said Steve Castonguay, spokesman for the US embassy in Bangkok. Among topics to be discussed is Prayut's upcoming visit to the White House, according to the ministry. The trip initially was expected in late July, but no date has been set yet. Regional issues to be discussed include the South China Sea territorial dispute and security on the Korean Peninsula, following North Korea's recent missile tests, the embassy said.

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China's exports increased at a slower-than-expected pace in July, the General Administration of Customs said Tuesday. In dollar terms, exports climbed 7.2% year-over-year in July, well below the 11.0% spike economists had expected. Similarly, imports rose 11.0% in July from a year ago, much slower the expected growth of 18.0%. The trade surplus totalled USD46.74 billion in July versus the expected surplus of USD45.0 billion. "This would appear to suggest that while global demand is still positive it may well not be as strong as initially thought, which might be a concern further down the line if it suggests a start of a trend," said Michael Hewson, chief market analyst at CMC Markets.

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Germany's trade surplus increased in June as the decline in imports was larger than the fall in exports, Destatis reported Tuesday. Exports declined 2.8% in June from May, when they climbed 1.5%. Likewise, imports slid 4.5%, in contrast to May's 1.3% increase. Exports and imports were expected to gain 0.2% each in June. As a result, the trade surplus increased to a seasonally adjusted EUR21.2 billion from EUR20.3 billion in May.

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South African legislators will use a secret ballot in an upcoming no-confidence vote against President Jacob Zuma, raising the chances that the vote could remove him from office. "Considerations of transparency and openness" are not always possible "where there are instances of intimidation," Speaker of the National Assembly Baleka Mbete said at a press conference in Cape Town on Monday. "No member can suffer any harm, hardship or punitive action" if they vote "according to their conscience." Mbete had delayed the announcement until the eve of Tuesday's vote. Zuma has already survived seven no-confidence votes since he became president in 2009, but they were held on open ballots. Nine out of a total of 13 parties had requested a secret ballot, which will allow members of Zuma's deeply divided African National Congress to vote against him without fear of reprisals.

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Venezuelan President Nicolas Maduro's attempt to rewrite the constitution and oust the country's attorney general have "further weakened the prospects for a peaceful return to the democratic order," the EU charged Monday. Maduro's government has come under harsh international criticism since last week's inauguration of a pro-Maduro assembly elected to rewrite the constitution through an allegedly manipulated vote. Venezuela's ***opposition***-led legislature accuses Maduro of seeking to seize complete power through the constituent assembly. The EU said that the latest actions have "increased the polarization of an already divided society," and called for respect for the separation of powers and free speech under the existing Venezuelan constitution. The EU called for a "negotiated solution" to the political crisis.

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French President Emmanuel Macron has invited Iraqi Prime Minister Haidar al-Abadi to France, Elysee Palace sources said on Monday following a phone call between the two leaders. Macron and al-Abadi reiterated their dedication to the fight against Islamic State and discussed ways of stabilizing areas that have been liberated from the Sunni extremist group.

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[***Social climbers; SOCIAL MEDIA TECHNOLOGY ; The recent Facebook scandal over illicitly distributed personal data has thrust social media into the spotlight, but banking is a sector that faces stringent compliance over privacy. So how are US banks using social media channels to best engage customers and promote their business? Jane Monahan reports.***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5S7T-YHR1-DY9P-N2V0-00000-00&context=1516831)

The Banker

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**Body**

US banks' use of social media is still at a formative stage. In a 2017 survey by the American Bankers Association (ABA), one-quarter of the 800 banks polled said they had been participating in social media for five or more years. One-third had been using it for three or four years, 18% for one or two years, and 12% were still getting their feet wet, having used it for less than a year.

The opportunities and challenges for banks using social media are also evolving. According to the ABA study, 76% of US banks believe having a presence on social media platforms is important to their business. This is unsurprising, given that the target audience of online, mobile and socially connected consumers has been mounting year by year (reaching 2.44 billion in 2018, according to ABA estimates), with people of all ages represented, not just millennials.

KEEPING UP Indeed, the pressure to keep up to date with technology and cope with the challenges of meeting consumer demands - and the risks of not doing so - is also unrelenting, say US bankers, their technology partners and media consultants. For instance, more and more bank customers want to conduct basic financial business from their smartphones or other digital devices 24/7, and without the need for cash or visiting a branch.

At the same time, customers are increasingly concerned about the security and protection of their personal data. Such concern reached a turning point two months ago with revelations that a UK-based voter-profiling company, Cambridge Analytica, obtained the data of 87 million Facebook users without their consent and used this to help Donald Trump's US presidential campaign in 2016.

Facebook founder and chief executive Mark Zuckerberg made an unusual apology in a conference call to journalists in early April. "For the first decade we really focused on all the good that connecting people brings. But it's clear now that we didn't do enough. We didn't focus enough on preventing abuse. That goes for fake news, foreign interference in elections, hate speech, in addition to developers and data privacy. We didn't take a broad enough view of what our responsibility is, and that was a huge mistake," he said.

During two days of congressional hearings on April 10 and 11, Mr Zuckerberg reiterated this apologetic line. But he was vague about what his company is going to do to fix the problem, telling legislators: "I'll have my team get back to you. The details matter a lot."

The upshot is that it is far from certain that his testimony has either reassured the public or mollified lawmakers, say commentators. The basic problem, they say, is Facebook's business model. It gives customers free things such as birthday reminders in exchange for their personal data, which digital marketers then use to sell products, ideologies and candidates.

For their part, ***opposition*** Democrats and ruling Republicans reached a consensus in Congress that privacy legislation is needed. But it is highly unlikely to be enacted any time soon, and certainly not before November 2018's congressional elections.

PROGRESS SO FAR But notwithstanding the current issues, how have US banks been engaging in social media so far? And in what ways, if at all, are they measuring the effect of their engagement on their business? Initially, US banks used social media for basic customer service. Bank of America, one of the first to actively participate, and the second largest bank in the country by assets, started posting alerts about the weather and announcements, for instance, on branch closings, on a Twitter handle in January 2009.

Banks also used the platforms to sponsor commu-nity events, outreach that continues to be popular with followers, and a natural fit for the US's 5000 or so community banks.

Take Citizens, a small bank in Edmond, Oklahoma, that is more than a century old. In 2014, it launched a street festival every third Saturday from March to October, using Instagram and a hashtag for the event where people shared photos to raise awareness. Now a fixture, the event has the feel of a bank-customer appreciation day, planned for and run by bank staff, with food, music and local shop and business stands. From an initial 500 attendees, in mid-2017 it was attracting up to 30,000 people, almost one-third of Edmond's population.

A further feature of social media is that community and regional banks find it an equaliser in terms of brand advertising. They can do this on digital platforms alongside the biggest US financial institutions without the need to pay the substantial advertising costs of print media and television, for example, that only the biggest US banks can afford. Technology consultants estimate the cost of advertising on the new channels is 50% to 60% less than on conventional outlets.

CUTTING THROUGH THE NOISE However, with so many tweets, posts, video chats and so on, it can be a challenge to create content that is compelling or valuable enough to attract users' attention, let alone convert them into bank customers. US banks post their bank and apps websites on social media but do not, generally, advertise or communicate directly about their services and products. As heavily regulated institutions, they face compliance requirements.

There are also practical considerations. Donna Townsell, senior vice-president and director of marketing at Alabama-based Centennial Bank, a small regional bank with $14.4bn in assets at the end of December, says: "You don't have the room on those platforms, you don't have the landscape for all the disclosures that would be necessary [for such advertising]."

The ABA study suggests US regulations for banks and other financial institutions on social media are also "deliberately vague", due to ongoing change in the industry, which can lead to ambiguities and create tension between a bank's compliance and marketing officers. But, the study says, banks are doing a lot on the new channels to ***win*** followers and fans without "product pushes" or advertising, with the aim of building trust and promoting a positive and caring image of the brand and its employees.

The focus on brand promotion highlights one of the many differences of the digital generation and the extent to which content on social media is demand driven. Chris Smith, head of social media at Bank of America, says more than 90% of 18 to 34 year olds follow the brands they engage with on social media. "The brands don't make that happen. You see people are associating with brands as a generation," he adds.

"If they have a good experience, almost three-quarters of them share that experience [on social media]. It's amazingly powerful."

But what can banks do to be interesting and useful while avoid falling foul of regulators? Many post content that is either playful, like a contest, or useful, for instance, providing financial education, advice and tips. They also use video chats profiling loan officers and financial advisers connected to the bank's relationship-based businesses, such as mortgages, wealth management or retirement planning.

Meanwhile, Facebook provides demographic and ***geographical*** tools that help banks target their audience. Sankar Krishnan, executive vice-president of banking and capital markets at Capgemini, a global business consulting firm, says: "From this promising pool, US banks create avenues to draw people to their website and find ways, with new types of analysis, to identify possible customers, so that the organisation can follow up with a message such as 'Are you interested in my card?'."

GETTING CREATIVE Many banks are using social media creatively, and in a very sophisticated way in some instances, the ABA study says. When Bank of America announced the integration of Zelle, the peer-to-peer payment feature, into its mobile and online banking app in late 2017, it posted a 'Pay Back a Friend Day' programme on Facebook and Instagram, encouraging roommates who owed money to see how easy it would be to make this payment using the new technology (and regain their friendship).

Kelly Colbert is head of brand advertising and social media at Minnesota-based US Bank, the seventh largest bank by assets in the country. The bank's financial education programme targeting young people just reaching adulthood has a vignette with the hashtag 'OneHouseWiser'. She says this raises its profile, without the bank having to push its brand or its products directly, by asking second-time home buyers to give advice to first-time home buyers and leaving it up to them to give guidance. The campaign "is very successful" and helps build trust among young people who may have seen the financial crisis of 10 years ago "in their rearview mirror", adds Ms Colbert.

Meanwhile, Citizens Bank has a programme called Cash Vault. Employees are given cash to shop at a particular store at a particular time and they take a picture of the store, tweet it, post it on Facebook and Instagram and tag the small businesses and the bank's websites. Chief executive Jill Castilla says the cross-promotion of the bank and local businesses has "solidified" existing relations and attracted new clients. "They are my main target group because as a community banker I can relate to them. They have similar challenges," she adds.

US banks are also using social media to recruit new employees and manage organisational change, something Citizens Bank is doing. Before it became the first community bank in the country to introduce a video ATM kiosk that enables customers to have face-to-face interactions with bank tellers from a remote location, Citizens sold all of its branches and consolidated the remaining two into one brick building in Edmond to help defray the investment costs.

"We were able to do this and retain all our customers. We only had net customer growth," says Ms Castilla. "I think that can really only be attributed to using social media and videos on YouTube to spread the message as to why we were making the change and what new technology we were investing in. We could get ahead of the story before it became a concern for our customers."

ENSURING COMPLIANCE But are there examples of US banks erring in their social media offerings? Yes, says Doug Wilber, head of marketing at Gremlin Social, a web-based firm operating from Missouri that advises some 200 US banks on their social media content. His company regularly finds posts that are either off-brand - that is, not aligned with the brand's overall message - or not compliant. Also, the ABA says, some banks do not differentiate their content enough, or time it appropriately, with a particular platform.

Over the years, most US banks have expanded customer service on social media to include inbound queries, to provide assistance to customers outside office hours, or if they encounter financial difficulties when travelling abroad, for example. In such cases the request is taken offline and once customer identification is completed, the customer has one-to-one service.

The expansion has accompanied the growth of messaging platforms, such Facebook Messenger and WhatsApp, which are now as big, if not bigger, and growing faster, than the original social networks, as the industry evolves.

But what happens when social media works against a business - such as the recent '***Delete*** Facebook' movement, with users telling friends and colleagues that they are closing their accounts and publicly criticising the platform for not doing enough to protect their personal data? To avoid such negative publicity, banks usually take criticism made by social media users offline as soon as possible, to discuss the matter privately. But Ms Colbert at US Bank says there can be advantages to facing criticism openly. "When a consumer makes a negative comment online it can go unanswered or you can treat it as an opportunity to answer them. We see it as the latter," she says.

MEASURING EFFECTIVENESS To assess the effectiveness of their social media presence, most US banks use 'soft' metrics, including the number of 'likes', 'shares' and 'comments' on a post, tweet or video. But a few institutions are probing deeper. In March 2018, Regions Bank, a $124bn-asset regional bank from Birmingham, Alabama, in partnership with SapientRazorfish, a US digital marketing company, announced a new approach, quantifying the value of the bank's presence on social media channels using hard, return on investment data-centric metrics.

According to Regions Bank's head of social media, Melissa Musgrove, and the head of global social insights at SapientRazorfish, Melissa Read, these evaluate the impact of a bank's social media involvement on the bottom line in a much more meaningful way. The findings of the new approach, when applied at Regions Bank, were also eminently positive, they add.

After tagging 9500 social media customers (a mixture of people who engage with Regions Bank for customer care, sales and general fan interactions) the bank learned that the average household revenue of its social media customers was 60% higher compared with its non-social media customers; the average household deposit was 76% higher; the average crosssell was 59% greater for social customers; and social media customers also had 32% more bank accounts per household.

Moreover, as budgets for marketing, and the headcount of social media teams, are now increasing at US banks, executives will be required to demonstrate more precisely how they are getting value out of their social media presence, Ms Musgrove says.

At Bank of America, Mr Smith says the prime measurement is engagement. "Are folks that have raised their hand in the network, are they engaging with the content? Engagement is really a Holy Grail for us. That's somebody with their time and their eyeballs saying 'I find this of value'," he adds.

US banks are spending a lot of time improving their social media channels, says Mr Krishnan at Capgemini. "They are investing a lot in the channels, and to make sure they are safe. They know their next 50 million customers will come from those channels, especially as every year we are seeing a decline in US branch traffic by as much as 30%."

When a consumer makes a negative comment online it can go unansWered or you can treat it as an opportunity to ansWer them Kelly Colbert

**Load-Date:** May 4, 2018

**End of Document**



[***Pat Kane: Here's why we ALL need to fight to protect Brand Scotland***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5PW7-5P11-JD39-X0HF-00000-00&context=1516831)

The National (Scotland)

November 4, 2017 Saturday

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**Section:** NEWS

**Length:** 1377 words

**Byline:** [*Pat Kane*](http://Pat Kane)

**Body**

I NOTICED them when they started to appear, several years ago: little blue Saltires on packs of food in mega-supermarkets. A flag is meant to catch your eye, and catch your heart, and both happened to me.

If the first half of your adult life has been about wanting your country to gain self-confidence, and get the recognition it deserves - then yes, you notice these wee things.

In large boardrooms, at the ***strategic*** point of a supply chain, some executive had looked at the undeniable facts coming from Scottish attitudinal surveys.

And they had concluded that some positive marking of Scottish produce would increase returns - probably first to the home audience, but maybe as a marker of passionate authenticity across the islands. For the Scots civic nationalist, it was a small, everyday indicator of momentum.

A few leadership changes, whirlwind elections and thudding referenda later, and we're now tripping over the ***opposite*** trend. And nothing escapes the Twitter activist with a working camera phone.

Our info streams are now regaled with shop-shelf pictures of "The Great British Haggis"; Arthur Bell on his whisky label, flanked by Big Ben and a red telephone box; Walkers' shortbread imprinted with the outline of the Union Jack; Harris Tweed labels side by side with the red-white-and-blue; broccoli from Fife and carrots from Perthshire branded as "British"... All curated from a Twitter hashtag called #KeepScotlandTheBrand (how easy to organise around an issue, in these networked days).

Both Marks and Spencer and Tesco have found themselves on the wrong side of digital protest here - and have hastily course-corrected. For M&S, Scottish whisky isn't subsumed under "Great Britain" on their website anymore. Tesco ***deleted*** a blithe tweet informing consumers that "British flags" would from now on replace "Scottish Saltires" on their food packaging - and have now committed themselves to using the Saltire flag "regularly ... and whenever possible".

Some say we live in a surveillance state - vast networks, whether state or corporate, recording our every click (and in city centres now, every facial expression). But to twist the French around, we also live in a society of "sousveillance" - where we are the ones recording the activities of authorities, watching the watchmen.

"Fake news" and "post-truth" is one aspect of this accelerated information-world. But a motivated community bringing actual examples of cultural elision to their fellow citizens is certainly another.

However, these meme wars only point to deeper problems of politics and power.

One small mitigating plea, on behalf of the mega-retailers: they are data-driven, highly consumer-sensitive operations. And post-Brexit, they will be undoubtedly picking up trends from customers, considered at the level of the UK market as a whole. Facing a Leave majority, it would be a surprise if they didn't respond in their marketing to a rise in pro-British sentiment and anxieties (though the clodhopping nature of the response is regrettable).

The anxiety may be even more acute than this. The first straw in this wind - when Tesco removed Saltires from Scottish strawberry punnets a few months after Brexit - was reportedly provoked by English consumers, complaining that English fruit was not equally and explicitly labelled. The political philosopher Anthony Barnett has written a whole book, The Lure of Greatness, trying to inform his metropolitan peers that Brexit was as much an "Engxit" as anything else.

That's maybe a coming trend for the marketing departments of food producers and retailers to consider. But in the meantime, and evidenced by the speedy backtracking going on, they are much more weathervanes in the blustery conditions of Brexit, than conspiring malefactors.

Certainly there will be a pressure coming from Westminster and Whitehall, seeking to unify a British "single market" and extract as much value from it as possible, as we face the likely economic carnage of leaving the EU. "Britifying" their operations - whether in terms of systems or messaging - is much more about businesses being adaptive, than ideological.

But as ever for the indy-minded, it's what we actively do and assert - with our available powers and desired sovereignty - that's most important in any situation.

As Jim Fairlie, head of Farmers for Yes, wrote brilliantly in these pages a few days ago, we need to defend Scotland the Brand in food and drink - because it is the result of a roaring success.

The National Food and Drink Policy for Scotland has helped propel Scottish farming, food and drink to £13.3bn a year (they have recently proposed a 2030 target of £30bn) - with strongly-identified Scottish produce in the forefront.

Yet Westminster is actively subverting this link between Scottishness and product. In recently signed EU-level trade deals with Canada and Japan, the UK did not assign a "Protected ***Geographical*** Indicator" (in other words, "made in Scotland") to any Scottish goods.

At some point, indy activists have to get across just what a barrier to progress a Scotland trapped in the Brexit model is. Around food and drink, the tensions are all too clear.

Holyrood has exerted its powers to enhance its comestible goods with strong environmental regulation. Banning both fracking and GM foods from Scottish jurisdiction is a global-level signal that we are deadly serious about the quality of our produce. The clear cascading waters and peaty depths on the marketing literature will now have hard science behind them.

But at what point will this ram up against a freebooting Brexit model, proclaiming these islands "open for dirty business", in a Westminster meltdown of standards and protections?

Subverting the Scottish brand in food and drink is to concretely knock economic value out of this country, let alone suppress its further growth. And before anyone starts talking about "the pettiness of arguing over symbols", let me point you to an amazing new book by an ex-colleague of mine, Stian Westlake, called Capitalism Without Capital: the Rise of the Intangible Economy.

His general point (along with co-author Jonathan Haskel) is that modern economies underestimate the value and worth of our investment in "intangibles" - intellectual property, software, ways of doing business... and branding.

Once invested in, a quality brand can land in any economic circumstance, and immediately start to do its work - set its values, its mood and tone, its expectations on the enterprise at hand (Starbucks or Facebook or Coke are classic examples). In the jargon, this is called "scalability".

The impact of the brand is potentially infinite, if the company's investment in it continues to uphold its consistency and quality.

The intangible (meaning cultural and symbolic) nature of a brand, says Westlake and Haskel, means that its benefits spills over into other areas - becoming fashionable, cultish or caught up in wider trends.

The power of branding, and other intangibles, drives the authors to consider whether we are really measuring investment in our economies properly. Companies tend to think of such "soft stuff" as part of their day-to-day expenses, rather than a deep investment in value. (Maybe some way-smarter folks than I could try to assess Scottish economic worth, in terms of intangible investment and value.)

But in any case, the Scottish brand in food and drink passes any of the tests that Westlake and Haskel - or indeed, any half-awake contemporary economist - might set out for a powerful intangible asset, worth both defending and extending.

The great perplexity of Scottish stasis on the path to indy persists - though many are trying to come up with answers (the Scottish Independence Convention's Build2 conference in Edinburgh today will be full of them, I hope and trust). But one that's always worth a try is that indy is an opportunity for best practice, in both economics and society, in the 21st century.

And from the perspective of the power of branding in contemporary business practice, the presence (or not) of a Saltire on your punnet of Scottish strawberries is certainly no trivial matter.

Capitalism without Capital: The Rise of the Intangible Economy, by Stian Westlake and Jonathan Haskel, is out now on Princeton University Press (£24.95).

**Load-Date:** November 4, 2017

**End of Document**



[***Summary of Russian press for Friday 2 June 2017***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5NP6-0651-JC8S-C2GJ-00000-00&context=1516831)

BBC Monitoring Former Soviet Union - Political

Supplied by BBC Worldwide Monitoring

June 2, 2017 Friday

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**Length:** 3615 words

**Body**

By BBC Monitoring

International Economic Forum in St Petersburg

Kommersant: Dmitry Butrin article headlined "Figures on arena" focuses on the macroeconomic session of the St Petersburg International Economic Forum, at which economic development strategies for Russia have been discussed; pp 1-2 (925 words).

Kommersant: Pundit Alexander Gabuyev article published in the regular column headlined "Rules of games" comments on foreign guests' attendance of the St Petersburg International Economic Forum as an indicator of Russia's relations with foreign partners; p 9 (397 words).

Kommersant: Elena Chernenko article headlined "Russia being promoted at UN" previews the agenda of Putin's meeting with UN Secretary General Antonio Guterres on the sidelines of the St Petersburg International Economic Forum. The Russian representative's possible appointment as the head of a new UN office for counterterrorism is said to be discussed at the meeting; pp 1, 7 (635 words).

Nezavisimaya Gazeta: Olga Solovyeva article headlined "Financial and economic bureaucracy not interested in population's problems" says that statements made by the Russian economic and financial authorities at the macroeconomic session of the St Petersburg International Economic Forum have virtually shown that people's well-being and interests are not important criteria for them; p 4 (1,460 words).

Nezavisimaya Gazeta: Anastasia Bashkatova article headlined "Kudrin encroaches upon Kremlin's sacred cow" says that former Finance Minister Alexei Kudrin has called for privatising state-owned oil companies at the St Petersburg International Economic Forum. The Kremlin has opposed the idea, and experts are sceptical about even a possibility of privatising the oil sector; pp 1-2 (1,121 words).

Rossiyskaya Gazeta: Igor Zubkov article headlined "Excessive dollar to get in the way" reports on the controversy caused by Kudrin's economic initiatives presented at the macroeconomic session of the St Petersburg International Economic Forum. The financial authorities have condemned Kudrin's proposals; p 3 (664 words).

RBC: Anton Feynberg et al. article headlined "'Everything is clear: structural reforms needed...'" reports on the first day of the St Petersburg International Economic Forum, at which the Russian economy and its development prospects have been discussed; pp 1-3 (1,100 words).

RBC: Igor Trosnikov and Kirill Tokarev interview with Deputy Prime Minister Arkady Dvorkovich, headlined "'It is better for our economy that exchange rate be slightly higher'", who shares his vision of the current economic situation in Russia and speaks about state support for certain industries, among other things; pp 1, 4 (950 words).

RBC: Kirill Tokarev and Elizaveta Golikova interview with former Finance Minister Alexei Kudrin, headlined "'State should slightly increase investment'", who speaks about his economic development strategy and urges for privatisation of oil companies and technological reforms, among other things; p 5 (1,250 words).

Vedomosti: Anastasia Kornya article headlined "Why Russia not England" reports on Prosecutor-General Yuri Chaika's speech at the St Petersburg International Economic Forum, dedicated to protection of businessmen in Russia and Russian jurisdiction being unattractive for investors; p 3 (450 words).

Moskovsky Komsomolets: Inna Degotkova article headlined "There is money, but you keep holding out" gives an account of the macroeconomic session of the St Petersburg International Economic Forum, focusing on statements made by the finance and economic development ministers and the Central Bank head; p 2 (639 words).

Putin's meeting with foreign journalists

Moskovsky Komsomolets: Elena Yegorova article headlined "Putin not afraid of hackers at 2018 election" reports on Putin's meeting with heads of Russian and foreign news agencies. The US ABM plans, NATO's expansion eastwards, Russia's forced participation in the global arms race, Russian hackers' alleged involvement in foreign elections and the rise of Russophobia in the world were among the issues raised at the meeting; p 2 (794 words).

Kommersant: Andrei Kolesnikov article headlined "What motherland wakes up with" gives a detailed account of Putin's meeting with foreign journalists; p 5 (1,503 words).

Rossiyskaya Gazeta: Kira Latukhina article headlined "Authorised to tell TASS" describes Putin's meeting with foreign journalists in St Petersburg; p 2 (813 words).

Izvestia: Egor Sozayev-Guryev et al. article headlined "We are not afraid of anything" features experts' comments on Putin's statements during the meeting with foreign journalists; pp 2-3 (800 words).

US sanctions over DPRK affect Russia

Vedomosti: Irina Chevtayeva et al. article headlined "Sanctions for DPRK" says that the USA has imposed sanctions against nine companies and three individuals for support for North Korea. Three Russian companies and a Russian citizen have found themselves in the sanctions list; p 4 (450 words).

Vedomosti: Alexandra Terentyeva and Vitaly Petlevoy article headlined "IPC subjected to sanctions" says that businessman Eduard Khudaynatov's Independent Petroleum Company (IPC) has been subjected to the recent US sanctions over Pyongyang's nuclear programme. An IPC subsidiary has reportedly supplied oil products to the DPRK; p 12 (350 words).

Navalny-Usmanov row

Moskovsky Komsomolets: Valeria Markova article headlined "Dimon to be ***deleted***. Will Navalny stay?" features experts' comments on how ***opposition*** leader Alexei Navalny's defeat in the legal battle with businessman Alisher Usmanov close to the authorities may influence his reputation and popularity; p 4 (586 words).

Novaya Gazeta: Sergei Lebedenko and Yulia Schastlivtseva article headlined "Trial for fun" gives a detailed account of the Navalny-Usmanov two-day legal battle over defamation; pp 2-3 (608 words).

Novaya Gazeta: Yulia Latynina article headlined "Which was to be ruled" points at Navalny's weak evidence basis in the trial with Usmanov and notes that the main question now is how many people will come onto the streets for the 12 June rally promoted by Navalny; p 2 (827 words).

Novaya Gazeta: Dmitry Glukhovsky article headlined "Damn and neuro-linguistic programming" comments on the use of criminal jargon against Navalny by Usmanov as "the demonstration of force of Putin's majority over the ***opposition***-minded minority"; p 3 (526 words).

RBC: Konstantin Gaaze article headlined "Why it is time for oligarchs to think about future" contemplates causes behind Usmanov posting two video clips addressing Navalny. Russian oligarchs heavily depend on Putin's favour and Usmanov's address to people is an "alarm signal" that the authorities' guarantees to him are insufficient given the "upcoming transit of power in 2018", the article says; p 13 (1,400 words).

***Opposition***

Nezavisimaya Gazeta: Daria Garmonenko article headlined "Navalny makes political gesture" says that the future of the 12 June rally in Moscow promoted by Alexei Navalny is still up in the air. Moreover, Navalny has had no right to submit an application for holding a rally as he is still facing two administrative punishments for the 26 March anticorruption protest. His address to the Moscow city administration was a mere "political gesture to show that the presidential candidate is bringing people onto the streets", the article says; pp 1, 3 (710 words).

Nezavisimaya Gazeta: Alexei Gorbachev article headlined "Disintegrated ***opposition*** comes to oppose ruling party" says that the democratic ***opposition*** has so far failed to consolidate and present a united front to stand in the Moscow municipal elections on 10 September. It will be difficult to do this given numerous disagreements within the ***opposition*** camp, the article says; p 3 (731 words).

Defence Ministry's air crash in 2016

Moskovsky Komsomolets: Olga Bozhyeva article headlined "Crew is tired" says that human factor has been named the cause of the December 2016 crash of the Defence Ministry's Tu-154 heading for Syria. However, not only pilots but also the organizers of the flight must bear responsibility for the air crash, the article notes; pp 1, 3 (896 words).

Novaya Gazeta: Irek Murtazin article headlined "'Maybe mass insanity'" says that experienced military experts polled by the journalist disagree with the official theory behind the December 2016 crash of the Defence Ministry's Tu-154 heading for Syria and looks at their arguments; p 7 (920 words).

Rossiyskaya Gazeta: Yuri Gavrilov article headlined "Lost horizon" looks at investigators' findings about the cause of the December 2016 crash of the Defence Ministry's Tu-154; p 2 (654 words).

Human rights

Novaya Gazeta: Nadezhda Shkuryonok article headlined "Photo catchers" outlines the first court session in the trial of Yuri Dmitriyev, head of the Memorial Society in the Republic of Karelia, facing prosecution for alleged pornography and weapon possession; p 5 (650 words).

Novaya Gazeta: Alexei Tarasov article headlined "Chechen fairy tales of Sayan mountains" accuses law-enforcers of being "politically and ideologically motivated" when dealing with the case on impeding journalist Mikhail Afanasyev's professional activities in Krasnoyarsk Territory; p 6 (1,197 words).

Novaya Gazeta: Elena Masyuk article headlined "'You complain to ECHR about Russia...'" is a report from a strict regime colony by former employees of the law enforcement agencies and judicial structures in Nizhny Novgorod Region; pp 10-11 (2,822 words).

Military

Nezavisimaya Gazeta: Vladimir Mukhin article headlined "Slavonic Brotherhood [drill] to respond to Western alliance" says that against the backdrop of military exercises in Ukraine and NATO member states, Russia has held a snap drill of combat readiness in the Southern Military District and has been preparing for the Slavonic Brotherhood joint exercise to be held in Belarus with Russian and Serbian servicemen participating; pp 1, 6 (753 words).

High-profile criminal cases

Moskovsky Komsomolets: Lina Panchenko article headlined "Falcon carries out go around" says that the case on the 2014 French Total CEO's jet crash in Moscow's Vnukovo airport, which claimed the life of Christophe de Margerie among others, will be considered by court from scratch as the judge has changed; p 3 (786 words).

Moskovsky Komsomolets: Daria Fedotova article headlined "Suspects in Nemtsov murder go down in flames due to phone" describes the oral statements of the parties in the trial on ***opposition*** politician Boris Nemtsov's murder case; p 3 (1,132 words).

Kommersant: Alexei Sokovnin article headlined "Colonel Zakharchenko fails to convince court" says that the term in custody has been extended for three months to 8 September for Interior Ministry Col Dmitry Zakharchenko, charged with corruption; p 6 (735 words).

Kommersant: Sergei Mashkin article headlined "Terrorists settle on Tyoply Stan [metro station]" says that four members of the Islamic State group, detained in Moscow on 25 May, have testified that they masterminded terrorist attacks on a restaurant and the Tyoply Stan metro station at the order from Syria, aiming to disrupt the FIFA Confederation Cup; p 6 (940 words).

Domestic political stories

Moskovsky Komsomolets: Alexander Minkin article headlined "Sick society" recalls the controversy about Culture Minister Vladimir Medinsky's thesis, focusing on arguments offered by his supporters and opponents; pp 1, 5 (1,295 words).

Moskovsky Komsomolets: Ekaterina Stepanova article headlined "Blown and forgotten" describes problems facing victims of the 3 April terrorist attack on the St Petersburg metro to get state compensation; pp 1, 5 (1,741 words).

Moskovsky Komsomolets: Mikhail Zubov article headlined "Putin in per cent" says that recent opinion polls by the state pollsters VTsIOM and the Public Opinion Foundation have shown a slight decrease in Putin's approval rating and features experts' comments, who say that there is nothing to worry about as there is no rival to Putin in the country; p 4 (780 words).

Vedomosti: Editorial by Pavel Aptekar headlined "Law enforcers do not make mistakes" slams the idea of introducing a "presumption of trust" to law-enforcers, meaning that they will not face prosecution for any action taken while on duty if the action was for a valid purpose and in accordance with the existing law, as "this may generate a new wave of abuse by police"; pp 1, 6 (400 words).

Vedomosti: Svetlana Bocharova article headlined "Freedom to be returned to officials" says that the Labour and Social Protection Ministry has suggested relieving officials of the obligation to report on their internet activity annually and only obligating officials who have made disciplinary violations to do this; p 2 (400 words).

Vedomosti: Elena Mukhametshina article headlined "Premier's negative" says that according to the Medialogia media-research company, media mentions of Prime Minister Dmitry Medvedev went up 1.5-fold in spring namely due to the anti-corruption rallies staged by ***opposition*** leader Alexei Navalny and his film about Medvedev; p 2 (550 words).

Domestic economic stories

Moskovsky Komsomolets: Dmitry Dokuchayev article headlined "Will we build communism by 2035?" suggests that none of socioeconomic development strategies developed by the government, former Finance Ministry Alexei Kudrin's Centre for ***Strategic*** Initiatives and the Stolypin Club will be implemented and notes that Putin has set the task to develop them to ***win*** over both liberal and state-minded voters ahead of the 2018 election; pp 1-2 (688 words).

Nezavisimaya Gazeta: Ekaterina Trifonova article headlined "Crimea's integration almost over" says that the All-Russia People's Front (ONF) has summed up the results of its operation in Crimea. People in the peninsula have the same problems and difficulties as people in Russian regions, which allows one to say that Crimea's integration with Russia is almost over, it was said at the ONF meeting; pp 1, 3 (533 words).

Nezavisimaya Gazeta: Editorial headlined "What hampers Russia's U-turn to East" says that a lack of clear and effective development strategy for Russia's Siberia and Far East complicates Russia's U-turn to Asia; p 2 (524 words).

Novaya Gazeta: Alexei Polukhin article headlined "Pensioners to be in tatters" says that the Economic Development Ministry has made a long-term macroeconomic forecast till 2035, which is quite pessimistic for Russian pensioners as the economic growth is planned to be provided at their expense; p 9 (735 words).

Rossiyskaya Gazeta: Sergei Kulikov article headlined "They to be engaged in construction" says that Russia has decided to cancel a number of economic restrictions against Turkey: the visa regime has been mitigated and Turkish specialists are welcomed at the Russian market once again; p 4 (431 words).

Kommersant: Ivan Safronov article headlined "UK, Russia get in satellite network" says that the British telecom company OneWeb and the Russian company Satellite system Gonets have signed an agreement on establishing a joint venture at the St Petersburg International Economic Forum; p 3 (429 words).

Kommersant: Irina Nagornykh and Taisia Bekbulatova article headlined "Applicants for presidential grants grow in number" says that 6,600 applications for presidential grants have been submitted, which is almost twice as much as in 2016; p 3 (678 words).

Kommersant: Alexander Borisov interview with Alexander Braverman, head of the Small and Medium Business Corporation, headlined "'When confidence in small and medium businesses increases, there will be no need to suppress large clients with quotas'", who speaks about difficulties facing small businesses in Russia; p 4 (2,032 words).

Kommersant: Tatiana Dyatel and Yuri Barsukov article headlined "Engie finds contact with Rosatom" says that the French company Engie has shown interest in potential partnership with the Russian nuclear corporation Rosatom on the wind power generation market; p 9 (623 words).

Kommersant: Yuri Barsukov interview with the Engie company CEO, headlined "'Russia must begin to build major renewable-resource-based power plants'", who speaks about the company's operation plans for Russia and partnership with Russia's Gazprom and Rosatom; p 13 (2,127 words).

Vedomosti: Anna Yeremina et al. article headlined "What to do in VTB" guesses how VTB24 bank president Mikhail Zadornov's resigning as a board member at the VTB bank will influence the bank's operation; p 14 (350 words).

Russia on the global arena

Komsomolskaya Pravda: Edvard Chesnokov transcript of an interview by Andrei Norkin with Foreign Ministry spokesperson Maria Zakharova headlined "Crimea joining Russia is a high example of democracy", who speaks about the Ukrainian conflict and a "Russian hand" in the US affairs, among other things; pp 6-7 (1,500 words).

Russia-Ukraine

Moskovsky Komsomolets: Nikolai Makeyev article headlined "Kiev forgives its debts to Moscow" says that Kiev has seen its Antimonopoly Court's decision to fine Russia's Gazprom for violations of antimonopoly rules as the go-ahead to pump Russian gas being exported via its territory to the EU. This comes amidst the Stockholm Arbitration Court's ruling that cancels the take-or-pay principle in the 2009 gas contract. However, experts say it is too early to celebrate victory for Kiev; p 2 (466 words).

Moskovsky Komsomolets: Maxim Artemyev article headlined "Anna Yaroslavna: Is she Kiev-originated, Russian or Ukrainian?" focuses on a dispute over the historical origins of Anna Yaroslavna, an 11th-century figure born in Kievan Rus who went on to become queen of France, initiated by Kiev following Putin's statements about her during his visit to France; p 3 (893 words).

Kommersant: Olga Mordyushenko article headlined "Kiev does not want heating from Moscow" says that Ukraine has presented a new energy strategy designed till 2035, which envisages giving up gas purchases from Russia; p 11 (615 words).

Russia-Montenegro-NATO

Moskovsky Komsomolets: Renat Abdullin interview with pundit Yuri Kvashnin, headlined "'Black list' for Montenegro", who tries to explain why Montenegro is rushing into joining NATO and why Moscow reacts to this so painfully; p 3 (597 words).

Vedomosti: Editorial by Nikolai Epple and Maria Zheleznova headlined "Sanitary days" comments on Russia resorting to the proven tool, a trade war, to express its displeasure with Montenegro's decision to join NATO; p 6 (300 words).

RBC: Georgy Makarenko et al. article headlined "'Developments are bad'" analyses causes behind a crisis in the Russian-Montenegrin relations. A Russian pundit suggests that the Russian authorities want to punish the stubborn partner for the desire to join NATO and mobilise the population; pp 8-9 (950 words).

Russia-USA

Moskovsky Komsomolets: Lyubov Glazunova article headlined "Trump vs hydra" focuses on an alleged campaign being conducted against US President Donald Trump by his opponents, who accuse him and his teammates of having ties with Russia. Experts say ties with Russia is Trump's "weak point" that the "Washington-based establishment is trying to take advantage of to make the president more obedient"; p 6 (1,706 words).

Nezavisimaya Gazeta: Igor Subbotin article headlined "Trump loses to virtual environment" says that Trump's opponents intend to summon the former FBI head and seven US officials to the Congress as part of the probe into his team's alleged ties with Russia. This comes amidst the anti-Russian hysteria rising in the US media. Meanwhile, some US law-makers are going to initiate new sanctions against Russia; pp 1, 6 (582 words).

Novaya Gazeta: Alexander Panov article headlined "Grand Master leaves" pays tribute to American political analyst Zbigniew Brzezinski, known for his anti-Russian views; pp 12-13 (1,918 words).

Rossiyskaya Gazeta: Igor Dunayevsky article headlined "Why does Trump need someone else's summer cottages?" says that US President Trump is reportedly inclined to return property owned by the Russian government in Maryland and New York, seized by the former US administration; p 8 (571 words).

Rossiyskaya Gazeta: Yevgeny Shestakov article headlined "Clouds gathered" says that US President Trump is expected this week to announce his decision on whether or not the USA will withdraw from the Paris climate agreement and suggests that Trump has already decided to quit the climate pact and "is just playing for time"; p 8 (736 words).

Eastern Ukraine conflict

Nezavisimaya Gazeta: Tatiana Ivzhenko article headlined "Normandy and Minsk formats get closer" says that truce has been at least maintained in Donbass as from 1 June after the operation of the Normandy Four format resumed. This proves that there are indeed effective influence tools to be used against the conflicting sides, the article says; p 5 (949 words).

Russia-Moldova

Izvestia: Alexei Zabrodin interview with Moldova's President Igor Dodon headlined "Expulsion of diplomats part of West's anti-Russian hysteria" who speaks about the reasons of the recent diplomatic scandal between Russia and Moldova; pp 1, 5 (500 words).

Komsomolskaya Pravda: Alexander Grishin interview with Igor Dodon headlined "I fall back on people, not corrupt elites" who speaks about the situation in the republic and its relations with neighbours, among other things; pp 10-11 (1,250 words).

Election race in UK

Nezavisimaya Gazeta: Yevgeny Pudovkin article headlined "Theresa May gets ready for final dash" looks at the election race in the UK ahead of the 8 June parliamentary election; p 6 (668 words).

Sources: as listedInclusion of items in this list of significant reports from some of the day's main Russian newspapers does not necessarily mean that BBC Monitoring will file further on them

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[***Managing menu innovation in a saturated market: An empirical evidence from the Chain restaurants in Malaysia***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:6BM4-FYP1-JBMY-H00M-00000-00&context=1516831)

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**ABSTRACT**

This paper presents the empirical results of a recently concluded research study about managing menu innovation in a consumer market that has reached to its saturation level. Such market condition resulting in increased competition and, therefore, a need for increased innovation is essential. In this study, an investigation was carried in substantiating the effect of market saturation toward the relationship between innovation orientations and new menu innovation process. The region of Klang Valley was chosen as the study setting for its dynamic and matured consumer foodservice market. In this investigation, the theoretical conceptualization and the empirical validation of the proposed menu innovation process as a second-order hierarchical model along with the moderating variable of market saturation as first-order constructs were first advanced using both Statistical Package for Social Science (SPSS version 19) and partial least squares. Empirically, the measurement and structural models of this study confirmed adequate estimations based on partial least squares path modeling parameters. In line with the strength of partial least squares to explain complex relationships, the use of path modeling has made it possible to advance the theoretical contribution to this study. The results show that the moderating effect of market saturation on the link between the exogenous and endogenous variables found to have a medium effect size (f2 = 0.289) and significant at ρ < 0.05). The findings point to managerial challenges in shaping competition as evidence of radical innovations is still being pursued, although slightly weaken. This study, apart from its contribution to the model development of menu innovation process, has meaningful implications for restaurateurs to stay afloat in such a market condition.

**FULL TEXT**

**Introduction**

In recent years, the vibrant transformation of the Malaysian consumer foodservice market has brought a diverse range of food services that presents challenges for restaurateurs to gain market shares. A recent global survey indicated that urban dwellers in major cities in Malaysia are increasingly dynamic and known to be affluent in a palate point of view, where 67% reported to eat out of home as least once a week (Nielson, 2011). Correspondingly, there has been a phenomenal growth rate of restaurants and food services in Malaysia arisen from 82,325 in 2001 to 145,320 in 2012 (Euromonitor International, 2012). Unfortunately, according to this report, much of the congregation of food service business remains at large in region of Klang Valley, Kuala Lumpur, Penang, and Johor Bahru that are already known for its saturated markets (Euromonitor International, 2012). Evidently, although these encouraging growth factors illustrate irresistible response from the industry’s practitioners, in a life cycle theory, continuous unit growth in a saturated market is likely to have an adverse effect on business sales values and operational transactions (Hashimoto, 2003). According to this theory, when a diffusion of similar product orientations has reached a point of saturation in the marketplace, further growth can only be achieved through new product innovation, and if the new product is developed in line with the consumers’ market trends, market share gains can be enlarged (Cobbenhagen, 2000; Drucker, 1985; Porter, 1985). Therefore, as the global consumer, foodservice markets are constantly evolving and many have been known to reach to its pinnacle point, this study seeks to ascertain chain restaurateurs strategy of adopting innovation orientations when engaging into menu innovation in the region of Klang Valley.

**Research background**

To date, the seeds of the nation’s Vision 2020 that was tabled in the Sixth Malaysian Plan in 1991 to become an industrialized nation have sown fruitful socioeconomic developments, but mainly ripened in selected cities. Corresponding to this and along with rapid changing global conditions amid the financial crisis 2007–2010, in 2009, new economic reforms were forwarded and the National Economic Advisory Council of Malaysia appointed to review the roadmaps of the Vision 2020. While such revisions are still in its infancy, earlier implementations of the National Economic Policy saw cities of Kuala Lumpur, Johor Bahru, Penang, and the region of Klang Valley continue to leap further as catalysts in socioeconomic developments. To a large extent, this has made the above-mentioned cities and the region of Klang Valley become the center of business attractions due to their vibrant society and high numbers of visiting tourists receipt as opposed to most other cities/towns that are rather lackluster in socioeconomic developments. In light of this disparity of socioeconomic developments, congregation of foodservice businesses continues to flourish in a phenomenal rate to tap the largely affluent consumers’ market of Kuala Lumpur, Johor Bahru, and Penang, and around the region of Klang Valley (Euromonitor International, 2012).

However, this trend of food services foothold that concentrates heavily at the above-mentioned ***geographical*** locations has turned its marketplace to a state of saturation (Euromonitor International, 2012). A closer review in the hospitality literature indicates that “me-too” product development is far too common in the foodservice industry (Jones and Wan, 1992). Hence, this makes the life cycles of the products become even shorter as fierce competition builds up in the marketplace (Cobbenhagen, 2000; Feltenstein, 1986; Mcllveen, 1994), particularly, due to low barrier to business entries (Davis et al., 2012). It is relatively unknown if these foodservice operators are actually aware of the threat of trading business in such a market condition. Such threat, that in theory can affect business sales due to shrinking market shares as the number of food service outlets continues to rise rapidly (Feltenstein, 1986; Hashimoto, 2003).

Theoretically, when a supply of products reaches the maximum level in the marketplace to a point called saturation, additional augmentation can only be attained through new product innovation, market share gains, or a sudden increase in consumers’ demands (Cobbenhagen, 2000; Hashimoto, 2003). Hence, if there is no sudden rise in overall consumer demand, the strategy for expanding business units in such a market condition is deemed logically unfeasible as this will only lead to decline in sales growth. In light of this, Feltenstein (1986) argues that for restaurateurs to be able to increase their market share gains and/or to resurrect sales growth, new menu innovation has to be introduced by either developing new ones or improving existing menus.

**Literature review**

Managing menu innovation has been long sought in hospitality literature (Feltenstein, 1986; Jones, 1996; Jones and Wan, 1992; Mifli, 2004; Mooney, 1994; Ottenbacher and Harrington, 2007, 2008). Ironically, despite the importance of food in daily consumption for every living society, studies of menu innovation in the foodservice industry are quite a new proposition compared to earlier studies of innovation management in engineering and manufacturing industries (Booz, Allan, & Hamilton, 1968; Cooper, 1979; Schumpeter, 1934). A close review of the literature reveals that menu innovation is managed through a systematic process (Feltenstein, 1986; Jones, 1996; Mifli, 2004; Ottenbacher and Harrington, 2007, 2008), akin to the traditional PIP in the engineering industry called “sequential product development process” (Iansiti, 1995). Mooney (1994: 46) advocates that this structured approach is a “type of disciplined approach” and widely adopted by foodservice management in many sectors of the industry.

In a broader perspective, PIP is generally commissioned in a sequential process. This stage-by-stage approach that is also commonly referred to as the traditional method is divided into two main stages: concept development and implementation (Iansiti, 1995; See Figure 1). In this two-stage approach of PIP, all the activities of innovation generations are executed at the first stage in a prescribed concept lead time. Once it reaches the concept freeze point, the so-called window of opportunity is closed and generation of new ideas is generally not permitted as the next implementation stage begins (Cunha and Gomez, 2004). Nevertheless, the activities at each stage are not explicitly detailed out in Iansiti’s (1995) study. Yet, a reasonable argument is that such stages are likely similar to the earlier work of Booz, Allan, and Hamilton’s (1968) new product development (NPD) process model, which then became the catalyst to the development of subsequently models (e.g., Booz, Allan, & Hamilton, 1982; Fuller, 1994; Graf and Saguy, 1991; Kotler and Armstrong, 1991; MacFie, 1994; Urban and Houser, 1993). In these earlier models, the stage approach to NPD comes in various stages, but predominantly included these four main stages: formulation, concept development, concept design, and testing and evaluation.

While this methodical disciplined approach to NPD sheds insight into the management of product innovation, a recent argument with a notion of constantly evolving environment changes, knowledge information, and technological advancements requires a flexible innovation management strategy as opposed to rigid process of product innovation (Cunha and Gomez, 2004). Cunha and Gomez (2004) argue that in today’s dynamic environments, management of product innovation should incorporate the elements of flexibility along the first stage of the NPD process. Therefore, they argue that the “window of opportunity” should be prolonged so that inputs of new information pertaining to external environmental factors can be incorporated accordingly and changes can be made along the concept lead time.

Logically, the argument by Cunha and Gomez (2004) sheds some valid points. Yet, other scholars argue that such flexibility occurring in PIP may ultimately lead to delays in launching products (Cooper and Edgett, 2003). Cooper and Edgett (2003) argue that the key to product innovation is not only to develop new products that can be sustained in the marketplace for longer period but also be quickly and timely launched. This is because in a competitive and constantly changing business landscape, development of a new product in a timely manner is equally critical in order to be first introduced in the marketplace ahead of competitors (Abernathy and Clark, 1985; Cooper and Edgett, 2003). In light of this, Cunha and Gomez (2004) propose new NPD process models called concurrent and integrative, which allow overlapping and integrated activities. Hence, inclusion of new information can still be addressed and incorporated even after the concept freeze point, and therefore, the original schedule of product launching is not jeopardized.

Indeed, the development of these models of PIP enriches the body of knowledge in product innovation management. Nevertheless, even though there has been considerable progress in developing the framework of PIP that explain differing competitive success at any given point in time (Booz, Allan, & Hamilton, 1982; Fuller, 1994; Graf and Saguy, 1991; Kotler and Armstrong, 1991; MacFie, 1994; Rodolf, 1995; Rudder, 2003; Suwannaporn and Speece, 2000; Urban and Houser, 1993), the understanding of the dynamic processes by which menu planners adopt and ultimately attain superior market positions is far less comprehended in the context of foodservice industry. Past study indicated that there are four types of approaches to menu innovation in the foodservice industry, namely “original product which is totally original,” incremental product development that is adapted from inside firm, “modified product which is adapted from outside firm,” and “*me too* product which is purely adopted from outside firm” (Jones and Wan, 1992). In a broader perspective, after carefully reviewing the literature (Abernathy and Clark, 1985; Booz, Allan, & Hamilton, 1982; Schumpeter, 1942; Tushman and Adersen, 1986), these four types of product innovations defined by Jones and Wan (1992) are in fact resembled to the paradigms of innovation orientations that suggests NPD is shaped either being radically or incrementally driven. Incremental orientation is defined as “a result of redefining prevailing knowledge,” whereas radical orientation arises because “prevailing knowledge get transformed” (Tushman and Adersen, 1986). Historically, almost all NPDs are incrementally oriented as opposed to radical orientation (Booz, Allan, & Hamilton, 1982; Dacko, 2000; Fuller, 1994; Hanna et al., 1995; Rudder, 2003). Therefore, it is reasonable to assert that development of product “newness” is rarely adopted despite claimed by others of its competitive advantage in market share gains (Miller and Friesen, 1982; Salavou and Lioukas, 2003; Saleh and Wong, 1993; Schumpeter, 1942).

**Innovation orientations**

The prevailing question of should NPD be based on radical or incremental has been long addressed (Abernathy and Clark, 1985; Schumpeter, 1942; Tushman and Adersen, 1986). Yet, due to the paucity of empirical study in the hospitality industry, little is known the realism of innovation orientations adoption in this industry (Jones and Wan, 1992). Hence, in light of this scarcity, most of the literature review presented in this section come from other industries, but equally critical in understanding the evolution of innovation management with particular reference to the orientation of NPD.

The infamous work of Schumpeter’s “creative destruction,” which has been the vehicle to the growth of radical innovation, shed a new dimension of how new technical breakthrough can uplift a firm’s competitive advantage in the marketplace with the expense of “killing” the old method of doing. Indeed, the revolution of Schumpeter’s theory of innovation saw many occurrences of “creative destruction,” such as the vanishing of the computer mainframe that was once the hallmark of innovation achievement. While much of today’s innovation management is credited to Schumpeter’s theory of innovation, Abernathy and Clark’s (1985) transilience map of innovations is equally accredited as they discreetly challenged Schumpeter’s theory of innovation as a unified phenomenon. In Abernathy and Clark’s work, the four categorizations of innovations are placed in a quadruplet matrix where vertical and horizontal lines across each other to form the dimensions of market and technology transilience scales, which they called it “transilience map.” Each of these innovations, namely niche creation, architectural, regular, and revolutionary plays distinctive roles in shaping the desire innovation outcomes. According to them, the “creative destruction” theory that promotes innovation as a unified phenomenon seems questionable as they found out that not all innovations lead to disruption, destroy, or a completely obsolete of past practice. In the second study of Booz, Allan, and Hamilton (1982) on NPD in the US manufacturing firms, 90% of NPD found not purely innovative or absolutely new to the marketplace, but rather incremental in nature. Similar studies on product innovation have also shown that trends of product incremental orientation appeared to be the strategy used in NPD (Dacko, 2000; Fuller, 1994; Hanna et al., 1995; Rudder, 2003; Samli and Webber, 2000).

The insight of this development appeared to suggest that most NPD are based on incremental innovation. Therefore, given the nature of incremental innovations is to reinforce prevailing market structure and conserve existing competencies (Abernathy and Clark, 1985), it is reasonable to conclude product newness is rather rare and, therefore, radical innovation, which is to reinforce prevailing new knowledge replacing the old one, is less likely the preferred ***strategic*** choice. Another school of thought suggests that strategy to innovation in NPD also reflects the degree of competitiveness and impact in the marketplace (Balachandra and Friar, 1997; Cooper and Kleinschmidt, 2000; Ettlie and Subramaniam, 2004).

**Theoretical development**

In line with the objective of this study to ascertain the adoption of innovation orientation used by restaurant chains in shaping the new menu development amid facing market saturation, dimension of market saturation is developed in this study in seeking its moderation effect on the relationship between innovation orientations and concept development, the first stage of NPD process. The inclusion of this market saturation, as moderator, between the links of innovation orientations and concept development is expected to unveil actual adoption of innovation orientation by restaurant chains. Such relationships proposed in this study’s research model are deemed practical in order to ascertain how far does market saturation played a part in moderating menu planners’ innovation orientation in shaping their new menu development process, which as far as it is known never been attempted in empirical research.

Theoretically, almost all new products would undergo some form of development process either through a structured or unstructured approach. Conceptually, although both approaches are managed differently, they in fact share a common goal. A goal that is to innovate a new product that is sustainably competitive in the marketplace and subsequently able to gain market shares. Understanding these approaches rests on the underlying theory of the firm’s ***strategic*** direction and the associated theory of innovation orientation, which in turn correspond to the development of the new menu. The theory of firm’s ***strategic*** direction is closely linked to ***strategic*** management orientations within the firm that commonly decreed by top management personals (Miller, 1987). Notably, there are several terminologies used to denote ***strategic*** management orientations, such as proactive, reactive, reaction, rationality, assertiveness, and bounded rationality, and each of them is theorized differently (Cyert and March, 1963; Miller and Friesen, 1982; Porter, 1980, 1985; Wood and Robertson, 1997). Similarly, Miles and Snow’s (1978) typology of ***strategic*** types, four archetypes—prospectors, analyzers, defenders, and reactors—has been long advocated in the literature and known to be closely related to firm orientations and/or individual decision-making behaviors toward product–market development.

In this study, the two-stage approach to product innovation and NPD models existed in literature is synthesized. Although, a three-stage model of product innovation has been documented in literature (Utterback, 1971), the two-stage model is considered to possess theoretical parsimony and widely cited in innovation literature (Frambach and Schillewaert, 2002; Henderson and Clark, 1990; Knight, 1967; Rogers, 1995; Van de Ven, 1986; Zaltman et al., 1973). Furthermore, the application of this two-stage model of product innovation is conceptually similar to NPD model of which the first stage, known as concept development, involves the activities of innovation idea generations whilst, the later stage focuses on the implementation of selected ideas that have undergone in several process stages. Figure 1.The two-stage approach of product innovation process. *Source*: Iansiti (1995).

As presented in Figure 2, both models of product innovation and NPD are placed parallel along with the NPD process model, which involves various stages. Nonetheless, the number of stages in NPD process models advocated in the literature is rather unstandardized (e.g., Booz, Allan, & Hamilton, 1982; Feltenstein, 1986; Fuller, 1994; Graf and Saguy, 1991; Jones, 1996; Kotler and Armstrong, 1991; MacFie, 1994; Mifli, 2004; Ottenbacher and Harrington, 2007, 2008; Urban and Houser, 1993). This is because most firms, if not all, face-varying degrees of environmental competitiveness that are conceived differently due to varying styles of managerial orientations, and therefore, variations in stage approaches to the NPD process are inevitable. We then present the structural theory in Figure 2 by linking market saturation, as a moderator, on the relationship between innovation orientations and concept development. Figure 2.Structural theory.*Note*: Solid lines represent the relationships that are examined in this study.

**Hypotheses development**

Generally, the success (or failure) of organizations operating in a competitive business landscapes has frequently been linked to the concept of ***strategic*** management orientations in both marketing and management literature (Miles and Snow, 1978; Porter, 1980). Evidently, ***strategic*** management orientation is widely viewed to have significant impact on both management expectation and organizational performances (Kohli and Jaworski, 1990; Miller, 1987; Mintzberg, 1994).

However, studies related to ***strategic*** management orientations on product innovation in the foodservice industry, as far as it is known, receive little attention in empirical testing (Jones and Wan, 1992). By large, most previous studies centered heavily on the assessment of PIP across different restaurant sectors (Feltenstein, 1986; Jones, 1996; Mifli, 2004; Ottenbacher and Harrington, 2007, 2008). Chakravarthy (1997) argues that identification and capitalization for emerging market and business opportunities rest upon managerial adaptability of “know how,” which in turn, implies changes to the direction of the organizational ***strategic*** postures (Oktemgil and Greenley, 1997). In a similar note, ***strategic*** management orientation has been noted to influence the degree to which strategies within an organization are coherent, stable, and assertive (Ansoff, 1965; Steiner, 1969). Given this consideration, a research question is forwarded to ascertain which ***strategic*** innovation orientations played a part in shaping concept development, the first stage of the NPD process. This study would then forward the following hypothesis: **Hypothesis 1a:** Radical innovation orientation has a significant impact on concept development.**Hypothesis 1b:** Incremental innovation orientation has a significant impact on concept development.

Indeed, the fundamental perspective of the direct linkage between ***strategic*** innovation orientations and organizational performance is well explored in management and marketing literatures. Yet, others argue that, as most industries face different environmental competitiveness, the adoption of ***strategic*** management orientations may also vary across and within industries (Montoya-Wess and Calantone, 1994). Furthermore, the fundamental assertion of ***strategic*** management orientations can be embraced as a range of domain characteristics of managerial preferences, namely risk taking, entrepreneurship, objectivity, assertiveness, and information use (Wood and Robertson, 1997). In addition, because there are inherent effects from the surrounding business landscapes (market saturation as in this case), which may be conceived in different levels of attention by the decision makers, this inevitably lead to variation in NPD strategies (Porter, 1980). Therefore, the next research question is to find out to what extent does market saturation moderate menu planners’ innovation orientation on concept development. Hence, the final hypothesis of this study is forwarded as follows: **Hypothesis 2:** Market saturation moderates the relationship between innovation orientations and concept development.

**Methods**

In this study, a newly designed questionnaire for market saturation and concept development constructs was developed. In Table 1, existing literature deemed relevant to the focus of inquiry was synthesized and the characteristics of variables suspected to be closely related to represent the respective constructs under investigation were put forward. A new set of questionnaires were designed to measure the impact of market saturation on the stages along the concept development lead time and demographic variables. To ensure complete clarity and readiness, a pretest was conducted by selected panels of experts who reviewed and revised the draft version of these questionnaires several times, which concurrently enhanced its content validity. As for innovation orientations construct, a bipolar semantic differential measurement scale of Salavou and Lioukas’ (2003) findings was adapted where minimal adjustment was made for the purpose of this study. This type of instrument scale was deemed appropriated and has been advocated in a previous empirical study on product innovation orientation (Abernathy and Clark, 1985), where the characteristics of both incremental and radical orientations were paired side by side, using a 7-point scale. Table 1.Total of scale items used from various relevant sources.

| **Constructs** | **Characteristics** | **No. of items** | **Sources** |
| --- | --- | --- | --- |
| Innovation orientationsa | **Original source** | 9 items | Single source |
| Market saturationb | • Complex and dynamic market • Volatile market conditions with sharp discontinues in demand and growth rates • Competitive advantages that are continually created in the market • Low barriers to entry/exit that continuously change the competitive structure of the market • Drastic changes in customers’ food preferences/demand • Changes in customers’ price acceptances • Rapid changes in the composition of competitors • Technological advances accelerate the rate of changes in the marketplace | 7 items | Multiplec sources |
| Concept developmentb | **Idea generations** • Culinary magazine • Cooking books • Competitors • Personal experiences • In-house market research • Customer comments/suggestions • Interdepartmental/group meetings **Concept testing** • Customer survey • Focus group • Pretesting in selected markets **Business analysis** • Recent competition actions among rival competitors • Changes in economic conditions • New legislation • Changing demographic patterns • Past and current restaurants’ success and failure **Product testing and design** • To convert the concept into an operational entity, testing and redesign are required • Testing and design of new products are performed by in-house specialists’ team • If in-house specialists are lacking, new ones will be hired or outside consultant is sought • By introducing new products, design of new production process is required • By introducing new products, installing new equipment is required **Preliminary marketing** • In-house panel • Focus group • Market survey • Food testing **Market trials** • Place card on dining table • Blackboard menu • Promotional campaigns-flyers, trade magazine, etc • Predetermined market areas **Customer feedback** • Quality • Price • Value perception • Intent to repurchase • Regularity of patronage | 7 items 3 items 5 items 5 items 4 items 4 items 5 items | Multipled sources |

aQuestionnaires were adapted from existing measures in the literature (Salavou and Lioukas, 2003).bNewly developed variables adopted/extracted from various sources and subjected to appropriate measures of purifications.cMontoya-Weiss and Calantone (1994), Iansiti (1995), Calantone et al. (2003), Dess and Beard (1984), Miller (1987), Glaser and Weiss (1993), Chakravarthy (1997).dFeltenstein (1986), Mooney (1994), Jones (1996), Ottenbacher and Harrington (2007, 2008).

The research instrument was then piloted, adopting a judgment sampling technique that was deemed appropriated to obtain information from the “expert” personnel (Sekaran, 2000). A total of 205 established foodservice companies were identified and arrangements for a survey interviewer-completed method were made to interview the expert personnel directly involved in managing the company’s NPD. Fifty companies agreed to participate but only 33 companies were successfully interviewed and rest were simply not interested along the process. The piloted data then underwent purification, using SPSS Version 19, to enhance and determine its reliability and structural factor of these newly developed 5-point measurement scales (Hair et al., 2010). Purification of each of the multi-item scales measuring variables was factor analyzed in order to assess their factorial validity, which is also a form of construct validity (Allen and Yen, 1979).

In Table 2, the results of the exploratory factor analysis (EFA) that considered significant with the value of Kaiser–Meyer–Okin statistic at 6.0, and based on factor loadings of the variables at or greater than 0.5 and anti-image correlation matrix cutoff value of 0.5, were retained (Comrey and Lee, 1992; Kline, 2005; Malhotra, 1996; Nunnally, 1978; Tabachnick and Fidell, 2001). In addition, raw scores of individual items pertaining to factors extracted, using principle component analysis (PCA) method, were summed in each dimension to arrive at overall measure along with the minimum acceptable Cronbach’s alpha value at 0.60 (Nunnally, 1978). Table 2.Results of preliminary statistical purifications.

| **Dimension 1: Market saturation** |  |
| --- | --- |
| Factor 1 | Loading |
| Competitive advantage that are continually created | .921 |
| Low barriers to entry that are continually created | .566 |
| Drastic changes in customers’ food preferences | .668 |
| Changes in customers’ price acceptances | .754 |
| Rapid changes in the composition of competitors | .733 |
| Percentage of total variance explained | 54.43 |
| Coefficient alpha | .78 |
| Number of items | 5 |
| Extraction method: Principle component analysis (PCA). |  |

| **Dimension 2: Concept development** | **Pattern Matrixa** |  |  |  |
| --- | --- | --- | --- | --- |
| (Coefficient alpha for scale: 0.69) | F1 | F2 | F3 | F4 |
| Factor 1: Idea generation |  |  |  |  |
| Culinary magazines | .653 |  |  |  |
| Cooking books | .751 |  |  |  |
| Meeting to discuss market trends | .870 |  |  |  |
| Value perception | .693 |  |  |  |
| Factor 2: Concept testing |  |  |  |  |
| Competitors |  | .903 |  |  |
| Testing and design are performed by in-house specialist team |  | .772 |  |  |
| Food testing |  | .677 |  |  |
| Regular customer |  | .747 |  |  |
| Factor 3: Product testing and design |  |  |  |  |
| To convert the concept into operational entity, testing and design are required |  |  | .868 |  |
| By introducing new product, design of new production process is required |  |  | .901 |  |
| Factor 4: Premarketing |  |  |  |  |
| Customer survey |  |  |  | .873 |
| In-house panel |  |  |  | .641 |
| Place card on dining table |  |  |  | .723 |
| Percentage of total variance explained | 29.99 | 15.09 | 15.00 | 12.38 |
| Cumulative variance (%) | 29.99 | 45.07 | 60.10 | 72.45 |
| Coefficient alpha | .76 | .78 | .90 | .62 |
| Number of items | 4 | 4 | 2 | 3 |

Extraction method: Principle component analysis (PCA). Rotation method: Promax with Kaiser Normalization.aRotation converged in eight iterations.

The final research instrument comprised of five parts. First, the original version of Salavou and Lioukas’ (2003) bipolar semantic differential 7-point scale was adopted with minimal adjustment to denote respondents’ product innovation orientations. Second, the characteristics of market saturation that have a link to moderate respondents’ decision-making process when engaged in managing menu innovation was measured using a 5-point Likert-type scale ranging from “greatly influenced” to “hardly any influenced” and “greatly influenced” to “not at all,” respectively. Finally, the hierarchical construct of concept development was measured using a 5-point Likert-type scale ranging from “very often” to “never” for the dimensions of idea generation and premarketing, and “very important” to “not at all important” and “strongly agree” to “strongly disagree” were used for the dimensions of product concept testing and product testing and design, respectively. Finally, the demographic variables of the subjects, such as gender, age groups, education levels, and business information, such as business tenure, restaurant type were measured.

**Specifying concept development as a higher order construct**

A higher order construct (HOC), which is also called a hierarchical construct, refers to a construct that has more than one dimension, where each dimension captures some portion of the overall latent variable (Edwards, 2001; Jarvis et al., 2003; Wetzels et al., 2009). Partial least square (PLS) path modeling (or component-based structural equation modeling [SEM]), using Smart-PLS Version 2.0 M3, was used to estimate the HOC of concept development by adopting repeated use of manifest variables (Ringle et al., 2005). The scores of lower order latent variables of idea generation, concept testing, product testing, and design and premarketing determinate in PLS path analysis were subsequently used as manifest variables for the HOC of concept development, which are illustrated in Figure 3. This method allows for estimating the hierarchical model to achieve more theoretical parsimony and reduce model complexity (Chin, 2010; MacKenzie et al., 2011). Figure 3.Concept development as a hierarchical model. Adapted from Chin (2010).

**Population and data collection**

During the period of final data collection, there were nearly 4000 chain outlets in operation across major cities in Malaysia by 112 local and international chain companies (Euromonitor International, 2010). Notably, most of these chained outlets, particularly in the fast-food sector, are international brand ownerships that are made possible through franchising agreements. In terms of brand names and numbers of outlets, the full-service restaurant (FSR) sector dominated the most with 86 brands and more than 1200 outlets (86/1200+), followed by fast-food (21/1000+), cafés/bars (7/160), street stalls/kiosks (2/108), and 100% home delivery/takeaway (1/19). Out of these 112 chained companies, a total of 71 data was successfully collected that took almost a year to complete.

**Analysis and results**

Smart-PLS was used to assess the hierarchical model of concept development in order to estimate the parameters in the outer and inner structural theories (Ringle et al., 2005). The application of nonparametric bootstrapping (Chin, 1988; Tenenhaus et al., 2005; Wetzels et al., 2009) was then applied with 5000 replications (Hair et al., 2014) to obtain the *τ* value and standard errors (*SEs*).

**Measurement outer model results**

In assessing the structural outer model, all the structural links among constructs were drawn and path-weighting scheme was set in the PLS algorithm settings (Chin, 2010). The preliminary evaluation of the reflective outer models is shown in Table 3. Subsequently, the structural outer model was reassessed of its goodness of measures. Loadings and cross loadings of the respective outer models were compared and all the items measuring each of the respective constructs and latent variables loaded highly and loaded lower on the ***opposite*** thus confirming construct validity. Additionally, the structural outer model was also assessed of its convergent validity and discriminant validity. Table 3.Results of preliminary evaluation of the reflective outer models.

| **Constructs/latent variables** | **Original items** | **Label items** | **Loadings** | ***Deleted* items** |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Innovation orientations | Less new product | 1–7 | More new products | IO1 | 0.598 |  |
| Changes in menu products have been mostly of minor nature | 1–7 | Changes in menu products have usually been radical | IO2 | 0.371 | ***Deleted*** |  |
| There is a strong emphasis on marketing of true and tried menu products | 1–7 | There exists a very strong emphasis on the development of new and innovative products | IO3 | 0.419 |  |  |
| There is a strong proclivity for low-risk NPD with normal and certain rates of return | 1–7 | There is a strong proclivity for high risk NPD with changes of very high return | IO4 | −0.253 | ***Deleted*** |  |
| Owing to the nature of the environment (saturated), it is best to explore gradually via cautious, incremental behavior | 1–7 | Owing to the nature of the environment (saturated),wide-ranging acts are necessary to achieve the restaurant’s objective | IO5 | −0.029 | ***Deleted*** |  |
| Typically we adopt a cautious, wait and see posture in order to minimize the probability of making costly decision | 1–7 | Typically we adopt a bold, aggressive posture in order to maximize the probability of exploiting potential opportunities | IO6 | 0.262 | ***Deleted*** |  |
| Typically we respond to action that competitors initiate | 1–7 | Typically we initiate action to which competitors then respond | IO7 | −0.324 | ***Deleted*** |  |
| We are very seldom the first business to introduce new products | 1–7 | Very often we are the first business to introduce new products | IO8 | 0.541 |  |  |
| We typically seek to avoid competitive clashes, preferring a “live-&-let live” posture | 1–7 | We typically adopt a very competitive, undo-the-competitors’ posture | IO9 | 0.641 |  |  |
| Market saturation | Competitive advantage that are continuality created | MS1 | 0.579 |  |  |  |
| Low barriers to entry that are continually created | MS2 | 0.909 |  |  |  |  |
| Drastic changes in customers’ food preferences | MS3 | 0.007 | ***Deleted*** |  |  |  |
| Changes in customers’ price acceptances | MS4 | −0.091 | ***Deleted*** |  |  |  |
| Rapid changes in the composition of competitors | MS5 | 0.379 | ***Deleted*** |  |  |  |
| Idea generations | Culinary magazines | ID1 | 0.880 |  |  |  |
| Cooking books | ID2 | 0.915 |  |  |  |  |
| Meeting to discuss market trends | ID3 | 0.373 | ***Deleted*** |  |  |  |
| Value perception | ID4 | 0.623 |  |  |  |  |
| Concept testing | Competitors | CT1 | 0.857 |  |  |  |
| Testing and design are performed by in-house specialist team | CT2 | 0.898 |  |  |  |  |
| Food testing | CT3 | 0.601 |  |  |  |  |
| Regular customers | CT4 | 0.835 |  |  |  |  |
| Testing and design | To convert the concept into operational entity, testing and design are required | TD1 | 0.959 |  |  |  |
| By introducing new product, design of new production process is required | TD2 | 0.950 |  |  |  |  |
| Premarketing | Customer survey | PM1 | 0.745 |  |  |  |
| In-house panel | PM2 | 0.892 |  |  |  |  |
| Place card on dining tables | PM3 | 0.088 | ***Deleted*** |  |  |  |

Note: NPD: new product development.Items with lower loading value below 0.4 were ***deleted*** in accordance to Hulland’s (1999) cutoff value at 0.40 in exploratory studies.

The results, which are shown in Table 4, saw the measures of the constructs/latent variables were theoretically related where most items loading values were higher than the cutoff value of 0.7 (Hair et al., 2012; Hulland, 1999) and significant at *ρ* < 0.01. In addition, the average variance extracted (AVE) and composite reliability (CR) values for all the constructs and latent variables of concept development were also found to exceed the threshold values of 0.5 and 0.7, respectively (Bagozzi and Yi, 1988; Hair et al., 2010), thus confirming strong evidence of convergent validity. In Table 5, comparison between the AVE values and the squared correlations among constructs/latent variables was also used to measure the constructs discriminant validity and found each of the constructs was highly related to its own measures than with others. With these results, the structural outer models, therefore, can be validly and reliably confirmed of its theoretical relationships. Table 4.Psychometric properties of the outer models.

| **Constructs/latent variables** | **Measurement items** | **Loadings** | **SE** | **τ** | **CR** | **AVE** |
| --- | --- | --- | --- | --- | --- | --- |
| Innovation orientations | IO1 | 0.786 | 0.168 | 4.683 | 0.811 | 0.523 |
| IO3 | 0.523 | 0.219 | 2.387 |  |  |  |
| IO8 | 0.782 | 0.215 | 3.638 |  |  |  |
| IO9 | 0.769 | 0.164 | 4.680 |  |  |  |
| Market saturation | MS1 | 0.579 | 0.329 | 1.757\* | 0.763 | 0.63 |
| MS2 | 0.962 | 0.320 | 3.010 |  |  |  |
| Idea generation | ID1 | 0.898 | 0.022 | 40.257 | 0.852 | 0.666 |
| ID2 | 0.927 | 0.015 | 61.205 |  |  |  |
| ID4 | 0.576 | 0.127 | 4.541 |  |  |  |
| Concept testing | CT1 | 0.861 | 0.076 | 11.342 | 0.879 | 0.649 |
| CT2 | 0.899 | 0.062 | 14.445 |  |  |  |
| CT3 | 0.593 | 0.166 | 3.572 |  |  |  |
| CT4 | 0.833 | 0.136 | 6.128 |  |  |  |
| Testing and design | TD1 | 0.958 | 0.012 | 78.217 | 0.953 | 0.911 |
| TD2 | 0.950 | 0.021 | 44.642 |  |  |  |
| Premarketing | PM1 | 0.804 | 0.081 | 9.935 | 0.841 | 0.726 |
| PM2 | 0.894 | 0.031 | 29.031 |  |  |  |

Note: CR: composite reliability; AVE: average variance extracted; *SE*: standard error.\*Significant at *ρ* < 0.10; the rest of the *τ* values were all significant at *ρ* < 0.01.Table 5.Discriminant validity of constructs.

| **Constructs/latent variables** | **1** | **2** | **3** | **4** | **5** | **6** |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Innovation orientations | **0.523** |  |  |  |  |  |
| 2. Market saturation | 0.004 | **0.630** |  |  |  |  |
| 3. Idea generation | 0.505 | 0.052 | **0.666** |  |  |  |
| 4. Concept testing | 0.000 | 0.069 | 0.182 | **0.649** |  |  |
| 5. Testing and design | 0.069 | 0.099 | 0.278 | 0.242 | **0.911** |  |
| 6. Premarketing | 0.026 | 0.045 | 0.135 | 0.121 | 0.175 | **0.726** |

Note: Diagonals (in boldface) represent the average variance extracted (AVE), while the other entries represent the squared correlations.

**Assessment of the second-order construct of concept development**

The second-order construct of concept development was measured by modeling each of the latent variables’ (i.e., idea generations, concept testing, product testing, and design and premarketing) coefficients to the second-order construct (concept development) (Chin, 2010). Accordingly, these latent variables, representing 11 (3 × 4 × 2 × 2) indicators (manifest variables) were pulled together as the reflective measure of concept development in Smart-PLS for statistical model and the results can be seen in Table 6. Table 6.Results of higher order construct and its associations with first-order latent variables.

| **Relationships** | **M** | **SE** | **β** | **R2** | **τ** |
| --- | --- | --- | --- | --- | --- |
| Concept development → Idea generations | 0.796 | 0.052 | 0.782 | 0.612 | 15.193 |
| Concept development → Concept testing | 0.792 | 0.091 | 0.787 | 0.620 | 8.775 |
| Concept development → Testing and design | 0.811 | 0.055 | 0.819 | 0.671 | 14.734 |
| Concept development → Premarketing | 0.670 | 0.051 | 0.616 | 0.379 | 11.877 |

Note: *SE*: standard error.*τ* values were all significant at *ρ* < 0.01.

As can be seen in Table 6, all the standardized path coefficients (*β*) were found to be significant at *ρ* < 0.01. In terms of coefficient of determination (*R*2), a measure commonly used in model predictive accuracy (Hair et al., 2014), latent variables of idea generations, concept testing and product testing, and designs was found to be at 61.2%, 62%, and 67.1%, respectively, which is nearly at 70% of the threshold value of high predictive accuracy. Whereas, premarketing was found to be at moderate level with 37.9% explained variance based on Hair et al. (2014) assessment of *R*2 values of 0.20 (weak), 0.50 (moderate), and 0.75 (substantial).

**Assessment of the structural theory**

To measure the structural theory appropriately, the predictive power of the linear structural model was carried out by linking the latent variable of innovation orientations and concept development. The results of the PLS algorithm analysis, a statistical measurement tool that emphasizes predictive accuracy of explained variance (Hair et al., 2014), indicated that an *R*2 value of 0.151 was obtained for concept development. Hence, categorically, in terms of its predictive accuracy, the structural model of this linear relationship was found to be slightly below weak level based on Hair et al.’s (2014) assessment of *R*2 values as only 15% explained variance yielded. On the other hand, a negative standardized coefficient value was obtained at 99% significance level (*β* = −0.388, *τ* = 2.382, *ρ* < 0.01).

**Testing the moderating effect**

A moderation analysis was performed by linking latent variable of market saturation to the endogenous construct (concept development) along with its generated interaction model as moderator (see Figure 4). With the inclusion of the interaction model, the value of the *R*2 for concept development increased to 0.418, it improves the structural model’s predictive accuracy to 41.8%. In establishing the significance of the interactions estimate, the results of this moderation analysis, which are shown in Table 7, it can be concluded that this study found support for significant moderating effect of market saturation on the relationship between innovation orientations and concept development at 95% significance level. Figure 4.Results of structural model testing.Table 7.Results of path coefficients, standard errors, and *τ*—statistics.

| **Interaction path in moderating research model** | **Path coefficients (β)** | **Standard errors (SEs)** | **τ—statistics** | **ρ Value** |
| --- | --- | --- | --- | --- |
| Innovation orientations × Market saturation → Concept development | 0.424 | 0.223 | 1.906 | 0.03\*\* |
| Paths in research model |  |  |  |  |
| Innovation orientations → Concept development | −0.314 | 0.133 | 2.356 | 0.01\* |
| Market saturation → Concept development | 0.239 | 0.135 | 1.775 | 0.04\*\* |

Note: A nonparametric bootstrapping applying 5000 replications as recommended by Hair et al. (2014) was performed to obtain the *t* statistic values of path coefficient and standard errors (*SEs*).\*Significant at *ρ* < 0.01. \*\*Significant at *ρ* < 0.05 based on a single-tailed test.

Following this result, the *f*2 effect size was performed to determine the effect size of the moderator by removing the moderator from the structural equation. Effect size *f*2 is defined where Rincluded 2 model and Rexcluded 2 model are the *R*2 provided on the endogenous (dependent) latent variable when the predictor latent variable is used or omitted in the structural equation, respectively (Chin, 2010). Reporting effect size *f*2 has been long advocated in research literature as indispensable when presenting empirical research findings since it facilitates the interpretation of substantive significance of the research result as opposed to the statistical generated result (Cohen, 1988; Ellis, 2010). Hence, the change in *R*2 value was used to estimate the impact of the moderator on the relationship between the exogenous variables and endogenous variables based on Cohen’s (1988) assessment of *f*2 effect size of 0.02 (small), 0.15 (medium), and 0.35 (large). The formula is presented below along with the results of the calculations. The results of the calculations indicated that the *f* 2 effect size for the moderator was found to be medium. f2InnovationOrientations×Marketsaturation→ConceptDevelopment=Ri 2-Re 21-Rj 20.418-0.2501-0.418=0.289

Predictive relevance *Q*2 was also performed to ascertain the predictive relevance of the interactions’ effect on concept development. Stone-Geisser’s *Q*2 refers to predictive sample reuse technique developed by Stone (1974) and Geisser (1974), using blindfolding procedures (Tenenhaus et al., 2005) to obtain the cross-validated redundancy (CV-Red) and cross-validated Communality (CV-Com), which is readily available in SmartPLS. Stone-Geisser’s *Q*2, widely used to provide a prediction of the endogenous latent variable’s indicators in a structural model, represents a synthesis of function fitting and cross validation, which fits the PLS–SEM path modeling approach “like hand in glove” (Wold, 1982).

Following the blindfolding procedure set in SmartPLS, an omission distance was specified in accordance with guidelines of which the omission distance number should not be the division of the number of observation used in the model estimation and the distance must be an integer (Hair et al., 2014). Hence, with 71 observation obtained in this study, an omission distance of *D* = 5 was chosen, and the endogenous construct of concept development was specified to be analyzed in blindfolding. Based on the blindfolding algorithm analysis performed in SmartPLS, the predictive relevance *Q*2 of innovation orientations and market saturation (as direct exogenous variable), and the moderator (as indirect latent variable) on concept development obtained a value of 0.156, indicating above zero, thus providing support of predictive relevance in regard to the respective path models.

In order to ascertain the effect size of the path models, *q*2 effect size was also assessed. The base formula for the calculation is similar to *f* 2 deployed earlier, where, instead of the *R*2 values, the CV-Red *Q*2 values of the predictive relevance were used as inputs. The summary of the results based on the computations are shown in Table 8. Table 8.Results of the *q*2 effect size.

| **Interaction paths in moderating research model** | **β** | **<mml\_math display="inline" id="mml-math3-1467358415614347"><mml\_mrow><mml\_mrow><mml\_mi>Q</mml\_mi></mml\_mrow><mml\_mrow><mml\_mtext>included</mml\_mtext> </mml\_mrow><mml\_mrow><mml\_mn>2</mml\_mn></mml\_mrow></mml\_mrow></mml\_math>** | **<mml\_math display="inline" id="mml-math4-1467358415614347"><mml\_mrow><mml\_mrow><mml\_mi>Q</mml\_mi></mml\_mrow><mml\_mrow><mml\_mtext>included</mml\_mtext> </mml\_mrow><mml\_mrow><mml\_mn>2</mml\_mn></mml\_mrow></mml\_mrow></mml\_math>** | **q2** | **Effecta size** |
| --- | --- | --- | --- | --- | --- |
| Innovation orientations × Market saturation → Concept development | 0.424 | 0.156 | 0.099 | 0.07 | Small |
| Paths in research model |  |  |  |  |  |
| Innovation orientations → Concept development | −0.314 | 0.156 | 0.049 | 0.13 | Small |
| Market saturation → Concept development | 0.239 | 0.156 | 0.150 | 0.01 | No effect |

aIn accordance to Cohen’s (1988) *f* 2 effect size assessments of 0.02 (small), 0.15 (medium), and 0.35 (large).

**Discussion and conclusion**

Although this study sets out with the aim of investigating the moderating effect of market saturation toward the link between innovation orientation and concept development, the structural model put forward in this paper contributes meaningful insights to the body of knowledge in hospitality research. The molecular second-order construct of concept development set forward in this study reflects a positivist notion as it put together an empirically testable theory to establish a new scientific paradigm that can be a valuable alternative reference for researchers in a field alike. To date, although the “priori knowledge” of PIP models from various restaurant sectors have been well documented in literature (see Feltenstein, 1986; Jones, 1996; Mifli, 2004; Mooney, 1994; Ottenbacher and Harrington, 2007, 2008), this study contributes further to the “posteriori knowledge” by revealing the significant components of concept development along with its activities that remain elusive in hospitality research.

Among the four components, our findings show that idea generations, concept testing, and product testing and designs are important dimensions in managing menu innovation as evidence of their respective models’ predictive accuracy shown in Table 6 and, although, premarketing has a slightly lower value at 37.9%, they all are significant at *P* < 0.01. Unlike previous studies (Jones, 1996; Mifli, 2004; Ottenbacher and Harrington, 2007, 2008) that used qualitative methods to identify the critical components of PIP along with its associated activities in different research setting and restaurant sectors, this study, as shown in Table 3 and Figure 4, has empirically substantiated the dimensions of concept development in the context of foodservice management. Interestingly, earlier results of the EFA have pointed none of the five predictors of business analysis associated along the menu innovation process of chain restaurants (see Table 1). In previous studies, the dimension of business analysis has been identified and ranked as one of the critical components to be adhered to when engaging into new menu innovation (Feltenstein, 1986; Jones, 1996). Yet, our findings discovered otherwise. It is therefore plausible to conclude that such activities of business analysis may have been carried out much earlier at the chains’ headquarters or still executed within the concept lead time, but in separate hierarchical processes. Hence, future research in this field alike is encouraged to consolidate this proposition.

This study, therefore, has extended existing theory of PIP in the foodservice industry with a particular reference to chain restaurants by incorporating the theory of innovation orientations along with market saturation, as a moderator, in the structural theory that is lacking in hospitality research. In particular, as far as it is known, such a structural model has never been forwarded in a statistical perspective and empirically tested. Thus, the study believes that it has made a valuable contribution to theory by developing and substantiating the hierarchical concept development construct, linking both domains of radical and incremental innovation orientations that are known to spur different direction of NPD, and assessing the impact of market saturation that moderates menu planners strategy on new menu development. With this structural theory put forward, this study provides a holistic view of what could be a close-to-reality about managing menu innovation. Furthermore, this study has provided a timely analysis of the effect of market saturation on menu innovation as most global consumer foodservice markets have been long reported to reach its maturity level (Feltenstein, 1986; Jones and Wan, 1992).

In the context of innovation management, innovation orientations, either radically or incrementally driven, are strongly correlated to PIP. Previous empirical findings have concluded that most NPD are incrementally driven, but they are mostly from engineering and manufacturing industries (Abernathy and Clark, 1985; Booz, Allan, & Hamilton, 1983). Yet, the only known research works in hospitality industry that are related to innovation orientations in menu development are the works of Jones and Wan (1992). In Jones and Wan’s (1992) study, they have highlighted four different types of product innovations based on the UK foodservice industry. In this study, they conclude that “product newness” that is totally new in the market is rarely practiced in this industry, instead the act of “copy-cat” or “me-too products,” which is a term they used to denote the characteristics of incremental product orientations, appears to be the most pursued strategy by industry practitioners when managing menu innovation. Due to this paucity of theoretical support, our findings appear to provide some evidence of “copy-cat” acts when the coefficient value of the interaction variable on the criterion variable (concept development) depreciates slightly to β=-0.314 from β=-0.338 of the linear relationship (excluding the moderating variables). Although these results can be argued to be inconclusive, as the evidence of radical orientations remains in force at 99% confidence level, we posit there are acts of “copy-cat” occurred, though minimal. This is because of the nature of market saturation that implies similar development of product concepts and features is abundant within the marketplace (Hashimoto, 2003).

Therefore, this discovery points to our understanding of innovation orientation in menu development in several ways. First, our study provides valuable insight into the issue of radical versus incremental innovation orientation in NPD. Over the years, radical innovation orientation, which is commonly associated with transforming new knowledge to the development process with the expense of killing existing one, is noted to be rarely implemented (Abernathy and Clark, 1985; Booz et al., 1968, 1982; Jones and Wan, 1992). The extant studies indicate that a large number of food-related products developed globally are not new to the world. Instead, product line extension, also known as incremental product orientation, appeared to be the ***strategic*** choice adopted by many firms simply because it presents a relatively risk-free development and require limited resources and “know-how” (Samli and Webber, 2000). While these previous studies are based from the manufacturing and engineering industries with the exception of Jones and Wan (1992), this present study extends further into this theory in the context of foodservice industry. As stated earlier, our findings appear to support in Salavou and Lioukas’ (2003) study, which they found significant evidence of entrepreneurship domains in managers’ decision-making process. Therefore, from a practical perspective, the results obtained imply that with medium forces of market saturation (*f*2 = 0.289; Cohen, 1988) on menu planners’ decision making in managing menu innovation, radical product innovation orientation remains steadfast and still being relied upon as opposed to the theory of managing incremental product orientation in a stable and predictable market (Cunha and Gomez, 2004; Drucker, 1985; Feltenstein, 1986; Iansiti, 1995).

Second, to substantiate further the “law likes generalization” of the present study’s structural theory, the result obtained from the Stone-Geisser’s *Q*2 value analysis (see Table 8) confirmed a small effect size (*q*2 = 0.07) of market saturation in menu planners’ radical product innovation orientation. Ensuring that new menu development embeds with necessary new knowledge innovated in accordance to novelty scale. With this chosen strategy for menu innovation, management in the foodservice industry needs to understand what knowledge to invest and pursue those novelty ideas ahead from rival competitors. Our results suggest that menu innovation of chain restaurants in the region of Klang Valley is radically significant. Yet, “me too” or “copy-cat” product is not new in global foodservice industry, a strategy that is well suited by new entrants to penetrate and imitate those rising menu concepts in a given marketplace. In this study, the sign of such business strategy found to be minimal and the study conducted by Euromonitor International about the consumer foodservice market in Malaysia only came about in early 2000. Thus, though such studies provide insights into the industry’s stage of consumer market, its saturation level is arguably not to the same level like those occurring in developed countries, such as in the UK and USA. This could be one of the reasons our empirical results appeared to be contrary to what were found by Jones and Wan’s (1992) study. Nevertheless, we strongly believe that this study can also serve as a reference to foodservice management across the globe with similar background of consumer foodservice markets, particularly, in the Asia Pacific regions.

Finally, the deployment of the concurrent assessment of market saturation as moderator on the relationship between innovation orientations and concept development sheds light to the realism of managing menu innovation. To date, most global consumers’ foodservice markets are already at the stage of saturation due to vibrant transformation of socioeconomic development in major cities across the globe. In light of this phenomenon, the study provides valuable insight into actual engagement of menu innovation that proactive management ought to be carried out through continuously gathering and using information from the surrounding business landscapes. To avoid further depletion of market shares, foodservice management not only must proactively seeks customers’ latent needs but also find ways to engage in research and development within the organization along with food purveyors in order to contribute to and facilitate the radical menu innovation.

To conclude, most research has limitations, and our study is no exception, as the observation of the respondents did not represent the entire spectrum of the chain companies that exist in Malaysia. Out of the five restaurants chain sectors, only FSR and cafés and bars were successfully interviewed and entered as data in this study. Therefore, the fast-food chains, which have the highest number of outlets and are known to have standardized and consistent product development, were excluded due to their preference not to participate in this study. The other two chain companies were street stalls/kiosks and 100% home delivery/takeaways with a total population that is quite small, and therefore, their exclusion is not an issue.

Apart from this, some of the respondents who participated in this study represented international chain companies such as Starbucks, Pizza Hut, Shakey’s, Sushi King, Dave’s Deli, Four Season, Coffee Bean and Tea Leaf, Gloria Jean’s, and Dome to name a few. Although, some local companies hold the right of being the master franchisees for a few brands here in Malaysia, we believe that product development or innovation is still largely being developed at the corporate headquarters. Therefore, if there are any changes of NPD, these are likely to be minimal, largely corresponding to the sociocultural food preferences, acceptances, and habits, as product standardization is essential to brand image of chains’ ownership. With this notion, the findings in this study cannot be generalized as a universally acceptable paradigm. Yet, it would be useful for future researchers to replicate our structural model to do cross comparisons between international and local brand ownerships or within the restaurant sectors.

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[***The Moral Voice of Corporate America***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5P93-HGC1-DYR7-C363-00000-00&context=1516831)

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**Body**

**ABSTRACT**

C.E.O.s are speaking out on social and political issues in sometimes startling ways, recasting the role business plays in the national debate.

**FULL TEXT**

The nation has split into political tribes. The culture wars are back, waged over transgender rights and immigration. White nationalists are on the march.

Amid this turbulence, a surprising group of Americans is testing its moral voice more forcefully than ever: C.E.O.s.

After Nazi-saluting white supremacists rioted in Charlottesville, Va., and President Trump dithered in his response, a chorus of business leaders rose up this past week to condemn hate groups and espouse tolerance and inclusion. And as lawmakers in Texas tried to restrict the rights of transgender people to use public bathrooms, corporate executives joined activists to kill the bill.

These and other actions are part of a broad recasting of the voice of business in the nation's political and social dialogue, a transformation that has gained momentum in recent years as the country has engaged in fraught debates over everything from climate change to health care.

In recent days, after the Charlottesville bloodshed, the chief executive of General Motors, Mary T. Barra, called on people to "come together as a country and reinforce values and ideals that unite us - tolerance, inclusion and diversity."

Jamie Dimon of JPMorgan said, "The equal treatment of all people is one of our nation's bedrock principles."

Walmart's chief executive, Doug McMillon, criticized Mr. Trump by name for his handling of the violence in Charlottesville, and called for healing.

And in a rebuke to the president, who suggested that both the racist groups and the counterprotesters marching in Charlottesville were to blame for the violence there, a wave of chief executives who had agreed to advise Mr. Trump quit his business advisory councils, leading to the dissolution of two groups.

The forthright engagement of these and other executives with one of the most charged political issues in years - the swelling confidence of a torch-bearing, swastika-saluting, whites-first movement - is "a seminal moment in the history of business in America," said Darren Walker, the president of the Ford Foundation and a board member at PepsiCo.

"In this maelstrom, the most clarifying voice has been the voice of business," he said. "These C.E.O.s have taken the risk to speak truth to power."

This transformation didn't happen overnight. Chief executives face a constellation of pressures, and speaking up can create considerable uncertainty. Customers can be offended, colleagues can feel isolated and relations with lawmakers can suffer. Words and actions can backfire, resulting in public relations disasters. All this as a chief executive is expected to constantly grow sales.

Even this past week, it was easy to discern careful calculations made by executives who chose to speak out against Mr. Trump. Many faced calls to resign from the presidential advisory councils, and the prospect of boycotts if they did not.

But they also faced notable and new kinds of pressure from within - from employees who expect or encourage their company to stake out positions on numerous controversial social or economic causes, and from board members concerned with reputational issues. In the past week, business leaders have responded with all-staff memos and town-hall meetings.

In short, while companies are naturally designed to be moneymaking enterprises, they are adapting to meet new social and political expectations in sometimes startling ways.

"Not every business decision is an economic one," said Howard Schultz, the chairman of Starbucks, who was one of the country's first company leaders to proactively address social issues. "The reason people are speaking up is that we are fighting for what we love and believe in, and that is the idealism and the aspiration of America, the promise of America, the America that we all know and hold so true."

Looking for Controversy

Companies have reckoned with issues of race, class and gender for generations now.

On Feb. 1, 1960, four black college students sat down at the segregated lunch counter at a Woolworth's store in Greensboro, N.C. The civil rights sit-in movement was born, and five months later, Woolworth's desegregated.

Decades later, activists called on American companies to divest from apartheid South Africa. Under pressure, many big companies, including General Motors and Pepsi, pulled out of the country.

But for the most part, companies got political only under duress. Rarely have chief executives gone looking for a controversy. Instead, the prevailing view was one articulated by the economist Milton Friedman in The New York Times in 1970: "the social responsibility of business is to increase its profits."

By the 1990s, some corporate actors began taking the initiative. Apple, Disney and Xerox extended health care benefits to partners of gay and lesbian employees, helping to pave the way for broader acceptance of gay rights. Still, promoting inclusion and advancing diversity were hardly part of the curriculum for emerging titans of industry.

"When I went to business school, you didn't see anything like this," said Marc Benioff, the founder and chief executive of Salesforce. "Nobody talked about taking a stand or adopting a cause."

Now, Mr. Benioff is at the vanguard of a group of executives who are more connected - to customers, employees, investors and other business leaders - than ever before, and who are unafraid to use their influence.

In 2015, after Indiana passed a law that would have made it easier for religious conservatives to refuse service to gay people, Mr. Benioff canceled all Salesforce events in the state and threatened to relocate employees away from Indianapolis.

The outcry from Mr. Benioff and other business leaders helped force politicians, including Vice President Mike Pence, then the governor of Indiana, to reverse course. Ultimately, lawmakers passed a watered-down version of the law.

"C.E.O.s wield economic influence," Mr. Benioff said. "Nobody wanted to lose those jobs in Indiana. But we had to make a statement that we were going to withdraw if they were going to create laws that were going to discriminate against our employees."

The business community's triumph in Indiana emboldened progressive executives, and many have become more willing to confront controversial topics unprompted.

Randall Stephenson, the chief executive of AT&T, recently reflected on racial tensions in America at a meeting of 2,000 employees. "Black lives matter," Mr. Stephenson said, "we should not say, 'All lives matter,' to justify ignoring the real need for change."

Hamdi Ulukaya, the founder and chief executive of the yogurt maker Chobani, has hired hundreds of refugees - drawing the ire of the far right, but making him a cause célèbre for progressives.

And even before the showdown in Indiana, Timothy D. Cook, the chief executive of the world's largest company, Apple, came out as gay - the most prominent executive to make such an announcement. "I'm proud to be gay, and I consider being gay among the greatest gifts God has given me," he wrote.

None of this is to say that all corporate leaders are now beacons of morality. The Uber co-founder Travis Kalanick was ousted amid a mushrooming sexual abuse scandal at the company, and reports that he had cultivated a frat house culture. Martin Winterkorn, a chief executive of Volkswagen, resigned amid his company's emissions scandal.

But faced with circumstances they cannot in good conscience accept, more and more chieftains appear unafraid to act. In June, after the president withdrew the United States from the Paris climate accord, Elon Musk, the chief executive of Tesla, and Robert A. Iger, the chief of Disney, resigned from presidential advisory councils, setting the stage for this past week's revolt.

"The C.E.O.s of big public companies don't walk out onto the plank of social and political leadership by default," said Nancy Koehn, a historian at Harvard Business School. "But today, to keep silent is to jeopardize the reputation of the company."

'Many Sides,' One Voice

Last weekend, as white nationalists protested the removal of a statue of the Confederate general Robert E. Lee in Charlottesville, chief executives were paying close attention to the president's response. Among those watching was Kenneth C. Frazier, the chief executive of the drugmaker Merck and one of dozens of executives who had agreed to advise Mr. Trump on economic issues.

Mr. Frazier disagreed with the president's stances on immigration and climate change, but he believed it was important to have a seat at the table. Yet for Mr. Frazier, the son of a janitor and the grandson of a man born into slavery, the president's remarks - in which he blamed the violence on "many sides" - were too much to bear.

On Monday morning, Mr. Frazier said he would step down from Mr. Trump's manufacturing council. "As C.E.O. of Merck and as a matter of personal conscience, I feel a responsibility to take a stand against intolerance and extremism," he wrote.

The president took to Twitter, lacerating Mr. Frazier and attacking Merck, bluster that alienated more chief executives. By the end of the day, the chiefs of Under Armour and Intel had dropped off the same advisory group. The following morning, three nonprofit business leaders also quit.

As the manufacturing council fell apart, another presidential advisory group was also tottering. The ***Strategic*** and Policy Forum, a group with chief executives of some of the country's biggest companies, held a conference call and agreed to disband.

The reaction from business leaders extended well beyond the confines of the presidential advisory councils.

James Murdoch, the chief executive of 21st Century Fox, pledged to donate $1 million to the Anti-Defamation League. The gesture was all the more remarkable because Mr. Murdoch is the son of Rupert Murdoch, a staunch supporter of Mr. Trump, and because his company operates Fox News, known for its favorable coverage of the president.

"What we watched this last week in Charlottesville and the reaction to it by the President of the United States concern all of us as Americans and free people," the younger Mr. Murdoch wrote in an email to associates. "I can't even believe I have to write this: standing up to Nazis is essential; there are no good Nazis. Or Klansmen, or terrorists."

Technology companies severed ties with white supremacist groups. Google and GoDaddy dropped domain registrations for far right publications. Facebook ***deleted*** articles that celebrated hate crimes. Spotify took down music by white power rock bands.

And in Seattle, Mr. Schultz held a town-hall meeting for more than 1,000 employees where he condemned bigotry and called for unity. "I could sense the anxiety," he said. "I felt a need to create a safe and loving environment."

All week, the business world's actions went beyond the donations to charity and pledges to plant trees that once defined corporate social responsibility.

"For a long time, corporate social responsibility was a buzzword marketing tool, walled off within an organization," said Alan Fleischmann, president of Laurel Strategies, an executive advisory firm. "Now it has to be central for the C.E.O., part of their everyday responsibility and leadership."

The Cost of Speaking Out

Kevin Plank, the founder and chief executive of Under Armour, the athletic apparel maker, built a brand that celebrates diversity, sponsoring athletes like the basketball player Stephen Curry and artists like the ballerina Misty Copeland. Yet when asked to serve on the president's manufacturing council early this year, Mr. Plank agreed, voicing his optimism about Mr. Trump.

His star sponsors made their displeasure known. "I strongly disagree with Kevin Plank's recent comments in support of Trump," Ms. Copeland said. Mr. Curry also expressed his distaste for the president.

So on Monday night, when Mr. Plank stepped down from his advisory role, he might have thought his troubles were over. Instead, Mr. Trump's supporters have risen up, calling for a boycott of Under Armour.

"The leaders of corporate America have demonstrated the courage to call out something that is unacceptable," said Mr. Walker of the Ford Foundation. "But speaking truth to power can come with huge costs."

Because companies have inherently diverse customers and employees, taking a stand can be a no-***win*** situation for chief executives. For every employee, investor and customer they make happy, they may well make someone else unhappy.

When Pepsi this year released an ad featuring Kendall Jenner offering a police officer a soda in the midst of an apparent Black Lives Matter protest, the condemnation was swift. Two years earlier, Starbucks drew wide ridicule when, as part of an effort by Mr. Schultz to start a national conversation on race relations, baristas were encouraged to write "race together" on coffee cups.

Companies on the conservative end of the ideological spectrum are also increasingly willing to stand up for their principles, and just as likely to face criticism. After it was revealed that the family behind the fast-food chain Chick-fil-A supported groups that opposed same-sex marriage, gay rights protesters targeted the restaurants.

Hobby Lobby, the craft-supply chain run by a conservative Christian family, challenged a provision in the Affordable Care Act that required family-owned corporations to pay for insurance coverage for birth control. Despite drawing the ire of the left, Hobby Lobby took its case to the Supreme Court and won.

Critics of Mr. Plank's decision cast their net wide, going after all the chief executives who quit the president's business advisory groups. "This is a remarkable moment in history," said Lou Dobbs, a Fox Business Network host. "Every one of those C.E.O.s, mark my words, is a coward - and the president is exactly right - a grandstander in the service of the left. And no one should make any mistake: This is a coordinated, orchestrated attack against this president."

John Carney, a business editor for Breitbart News, the conservative news site, wrote that "corporate America is part of the ***opposition***."

"The confederacy of the media institutions, the American left, and Corporate America has aligned itself against the populist uprising that brought Trump to the White House," Mr. Carney wrote. "The battle lines are clear."

Those executives who go out on a limb know the risks. "We all recognize that with every decision we make, there is group of people that are not going to agree with us," Mr. Schultz said. "But you must define your core purpose for being. We stand in the interest of something greater than just making money."

A Diversity Paradox

Diversity - of opinions, ideologies and religions - is what makes taking a stand on moral issues so treacherous for C.E.O.s. Yet paradoxically, it is also diversity - of races, genders and worldviews, among customers and the work force - that makes many of the executives, when forced to take a stand, come down on the side of inclusion, tolerance and acceptance.

Business leaders looking to the future are accepting that it is unwise to isolate swaths of the population by coming off as racist, sexist or intolerant. Instead, for the sake of the bottom line, it is imperative that they appeal to the widest possible audience. "Business leaders aren't threatened by an America that is browner, an America that is more diverse; they welcome that," Mr. Walker said. "Business leaders are bullish on diversity."

What's more, some executives have concluded that speaking out on issues of morality can improve more than their reputations - it can benefit recruitment, morale and even sales. "Our employees come here knowing that this is something that is extremely important to us," said Mr. Benioff of Salesforce. "Business is the greatest platform for affecting change."

If the voices of business leaders seem amplified, that is perhaps because in such partisan times, few politicians can speak to both sides of the aisle, leaving a vacuum for business leaders to fill. This last week, the executives on Mr. Trump's business advisory councils piped up, led by Mr. Frazier of Merck.

The black chief executive of a $172 billion company - a multimillionaire who was born in a poor neighborhood, a former lawyer who fought for civil rights and had agreed to advise the president - Mr. Frazier offered remarks that set the tone for the business world at large.

"Our country's strength stems from its diversity," he wrote, adding, "America's leaders must honor our fundamental values by clearly rejecting expressions of hatred, bigotry and group supremacy, which run counter to the American ideal that all people are created equal."

The C.E.O.s had found their voice.

*Follow David Gelles on Twitter @dgelles.*

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[***Anti-system Contentions and Authoritarian Response in China: Evolution and Mechanisms***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:6BH2-VXY1-JBMY-H41T-00000-00&context=1516831)

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**Body**

**ABSTRACT**

This paper proposes a new framework to analyze social contentions in China from the perspectives of contention motives and mobilization channels, explains why traditional forms of contention do not undermine the Chinese Communist Party’s (CCP) rule, and identifies anti-system contention as a distinctive form of contention that poses the greatest challenge to the CCP’s rule. Through analysis of political opportunity structures and mobilization mechanisms that allowed anti-system contentions to rise, this paper argues that since such contentions mainly consist of value-oriented social actors mobilized via informal channels, it would require the Chinese regime to adapt to a more targeted and coordinated model of repression to address the new challenges. The paper further provides empirical case studies to show the effectiveness of the regime’s adaptive repression and shows that anti-system contentions in China face their own hurdle to develop into more prominent contentions.

**FULL TEXT**

**Social contentions in contemporary China**

The Chinese authoritarian state has been noted for its rigidity and durability ever since its foundation (Nathan, 2003; Shambaugh, 2009). Throughout different global waves of democratization and regime turbulences, the Chinese Communist Party (CCP) has successfully weathered multiple challenges to its authoritarian rule. Since 1989, it seems that the regime has so far blocked nationwide large-scale protests and threats against the Chinese state. Yet this does not translate to a picture of autocrats sitting safely on a dead social volcano. While not having to deal with acute eruptions of overwhelming social unrests, the CCP has been busy coping with daily challenges arising from virtually every corner of the society. Various government and unofficial estimates all point to the fact that the number of social contentions in China has kept rising to an annual count of 90,000 to 180,000. Their forms range from petitions (*shangfang*), strikes, public assemblies, marches, and demonstrations, to extreme forms of taking hostages, beating party cadres and government officials, or small-scale armed resistance.

As the number of these contentions rises, their participants also infiltrate many parts of the social fabric, including peasants (O’Brien and Li, 2005), workers (Lee, 2007), urban residents (Huang and Yip, 2012), and dissidents (Chase and Mulvenon, 2002). Additionally, since the inception of the internet, protest participants have been using the web to mobilize, organize, and broadcast their resistance, which has given new shape to their activities (Bondes and Schucher, 2014; Esarey and Xiao, 2011; Yang, 2003). In an effort to explain the paradoxical coexistence of China’s ever-increasing social contentions and strong authoritarian durability, this paper seeks to break down social contentions into nuanced types and analyze how and why one particular type of contention shapes the dynamic of China’s regime durability and state–society relations.

Researchers have done extensive works on many kinds of social contentions in contemporary China. O’Brien (1996) raised the concept of “rightful resistance” to analyze rural protests in China. Such protestors would often frame their claims in accordance with the regime’s policy and ideology discourse. O’Brien and Li (2006) further classified Chinese peasant resistance movements as “legal resistance,” or “policy based resistance.” In studying labor movements, Hurst and O’Brien (2002) proposed a type of resistance consisting of unemployed former state-owned enterprise workers and retirees, calling it “moral economic resistance.” Xi Chen (2007) proposed the “opportunistic trouble” strategy, in which protestors decide to act however and whenever they think they are most likely to obtain their interests.

We argue that despite the existing literature’s important contribution in helping us understand the state–society relationships in China, they do not resolve the paradox of a large number of protests in a generally stable authoritarian state. In fact, most of the contentions under study, such as anti-levy rural protests in the 1990s and confrontations against the government on disputed eminent domain cases in the past decade, do not pose severe challenges to the regime’s survival.

There are three reasons to explain this paradox. First, the claims of most such contentions are parochial and personal interest-oriented. Protestors are primarily citizens whose own interests are violated by local government actions. This constrains their claims toward only a fraction of the regime apparatus, without questioning the fundamental aspects of the regime. Such contentions also tend to be ***geographically*** limited, very often locating in only one village or town, which tends to go under the news radar for a country with almost 700,000 villages. Contentions tend to stay where they are without diffusion, and tend to have limited participation without coalescing with other actors. These factors all reduce the likelihood that such contentions will escalate into a broad mass contention that shakes up the pillars of the regime.

Second, such protestors often do not question, and even voice support for the Chinese political system, thus showing no fundamental conflict with the system. As it is shown in O’Brien’s studies, many protestors quote official ideology in support of their own claims. Researches also show that protestors engaged in local, personal interest-oriented contentions tend to show lower trust for local government, while maintaining a high level of trust in central government (Li, 2004). Scholars propose that such a dynamic is achieved by the Communist regime’s intentional design of administrative hierarchy (Cai, 2008). Local governments play the bad cop and take all the blame when there are backlashes in the society, and the central government stays away from problems and often plays the good cop by coming to rescue protestors from their plights. The regime receives credit by turning contentions from potentially against the state to dependent on the state.

Third, the regime has accrued enough institutional and financial capacity to deal with routinized daily contentions. Many rural, environmental and labor contentions have already become institutionalized, with repertoires and discourses familiar to both the protestors and the regime. People would most often resort to petitions, which are directly submitted to the petition bureaus in different levels of government and then wait to be processed by the government. Protests, strikes, and demonstrations are legally possible but practically always blocked by the police bureaus who do not issue permissions as required by law. Yet these forms of contentions still go on and the government has prepared standardized procedures to dismiss mass gatherings. The regime has also established a stability-maintenance system to institutionalize their effort to dissuade such contentions (Su et al., 2013). Moreover, with the ever-growing financial capacity of the second largest economy in the world, the regime is often in a powerful position to offer protestors satisfactory compensations to resolve troubles. For instance, the anti-levy contentions were once rampant in rural China, when poor peasants violently resisted local government excessive charges. As the Chinese economy grew, abundant fiscal revenue led the government to gradually abolish the agricultural taxes and most other levies within 5 years. The once severe rural contentions then disappeared quietly across the nation (Smith, 2010). Since such grievances can be easily addressed by the state’s overwhelming capacity, they do not pose long-lasting danger to the stability of the regime.

Hence, while the accident of a street vendor setting himself on fire triggered a national turmoil in Tunisia that finally led to regime change, the grievances of many Chinese citizens who receive a similar level of treatment from the state do not grow into a threat to the rule of the regime. That being said, contentions discussed above are not the only type of contentions in China, and we argue that a distinct form of contention, anti-system contention has been burgeoning in China. It receives special attentions from the CCP regime and is a key factor to understand how the regime and society co-evolve and adapt as the authoritarian regime keeps hanging on.

**Anti-system contentions in China**

We define anti-system contentions as social contentions in authoritarian regimes that fit into the criteria listed here. First, anti-system contentions primarily involve *value-oriented social actors*, that is, people who participate in actions against the state not for their own material gains (as opposed to peasants who fight against the government for excessive levy, or urban residents who fight against chemical plants projects in their neighborhood). It is possible that the initiator and some key organizers of such contentions may be interest-oriented, but participants of such contentions have to be value-oriented, that is, non-stakeholders who do not have direct material interests in movement claims. For instance, many petitioners who started out to seek remedies for their own grievances only to find out the futility of the process are transformed into active members of other social contentions that do not necessarily pertain to their own interests. A close inter-personal network then developed among such petitioners that allowed them to mobilize and organize effectively for contention.

Second, anti-system contentions are mobilized via *informal channels*. By informal channels, we mean that the contentions’ mobilizing structures are predominantly informal (McCarthy, 1996), and their repertoires and discourse are also informal, which means that such contentions’ forms are flexible, innovative and often disapproved by the state. The fact that the state does not permit or endorse such contentions’ repertoires and discourse puts the protestors in direct ***opposition*** to the regime, which makes them more confrontational and dangerous to the regime. Most notably, online activities have become an important channel for Chinese activists to organize and coordinate contentions in unprecedented forms.

Last but not least, we are speaking of contentions in the context of an *authoritarian regime*. It is because of this context that virtually all value-oriented contentions via informal channels lead to some kind of challenges against the regime’s rule. To borrow the term “anti-system parties” who compete in democratic elections to threat democracies (Linz and Stepan, 1978), “anti-system contentions” work in authoritarian regimes to threaten autocrats.

Situating anti-system contentions in the big picture of Chinese social contentions, we propose a 2 × 2 chart (Table 1) to show where anti-system contentions stand in relations to various other contentious activities. The upper-left cell covers most of the social contentions discussed in the previous section. They happen locally and the agents are those people whose interests are directly connected to their contentious activities. Examples of this type include protests against house demolition projects, laborers’ movements, environmental protection acts, or property rights defense movements, etc. These contentions are often collectively referred to as “Rights Defense Movement”.1 The upper-right cell covers what the Chinese government refers to as “Mass Incidents”; Participants’ primary motive is still interest-oriented, but they often take more extreme course of actions, such as destroying public goods, threatening government official’s safety, or even upsetting the local social order. Notable cases include the Shishou County incident2 and the Weng’an Incident.3

**Table 1.**

Contention types in China.

|  | **Formal channel** | **Informal channel** |
| --- | --- | --- |
| Interest-oriented | Labor movementsPetitions and demonstrations | Mass riotsViolent anti-government confrontations |
| Value-oriented | Human rights lawsuitsNon-governmental organization-organized contentions | Anti-system contentionsNetizen movementsPolitical dissidence |

The lower-left cell includes many other contentions that pose challenges to the state, but not to the extent of anti-system contentions. These contentions are primarily mobilized by value-oriented actors, such as human right activists and non-governmental organizations (NGOs). They engage in social contentions for claims that are not directly related to their personal interests, but for general values such as religious freedom, judicial transparency and environmental public goods. Their chief difference to the anti-system contentions lies in their acceptability to the state, or dependence on state approval. In China, human rights lawyers have to rely on the state to approve their bar qualification (which is annually re-authorized by the Ministry of Justice) and allow their active practice. NGOs have to keep official registrations with the Ministry of Civil Affairs, and their fundraising and employment activities are also heavily regulated at the discretion of various government departments. By making such contentions highly dependent on state acquiescence, the regime remains powerful when it comes to punishing “troublemakers”. In order to make their contentions acceptable to the state, actors must often limit themselves in both claims and actions. Once they cross the line and become repressed by the state, their actions will enter the zone of anti-system contentions.

The lower-right cell then represents the anti-system contentions. We argue that these contentions are important to the survival logic of the Chinese authoritarian regime for three reasons. First, since actors involved in anti-system contentions are value-oriented, their claims are very hard to be satisfied by the regime without making fundamental concessions regarding the political system4. Therefore, it is more difficult for the regime to co-opt or placate such protestors, which will make contentions more persistent. The contention claims also often pose direct or indirect challenges to the legitimacy of the rule of the regime, making such activities more dangerous to the regime.

Second, the fact that participants of anti-system contentions are primarily value-oriented also expands the constituents of the contentions. Participants will not likely to be ***geographically*** concentrated in certain localities where some policies are implemented. Anti-system contentions tend to involve participants scattered across the nation in various professions and social status, with different social capital and networks. Such heterogeneity makes it harder for the state to come up with a general strategy to wipe out all protestors, and hence anti-system contentions are more likely to sustain government repression or at least be more recurrent than other types of contentions.

Third, since anti-system contentions are organized via informal channels, they are less dependent on and controlled by the state. Therefore, the state is less able to follow institutionalized mechanisms to target and repress such contentions, as it often has no experience with non-traditional contentions. Participants of anti-system contentions used to organize “group side-walking” to skirt official discretion of allowing demonstrations, they also create tons of innuendos and puns to convey messages and mobilize, leaving the censoring apparatus far behind those linguistic and organizational innovations.

Scholars such as Minxin Pei (2003) have divided contentious activities in China since 1989 into “ordinary resistance” and “dissident resistance.” The former’s participants normally come from the ordinary masses, and they fight for specific interests. In contrast, the latter’s participants are primarily intellectuals and activists whose aims are far more political. It should be noted that anti-system contentions include but are not limited to explicit political dissidence. Actors do not have to engage in open criticism of the authoritarian rule to qualify for anti-system contentions, so long as their claims and acts (explicitly or implicitly) clash with the fundamental interest of the regime. Examples of this type include: the Deng Yujiao incident;5 the Sun Zhigang incident;6 etc.

The 2 × 2 chart in Table 1 of course cannot categorically differentiate social contentions in China. A local contention with only rural victims involved could stay on as a right-defense contention, but it could also escalate into a riot if the policy problem persists and impact more people in the same locality. It could also evolve into another different category if outsider lawyers or NGOs get involved to aid contentions, or if more information dissemination leads activists nationwide to come to help and organize new contentious campaigns which will become anti-system contentions.

Speaking of the last possibility, the internet in China has greatly aided in spreading awareness for each of the public incidents that have attracted widespread interest since 2002, a factor we consider as key to the rise of anti-system contentions. Other forms of contentions today of course also use the internet to varying extent, but the degree to which anti-system contentions rely on the internet for spreading information, organizing, and mobilizing is much higher. While Chinese citizens’ online activities have received some scholarly attention, such as descriptions of netizen strategies and behavior (Esarey and Xiao, 2008), political resistance movements (Béja, 2009; Pu, 2010), and the ways that the government now permits more “internet vigilantism” (Herold, 2008), there remains a gap in connecting these netizens’ online behavior to the larger development of offline social contentions. Furthermore, most of these articles only provide descriptions of netizens’ online activities up until 2008, when the state has not crafted a pattern to deal with such contentions.

Anti-system contentions existed in Chinese contentious politics before the age of the internet, as political dissidence was a key factor that led to the 1989 pro-democracy movement. A few years after 1989, intellectuals once again began publishing public letters expressing their strong political demands. For example, in March 1994, Xu Liangying and others called for the government to stop persecution against dissidents and release people who had been imprisoned for speaking out for human rights and liberty. In 1995, Wang Ganchang and 45 others called for an end to restricted speech and renewed discussion of the Tiananmen Square incident. However, owing to the continuous high pressure from the post-1989 government and the small extent to which contentious ideas circulated, anti-system contentions in the 1990s did not have any noticeable effect on Chinese society at the national level.

After the year 2000 when the internet had become more commonly used in China, contentious protestors quickly learned how to utilize its functions to express their views and to organize and mobilize resistance movements. Thus online citizen or “netizen” movements came into existence. The earliest netizen movement began in 2002;7 after 2002, public letters published on the internet and group netizen signature petitions became the most common contentious repertoires of netizen movements, and they are still in use today.

Netizen movements’ contentious repertoires began to diversify after 2003. In this year, there were 4 incidents that had a deep impact: the Sun Zhigang incident; the Huang Jing incident;8 the Liu Di incident;9 and the Du Daobin incident.10 Among these, the Sun Zhigang incident received the most media coverage and became the most widely known. Surrounding this incident, there gradually formed a new repertoire of contention: internet onlooking (*wangluo weiguan*). The elements of this repertoire included: media reports; public letters; acts of artistic expression; and internet opinion leaders posting their remarks.11

Internet on looking has usually taken the following form: a certain incident attracts widespread comments on internet forums and eventually becomes a popular discussion topic, which leads to its publication in the media, attracting even more subsequent attention. Popular internet intellectuals publish articles online or in the media commenting on the events, and thereby spur internet followers in various forums to join with them in putting forth their own opinions. Internet opinion leaders may then write a public letter calling for people to sign their names on a collective petition. Human rights lawyers provide legal advice and support, and people begin putting on displays of public artistic expression. In addition to internet opinion leaders, human rights lawyers, and media reporters’ direct involvement in the incident, other internet followers post comments to express their support and interest. Because it attracts such extensive public interest, the media is driven to report on the event, thereby creating comprehensive public opinion pressure. Over a long period of time, internet on looking has become netizen movements’ primary mode of resistance.

From the start of 2003 to the end of 2011, many anti-system contentions had been happening in quick succession. As their participants increased in number and regional representation, their influence also had deepened and spread far and wide. In fact, many movements transcended China’s borders, gathering supporters and influence internationally. Such contentions uniquely display tendencies of being proactive, politicized, decentralized, and having a snowball organizing effect. Moreover, they were in a process of incessant evolution and development. They cannot be explained as reactive resistance, as policy-based resistance, or as interest-oriented actions. This distinct form of contentions then deserves explanations for its origins and development mechanisms.

**Mechanisms of anti-system contentions**

We think it is important to look at the origin and evolution of anti-system contentions in China from perspectives of political opportunity structures and mobilization mechanisms. As Tarrow (2011: 16) puts it, “contentious politics emerges in response to changes in political opportunities and threats when participants perceive and respond to a variety of incentives: material and ideological, partisan and group-based, long-standing and episodic.” Once an inconceivable scene in pre-1978 Communist China, mass social contentions were able to develop through the political opportunities provided by the changing social and political landscape in China since 1992. Meanwhile, mobilization mechanisms would best explain how anti-system contentions come into today’s shape and adapt as the state and society evolve.

**Political opportunities structure**

**The recession of state control and the rise of the private sector**

According to Tang Tsou’s (1994: 69) terminology, before 1978, the Chinese state operated as a “total state”. The government maintained total control over all politics, economics, and society. The majority of people at the time were incorporated into state control mechanisms such as People’s Communes and *danwei* (place of employment), while those left outside these bodies were placed under the control of neighborhood committees. China’s government, having assumed control over the nation’s economic resources, made the public completely dependent on their system for their livelihoods. To leave one’s *danwei* or commune would in general result in destitution and ruin (Walder, 1986).

The 1989 Tiananmen Square incident had cast many doubts on the course of China’s reform and opening up. However, following Deng Xiaoping’s Southern Tour in 1992, China entered an era of increased economic marketization, and the state’s control over society gradually began to relax. During the 1990s, employment opportunities in state-owned enterprises rapidly decreased. Concurrently, private enterprises’ economic strength suddenly skyrocketed. This led more and more workers to find jobs in the private sector or even to start their own private businesses, thereby breaking off their dependence on the system. In the following decade, millions of people left their places of *hukou* residence to seek work in new cities, effectively throwing off the system’s economic and political control over their lives. Consequently, participating in contentious activities no longer necessarily led to economic ruin. Now, the majority of political entrepreneurs operate far outside state or *danwei* control. To put it another way, many political entrepreneurs like rights defense lawyers or movement reporters have created their own employment beyond and against government control.

**The development of contentious claims**

In China’s new netizen movements, the most frequently used contentious claims are simply demands for universal values such as liberty, human rights, democracy, civil society, judicial justice, or anti-corruption. Several sources aided in the formation of these contentious claims.

The first source lies in the changes in values, changes in state policies regarding rights, and changes in shared expectations about behavior that have increased the public’s awareness of their own rights (Lorentzen and Scoggins, 2015). The second source comes from the relatively free speech that internet dissidents have been able to use in their online discussions. Research has pointed out that the Chinese censorship machine is far more interested in censoring speeches that have immediate potential in inciting collective actions than they are in paying attention to speeches that are only critical of the regime (King et al., 2013). Influential opinion leaders’ audacious speeches have enabled the spreading of clear and accurate descriptions of the meanings of these value-laden words, thereby helping an increasing number of people accept and understand them.

Thirdly, the rise of China’s “marketized media” has also promoted the spread of these values. China’s economic growth and increasing social diversity have stimulated the society’s appetite for all things cultural, recreational and informational. Official media responded to this new demand by supplying “marketized media” sources such as popular newspapers and magazines;12 the public’s new craving for more open viewpoints and more information has also spurred certain “marketized media” sources to become bolder in presenting criticisms.

While the Chinese government keeps censoring the media’s content, it has also long given the news media the task of gathering information on local problems which allowed the publication of reports of high-profile local scandals and criticisms of local governments and officials (Lorentzen, 2014). On the other hand, the profit-driven “marketized media” has increasingly adapted to the tastes, preferences and values of the public. Popular news sections, such as columns, opinions and commentaries often scrutinize the behavior of local officials, national policies and various social phenomena. While the “marketized media” is still state-owned, it offers a relatively open platform for free expression that differs from the state’s official ideology.

In sum, the “marketized media” has diminished the effectiveness of the authoritarian regime’s control over information and expression while spreading greater public awareness of universal values.

**The dissipation of political apathy**

Ordinary political resistance participants by the very nature of their identity keep a high degree of interest in politics. During the 1990s, a wave of political apathy had swept over the nation, but after the year 2000, attitudes began to change because of transformations in class characteristics, policies, information sharing methods, and because of structural flaws.

Chinese society is home to a vast number of people who have had their interests harmed, such as unemployed labor, low wage workers, migrants, landless peasants, or victims of the unjust legal system, etc. To protect their remaining interests or rights, people in this group must pay close attention to politics (Lorentzen and Scoggins, 2015). People’s awareness of their rights has grown in recent years. Following China’s economic development, the government has put forth all kinds of people-oriented public welfare policies. In order to ensure and check the implementation of these policies, the public needs to keep a close eye on regional political developments. Marketized media has also strengthened the public’s interest in politics with their coverage of issues that have harmed the public good such as high housing prices, the income gap, serious corruption, environment pollution, etc. The interaction of these elements has brought about a reawakening of political consciousness in the Chinese public.13

**The declining fear of government and the incentives associated with resistance**

As already mentioned, the number of resistance participants in today’s China has increased largely because people have become more daring. Those who have entered into non-*danwei* employment, individual businessmen, and migrant workers, etc. have not only thrown off the system’s economic control, but also have freed themselves from the authorities’ coercive propagandized thought control. Opinion leaders and political entrepreneurs have been the first to explore the new reaches of this freedom. Their bold speeches and audacious resistance activities have become models for other netizens, showing them that one need not fear the government. After 1989, officials’ reactions towards several high pressure protests were actually quite low-key, which prompted the youth of the following decades to grow up without any memory of or fear towards government repression.

Government punishment towards resistance activities in all actuality is rarely harsh, as they very infrequently prosecute activists and instead primarily only take them to “drink tea”. Often after their tea drinking experiences, activists will post written accounts of their experiences on the internet, and as a consequence, readers slowly have overcome their fear of government reprisal. With more and more people having been taken to “drink tea,” this experience has become an acclaimed internet symbol of one’s courage and spirit and a “rite of passage.” Moreover, the mutually supportive social network also lowers participants’ estimation of potential risks. Being chosen as a target for repression has become an honor and brings activists political capital, which has encouraged more people to take the risk.

**Mobilization mechanisms**

**The lack of contention resolution channels**

The causes of social contention in Chinese society include the serious income gap, government official corruption, civil rights abuse, an unjust legal system, environmental pollution, and many others. Consequently, many citizens live with a strong sense of relative deprivation. Moreover, they lack both the economic resources and the political resources to defend their interests. For example, workers are not allowed to establish their own labor unions independent of the government-controlled All-China Federation of Trade Unions. When any rights abuse victim tries to put forth an appeal against the government or an enterprise before the courts, they have a very difficult time obtaining legal support. Regarding petitions (*shangfang*), which are China’s unique channel of contention resolution, many local governments will harass and attack citizens who file such petitions. Public protests and other contentious repertoires often used in Western countries almost never obtain the Chinese government’s endorsement. Owing to this serious lack of legal contention resolution channels, victims and other people started using informal channels almost immediately after their inception to express their dissatisfaction and resistance.

**The emergence of political entrepreneurs**

As Charles Tilly (2004: 13) puts it, “As compared with locally grounded forms of popular politics, social movements depend heavily on political entrepreneurs for their scale, durability, and effectiveness”. Indeed, the majority of China’s anti-system contentions have relied on the leadership of political entrepreneurs. Their ranks are formed of university or college professors, reporters, lawyers, media workers and dissidents as well as other professional workers, and enterprise owners and executives, etc.

Political entrepreneurs’ role consists of many duties and practices. Naturally, political entrepreneurs’ methods are as varied as the events they mobilize against. Generally, political entrepreneurs’ first important role is to sift through the many rights abuse or other types of incidents that occur regularly and choose events to analyze. These political entrepreneurs clearly define the contentious movement’s program claims and publish them in articles and public letters. Writing with audacious language that cuts to the heart of whatever issue they have discovered, they stimulate people’s interest and build support. In so doing, they arouse participants’ sense of their shared “identity claims” (Tilly, 2004: 12). Their works have a snowballing effect on the readers: those who read their works tell others, thus gathering an increasing amount of internet followers’ attention and sparking responses from the general public. Another way political entrepreneurs build support is by hosting large online discussions, which attract many followers not only because of the entrepreneurs’ fame and acclaim but also for the fresh information they are able to give out. These entrepreneurs are the architects of most new contentious repertoires. They are the minds that create richly diverse and effective forms of resistance activities to transform netizens’ claims into action.

Two of the most well-known examples of political entrepreneurs’ work come from artist Ai Weiwei.14 Firstly, after his studio had been demolished in November 2010, Ai Weiwei invited netizens to attend a dinner – a banquet of river crabs, which have ironic symbolism stemming from the Chinese homonym “social harmony.” In the end, it is estimated that 1000 netizens attended to demonstrate their mutual support for Ai Weiwei and their contempt for the government’s fake “social harmony.” On another occasion in November 2011, after the government fined Ai Weiwei 152.2 million RMB (2.3 Million USD) for purported tax evasion, many people offered to help him pay the fee. At their behest, he used the internet to broadcast a request to netizens to loan him money to pay an 8.45 million RMB deposit in order to guarantee his legal standing in the appeal of the tax evasion case. In only 15 days, by using websites, cash, bank money transfers and anonymously throwing money into his yard, over 27,000 people donated 8.2 million RMB. Many people demonstrated great pride at having helped Ai Weiwei.15 Through these examples, Ai Weiwei quintessentially demonstrated a political entrepreneur’s creativity and ability to bring people together under a common identity for a common cause.

During long-term resistance movements, entrepreneurs develop a sort of moral charisma; they become the representatives and symbols of resistance movements. As resistance activities’ frequency has increased, political entrepreneurs’ influential power has also grown, with some reaching beyond the internet realm to the traditional public media, and many of them have become public political dissidents subsequently.

**The emergence of mobilization means**

Due to the atrophied development of civil society before the rise of the internet, national resistance movements had almost no chance of occurring. After the internet came about, people’s ways of communicating with and relating to each other changed. Currently, there are two identified methods that bring together resistance scattered around the country: mobilization via the internet; and mobilization via interpersonal networks. The two methods are often combined by resistant people in pursuit of their cause.

Even though the Chinese government still maintains strict censorship control over internet users’ speech and has established the “Great Firewall of China,” it cannot completely shut down discussions or the sharing of information. In the last ten years, the internet has become the most up to date platform for new information, the number one source for the most incisive and audacious speeches, as well as the most effective tool for mobilization. At the same time, after many rounds of protests and contentious activities, resistance participants have become familiar with each other and have begun interacting with each other offline. They often will host dinners together, creating the Chinese pun, “*fanzui*,” which means both “eating and drinking” and committing a “crime.” By getting together to eat, drink, and criticize the government, they thumb a figurative nose at the current political regime. At first, political entrepreneurs formed the majority of this group, but over time many ordinary netizens have joined their ranks. They are the most dedicated and proactive discussion forum and microblog contributors, and have now become the central force powering contentious activities.

**Resistance repertoires**

During the process of developing netizen movements, a certain contentious repertoire has formed which, among many things, includes on looking, public letters, “human flesh hunts” where netizens expose all the personal information of the officials who committed an injustice, and artistic expression. The most important item in this contentious repertoire is on looking, including internet on looking and on-site on looking. Similar to the previously explained internet on looking, on-site on looking means non-stakeholding netizens go to a site where an incident is taking place to conduct surveys, interview local people, and express support for the incident’s victim. Though when asked by police, they innocently say they are simply there to “buy soy sauce,” netizens’ presence serves to express their disapproval of the officials involved in the incident.16 Online, on-site on looking participants call what they do “tour-group-ing” because they will post a tour group proposal online followed by their touring agenda. On their “tour,” they post what they did and what they encountered like a live TV broadcast. The fresh information acts as an incentive to attract people to follow the story on the internet. These netizens then virtually participate online in the “on looking,” putting added pressure on their ***opposition***.

Overall, the public’s greater willingness to resist as well as political entrepreneurs’ ability to mobilize people and create widely acceptable contentious repertoires has enabled citizen movements to spring up naturally. A resistance network had also formed during the continuous cycle of anti-system contentions. This resistance network is made up of the following groups: first, victims of rights abuse, second, media reporters who have abandoned traditional media topics or practices to become “social movement reporters,” and third, volunteers such as professional rights protection figures, political dissidents, and past heroic petitioners17. Even though people constantly come and go within this network, the increasingly large numbers of people who join each year far outnumber those who leave. This resistance network has not only the ability to respond quickly to issues, it also has the ability to proactively create resistance issues such as the illegal Google flower tribute after Google left China18, and the three Fujian netizen court case on looking incidents19.

**Authoritarian responses**

It is not surprising that anti-system contentions have drawn the attention of the Chinese government. Taking aim at these movements’ challenge to the government’s control, the government adjusted its Stability Preservation System (SPS, *weiwen tizhi*) to adapt to these new challenges (Yang, 2016), which also pushed the anti-system contentions to make their own adjustments.

Before the reform and opening up in 1978, the government’s system of social control consisted of three parts: law enforcement departments and the *siloviki*20; the functional departments of CCP and state administrations, for example, the Propaganda Department; and public organizations led by various CCP committees, such as the Labor Union, the Youth League, the Women’s Federation, and community and village committees. However, the regime needed to maintain complete control of resources in order to sustain this system, and following the reform and opening process, changes that occurred in state–society relations weakened the state’s domination. Therefore, the regime was forced to readjust its focus to exert direct control over specific individuals and organizations that are deemed as threats to social stability. It is under such conditions that it created the modern SPS.

This modern SPS involves many levels performing separate functions. For example, the Domestic Security Department suppresses the country’s most active political dissidents, and local government departments block citizens’ petitions and appeals. The SPS has two primary goals. The first is to effectively “nip all factors of instability in the bud”, and the second is to put down mass incident emergencies with professionalized operating plans. Following the recent increase in mass incidents, preserving stability has become a top priority for the government. The SPS’s effectiveness is clearly visible in cases where it was needed to stifle rights defense movements or mass incidents. Even in incidents involving large numbers of people, such as those that occurred in Weng’an and Shishou, the SPS was still able to quickly bring the situation under control.

However, the SPS has not been able to effectively control the development of anti-system contentions in the 2000s. Even though netizens’ use of the internet to organize movements attracted close government supervision and many measures were taken to block netizens’ organizational efforts – for example, shutting down websites, ***deleting*** posts, threatening active netizens with “drinking tea”, etc.– netizen movements have not only persisted, the rate at which they are occurring and the influence they have are also increasing. Even though the government updates the SPS’s enforcement methods, netizen movements continue to develop.

As discussed in previous sections of this article, distinct characters of anti-system contentions best explain the government’s unpreparedness when it comes to repression. First, they could not use armed forces to carry out standardized repression, as the forms of anti-system contentions vary. (How can you manage to use armed forces to stop Ai Weiwei’s fundraising efforts?) Second, the propaganda department is also often inefficient in censoring new messages innovated in myriad ways. Information spreads since the emergence of microblogs have compromised the government’s ability to seal off information. Third, the widespread nature of anti-system contentions makes it difficult for the SPS to predict where to focus its suppression, and therefore unable to nip the buds when it cannot pre-emptively identify them.

Such incidents clearly alarmed the CCP regime, whose vigilance in post-1989 had helped itself through many potential political challenges. The new pattern of repression emerged in government response to anti-system contention after around 2010. The main strategy is harsh, retrospective and precise repression of political entrepreneurs. Many activists involved in previous cycles of anti-system contentions were harassed, detained, or economically punished. As a consequence, those leading activists were silenced or removed from the public sphere. It is true that in anti-system contentions, netizens’ resistance network is like a web in which political entrepreneurs are simply single strands, but these entrepreneurs are important strands. Controlling or cutting out the leaders will not destroy the web, but will severely damage the existing structure of mobilization. When leaders are removed, their networks cannot be easily inherited by someone else, nor can their repertoires or contention discourses be easily replicated, since these aspects are often innovative and individual tailored. For instance, Ai Weiwei’s identity of artist enables him to organize many contentions under the name of art which triggers public interest and provides smart cover against state repression; both advantages cannot be easily picked up by other leading activists. By leaving general participants out of the range of repression, the government draws out a line for contention activists, efficiently spends its resources by not wasting money on identifying every grass-root members of anti-system contentions, and reinforces the political deterrence for people who plan to become political entrepreneurs in such contentions.

The anti-system contentions naturally suffer a blow, with leaders silenced and mobilization cooled off. Among them, it is the loosely-organized anti-system contentions that suffered the most. Through their common experiences of mobilizing and participating in anti-system conventions, rights-defense lawyers, intellectual activists, journalists, and dissidents became acquainted and loosely organized which enabled genuinely national anti-system movements to rise. Such movements are equipped with a relatively stable set of core leadership, clear claims, and effective repertoires. We now briefly discuss two prominent cases of such contentions and also highlight the specific means through which the regime succeeded in repression.

The New Citizens’ Movement was founded by Dr. Zhiyong Xu, formerly a lecturer at the Beijing University of Post and Telecommunications. Xu was a key activist involved in the 2003 Sun Zhigang incident and had become an active political entrepreneur ever since. In the beginning, Xu organized his contentions largely in the form of NGO-mediated mobilization, the kind of contention that fits into the lower-left box of Table 1. However, after *Gongmeng*, the NGO vehicle Xu founded was shut down by the state in 2009, Xu moved toward less institutionalized channels to organize his contention. In 2012, along with a dozen intellectual activists, Xu founded the New Citizens’ Movement, calling for people “starting from one to act as a citizen”. He described the movement as a trailblazer in “coalescing and growing healthy forces that favors democracy and constitutionalism”21. The movement used the internet to publish its claims and distributed a “citizen badge” online. Famous campaigns organized by the New Citizens’ Movement include equal rights to education22, financial disclosure of civil servants23, local *fanzui*, and attacking the black jails24. The rise of the New Citizens’ Movement as a contention network that not only connects political entrepreneurs but also incorporates any netizens who identify with the movement’s claim marks the transformation of Xu to an anti-system contention leader. As Xu puts it, “in the past, I may choose to concede, for I’m not fully prepared. Now I will make no concessions.” 25 The regime took a quick response: Xu was arrested in July 2013 and was later sentenced to four years in prison. At least 45 “New Citizens” nationwide were detained in the 4 months afterwards. Microbloggers who use the citizen badge as their profile image to show their affiliation with the movement had their accounts ***deleted***. The New Citizens’ Movement was hence quickly put to rest.

Another transition similar to that of Xu can be found in the group of rights-defense lawyers. In the rights-defense movement, lawyers have always been crucial actors: they are instrumental in both providing the actual legal defense and popularizing the cases of human rights violation. Lawyers would often publish their cases online and seek to increase the relevance of their cases to a broader range of audience. Individual cases therefore become politicized and bear marks of anti-system contentions. In the course of their work in similar cases, such lawyers have developed a repertoire of “public and collective fundraising and spending, online and offline coalescence, trans-regional onlooking, and direct expression of contentions”. While these lawyers used to identify themselves as rights-defense lawyers, many have now opted for “diehard lawyers” to represent their resolve in fighting on. Prominent campaigns organized by such lawyers include the on looking of Zhengzhou Police Bureau26 and the on looking of Fan Mugen’s trial.27 The regime has always been vigilant toward these lawyers as they grow in number and influence. Individually targeted repression was frequent and included oral warning, disbarment, and even arrests and convictions. In July 2015, such repression upgraded from local and individual operations to a nationally coordinated operation, with 12 lawyers arrested and more than 260 lawyers detained or subpoenaed. The official news release says that the police have cracked “a major criminal gang that coalesce lawyers, activists and petitioners to disrupt public order under the guise of a law firm.” The police accuse these lawyers of orchestrating more than 40 contentions and published videos in which these lawyers were interviewed to show remorse. After this national repression campaign, the lawyers’ anti-system contention also went quiet.

Beyond targeting political entrepreneurs, the regime has also upgraded its control over netizens. The Chinese Supreme People’s Court issued a judicial interpretation making it a criminally liable offense for posting online “libelous” posts that are retweeted more than 500 times. Such actions, together with the state’s stringent management of prominent microblogger accounts, were considered as a new move to silence potential dissidence online.

Based on these recent developments, the Chinese regime’s adaption to new forms of repression seems rather successful. On the one hand, active political entrepreneurs all received harsh repressions and were either imprisoned or forced out of active movements. On the other hand, loosely-organized anti-system contentions have been obliterated after waves of nationally coordinated repression campaigns. Besides, as the chilling effect builds up on the microblog, the website has lost its prominence in facilitating communications on value-oriented contentions, leaving interest-oriented contention as the main form of contention rising in volume.

This of course, does not mean that the regime has once and for all eliminated its threats. Without addressing the structural factors that led to the rise of anti-system contentions, and without pre-emptively targeting all potential participants, the state will never be able to placate anti-system contentions, and we expect such contention to remain in a high-frequency, low-intensity, and innovative pattern, and continue to be a threat greater than any other social contentions to the Chinese authoritarian regime. The innovation competition will keep going on both for the political entrepreneurs and for the authoritarian state.

**Conclusion and discussion**

This paper has discussed anti-system contentions as a new form of contention that has been rising in China but has not yet been analyzed in the literature. By comparing anti-system contentions with other forms of social contention in China, this paper demonstrates the political opportunity structures and mobilization mechanisms that give rise to anti-system contentions, and further analyzes the Chinese’s regime’s response and the corresponding evolution of anti-system contentions.

China has long witnessed endless social contentions that had an effect on the landscape of Chinese politics and governance. But different forms of social contentions also vary in their political implications. Interest-oriented contentions’ impact is largely regional. While the central government would intentionally allow such contentions to emerge as a way to extract information and monitor local officials (Lorentzen, 2013), local governments could always use cooptation and/or repression to eliminate such contentions before they spin out of control. Therefore such contentions are unlikely to challenge the political rule of the CCP. Value-oriented contentions mobilized through formal channels often have a clear set of activists’participants who are identifiable to the state. Therefore the state would be better-equipped to target activists involved in such contentions and use a wide range of repression tools such as warning and sentencing to neutralize the threats.

Anti-system contentions have a more long-term impact on the CCP’s political rule as they call strictly for political reform. So far, most of their activities have ended quietly without the government wholly responding to their political demands. However, numerous thorough and heated online political debates are attracting more and more netizens calling for systematic government reform. This has led to a decline in the public’s estimation of their government’s legitimacy. Furthermore, China’s netizen movements and political entrepreneurs’ constant political whistle-blowing has attracted the attention of the international community. China’s government must now deal not only with heightened domestic pressure but also heightened international political pressure.

Predicting the course of anti-system contentions’ development is difficult. Despite the important impact of anti-system contentions and the staunch resolve of activists, anti-system contentions still has a quite limited pool of participants. It is therefore so far quite difficult for anti-system contentions to develop into more prominent forms of contention that shakes the regime’s rule. Such difficulty can be explained by several reasons. The first is the relatively high level of political trust in the Chinese government. Capitalism-oriented economic reforms, nationalism propaganda, moderate improvements in protection of civil and political rights (Dimitrov, 2008), strict control over the media and education system (Kennedy, 2009; Su et al., 2015), and Chinese cultural tradition (Shi, 2001) have all contributed to the public’s trust in its government. Even though the wealth gap has grown significantly, everyone’s standards of living have at least somewhat improved in the thirty-year-long high speed growth. Government improvements to its healthcare and pension programs have been a positive improvement for all levels of society, which has also strengthened the government’s public approval ratings. Even if grievances arise, the central government could also use the pattern of hierarchical trust it constructed to deflect blame to local governments (Su et al., 2016). Thus, the poor economic conditions that would produce a nation-wide contentious political atmosphere do not exist anymore. Anti-system contentions participants’ reasons for protests therefore must stem from demands for political reform, but only a small percentage of people have that perspective, and even fewer have the audacity to act.

Second, the Chinese government has developed an effective system to collect information and manage social protests. On the one hand, the e-government initiative allows the central government to extract economic information and efficiently monitor and potentially steer economic activity at a more abstract level (Ma et al., 2005). On the other hand, as Lorentzen’s studies show, the Chinese government’s attitude toward social protests is neither completely repressive nor entirely supportive (Lorentzen, 2013, 2017); Popular protests reveal true information on local politics for the government to improve its governance and also help the government to identify key social activists. The high cost of participating in popular protests and the fact that protestors come from grassroots level make social protests a channel of monitoring society and extracting information superior to more institutionalized channels such as the People’s Congress and the petition system. As long as the information keeps flowing to the central government from local levels, social protests in China can actually serve as a safe valve for the public to release their discontent. At the same time the government has made great effort to keep information from flowing among the public which could preempt systemic protests against the political system. This set of strategy has allowed the Chinese central government to maintain a delicate balance between tolerating social protests and maintaining social stability (Lorentzen, 2013, 2017). This is also evident in the fact that none of the cases of protest discussed in this paper had escalated to national and prominent contentions.

The third reason pertains to the fact that civil society organizations have not fully developed or matured in China. Current civilian organizations all function under the government’s control and their connections with contentious actors are by no means strong or close. Lacking the support of these organizations, the public lacks the ability to organize and mobilize on its own, and would not be able to support any wide-scope or large-scale contentious activities.

Fourthly, the SPS logistically and physically functions quite well. In terms of organizational set up, the SPS is present in every Chinese town and street with the ability to quickly and effectively control active resistance actors (Yan, 2016). Its operational tactics are flexible and adaptive enough to develop appropriate measures to control many different targets. As a consequence, the SPS can and often does “nip” national-scale contentious activities “in the bud.” Even though the government’s SPS operational costs have increased over the years, the high-speed economic growth in the past thirty years has provided sufficient revenue for the state to maintain the SPS.

On the other hand, though, these elements do not necessarily hinder the development of anti-system contentions. Since anti-system contentions’ fervently demand large-scale systematic political reform, they will not stop until they have achieved their goal and seen to massive overhauls in the political system. This is a race between society and the current regime to influence China’s future. Who will ***win*** depends on who can adapt faster and ***win*** the hearts of the common people.

**Notes**

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Protesters started gathering outside the hotel and clashed with the police for two days. The incident later became a mass riot involving over 10,000 people and 10,000 police officers.; 3.On 28 June 2008, in Weng’an County, Guizhou Province, rioters involving tens of thousands of residents smashed government buildings, torched several police cars and eventually burnt down the local Chinese Communist Party’s head office to protest against an alleged police cover-up of the death of a girl who was rumored to have been raped and killed.; 4.That being said, we do not mean that interest-oriented contentions will not pose fundamental challenges to an authoritarian regime; factors such as income inequality could propel large-scale contentions (in extreme form revolutions) to democratize the state (Acemoglu and Robinson, 2009). But in the context of China, there has been no sign of such contentions yet.; 5.On the night of 10 May 2009, in the town of Yesanguan in Hubei’s Badong County, three government workers went to an amusement park and demanded a worker named Deng Yujiao service them sexually. Using a paring knife, Deng Yujiao killed one of these men and injured another. However after she went to report the incident, the next day the policy arrested Yujiao under the charges of “willful homicide.” This incident aroused national attention, and many people across the country spontaneously went to Badong County to support Deng Yujiao. In the end, her sentence was lifted.; 6.On 17 March 2003, there was a youth named Sun Zhigang working in Guangzhou. He was seized by the policed because he lacked a temporary residence permit. He was assaulted and beaten barbarously, and died on 20 March 2003. After the news of his death was published, widespread protests sprang up. Finally the government abolished the law empowering police to seize and repatriate the homeless and beggars.; 7.Even today one can find the very first public letter published on 16 July 2002, entitled “The Netizen’s Declaration of Rights.” This letter ended up garnering over 200 signatories. There are two types of content within these public letters. The first are those letters that criticize a specific incident of rights abuse. The second type is those letters that purely express traditionally political demands.; 8.A female teacher, Huang Jing, was found dead and naked on her bed on 24 February 2003 in Xiangtan city in Henan Province. The police investigation found that she had died of a heart attack, but Huang Jing’s family and the internet community could not accept this verdict. They found it obvious that she had died from rape.; 9.Liu Di was a student at Peking University. On 9 November 2002, the Beijing police took her in custody on charges that she was involved in an illegal organization. Her year-long imprisonment stirred up strong reactions from people all over China. There were over 2000 people who signed the petition for her release.; 10.Du Daobin was a Hubei government worker who was famous for holding “different” views. Since October 2001, he has published many articles online criticizing the government, but was detained in October 2003 under the charge that he was trying to incite the overturning of the government. He was sentenced to three years in prison. His case aroused broad concern online amongst netizens and intellectuals who demanded his release.; 11.Internet on looking refers to when the online community of resistance participants or whistle-blowers watches a phenomenon occurring or scrutinizes an entity’s behavior. The goal is not to criticize or prevent the abuse or crime from happening but rather to merely place pressure on the one committing the act through their attention.; 12.In contrast to the Chinese Communist Party’s published *People’s Daily* newspaper, less propagandized or politicized newspapers like the *Southern Metropolitan Daily* (which published the earliest media-accepted resistance story of Sun Zhigang mentioned in note 6), are much more favored by the ordinary populous.; 13.What role the internet has played and will play in this dissipation of political apathy remains a highly disputed topic. Scholar James Liebold (2011) in his article, “Blogging Alone,” paints a pessimistic picture of Chinese political consciousness by applying Evgeny Morozov’s (2011) work and Robert Putnam’s (2000) thesis to China, and noting that modernization could likely lead to greater individualization, social dispersion and diversion, and thus political apathy. He asks whether “the digital activism required to ignite a prairie fire of revolutionary, democratic change in China is being snuffed out by the dull flicker and gentle tapping of millions of isolated, individual computers and their smiley-faced bloggers” (Liebold, 2011: 14). While the statistics and focuses Liebold addresses *do* reveal that the majority of internet content’s purpose is mindless entertainment, trivial discussions, and misinformation, no empirical evidence as yet shows any increase of political apathy. In contrast, the numbers of social protests have risen steadily, and they start not from a majority but from a small number of devoted, trustworthy, and charismatic netizens in the political activist community. China has not yet reached the point in development where political apathy would be an option for the majority of the population.; 14.Ai Weiwei was born in 1957 in Beijing and is currently one of China’s most famous artists and political dissidents. His father is also one of China’s most famous poets.; 15.People posted pictures of the bank notices or withdrawal slips they had received when loaning Ai Weiwei money. Many said, “Finally we’ve become the owners of Ai Weiwei’s debt!” They also claimed they wanted to make sure he did not go anywhere with their money – a means of also saying they did not want the police to drag him away.; 16.This phrase is a set saying in Chinese referring to a passive attitude adopted in a tense situation. In the context of on-site on looking, it means that netizens go to the site of a politically tense incident but do not express any of their disapproval verbally.; 17.The interesting thing about Chinese audience petitioners is that after many of their petitions failed, they gave up on their individual cases and instead became professional general human rights defenders.; 18.Regarding the illegal Google flower tribute, the government had warned people against displaying support for Google after it left China in January of 2010. Despite this warning, many netizens gathered to present flowers and to sing in front of the former Google headquarters in Beijing in order to show their support for Google’s decision and actions.; 19.Around 16 April 2010, many contention activists across China gathered around the courthouse in Mawei District, Fuzhou City, where the 3 netizens were held in trials. These activists spread handouts and demonstrated to protest the trial. The campaign also drew much coverage online.; 20.*Siloviki* is a Russian term that is used similarly in the Chinese context. It refers to a country’s national security department, military, police forces, and other special departments responsible for stability preservation, public security management, social inspection and monitoring, etc.; 21.Xu, Zhiyong (2013) Gongmin Zimian: Fuwu, Dandang, Fangxia. Available at: [*http://xuzhiyong2012.blogspot.com/2013/04/blog-post\_6636.html?m=1*](http://xuzhiyong2012.blogspot.com/2013/04/blog-post_6636.html?m=1).; 22.Xu organized activists periodically and publicly to petition (not following the traditional *Xinfang* channel) the Ministry of Education for equal access to college entrance exams for migrant children who do not have Beijing local *hukou* registration.; 23.Xu organized and encouraged citizens to demonstrate to call for civil servants to disclose their income and personal property as an institutional policy to curb and address corruption.; 24.Black jails are extralegal detention centers established by Chinese security forces and private security companies to detain, without trial, petitioners who travel to Beijing to seek redress for grievances unresolved at the local level. Xu would identify black jails and visit them to rescue jailed petitioners.; 25.Li, Heping (2013) Diandian Didi Xu Zhiyong’. Available at: [*http://www.64wiki.com/info/eventinfo.php?pid=2302*](http://www.64wiki.com/info/eventinfo.php?pid=2302).; 26.In May 2014, multiple Zhengzhou local residents were arrested by the police for “collectively disrupting public order”. The lawyer representing an arrested journalist was also detained by the police. On 5 June 2014, two dozen lawyers from 10 nearby provinces gathered in Zhengzhou and held a conference on these arrests. The lawyers later visited the Zhengzhou Police Bureau for “on looking” and demanded to talk to the police chief.; 27.Suzhou local resident Fan Mugen and his family members were charged with murder for killing two men when defending their homes from being forcefully demolished by the state. When the case went to trial on 4 February 2015, more than 300 lawyers and citizens arrived at the court to on look. A number of other activists also tried to visit the court from afar but were preempted by their local police.

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HINA Digest

13 April 2018

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**Length:** 9436 words

**Body**

Zagreb, 13 April 2018 (Hina) - Parliament ratifies Istanbul ConventionZAGREB, April 13(Hina) - The Croatian parliament on Friday ratified the Council of EuropeConvention on preventing and combating violence against women and domestic violence, better known as theIstanbul Convention, with 110 votes in favour, 30 against and two abstentions.About a dozen of the 55 MPs of the ruling HDZ party were against the ratification of the document.What made the vote unusual was that a significant portion of the parliamentary majority voted against the government's proposal to ratify the document.Gov't: Convention is about prevention of violence against womenThe purpose of the convention is to prevent violence against women and domestic violence. According to police figures, in the period between 2013 and 2017, 195 murders were committed, and of that number 91 victims were women.The ratification of the convention will strengthen the legal, institutional and financial framework for dealing with the socially unacceptable and punishable crime of violence against women and domestic violence, the government said.The government insists that the document does not imply any legal obligation to recognise a third sex or change the constitutional definition of marriage."There is nolegal obligation for Croatia to introduce into school curricula any content that would be contrary to values that I share, there are no such obligations, they do not exist," Prime Minister Andrej Plenkovic said in the parliament recently.He said that the ratification of the document was an expression of the government's political will to strengthen the legal and institutional framework to prevent domestic violence.PM denies claims about convention costing one billion kunaPlenkovic has dismissed on several occasions claims that the ratification of the convention would require Croatia to set aside a billion kuna for its implementation.Croatia has its national programme for the prevention of violence that was adopted last autumn, and for that purpose it has allocated budget funds in the amount of HRK 70 million this year.

A portion of the funding isintended for the implementation of the convention, Plenkovic said.He also sent placating messages to the public regarding GREVIO, a group of experts who are to oversee the fight against violence against women.GREVIO is not anunusual supervisory body as such bodies exist for various Council of Europe conventions, he said, mentioning in that context GRECO and GRETA, bodies in charge of overseeing efforts in fighting corruption and human trafficking.Along with ratifying the Istanbul Convention, the parliament also adopted an interpretive statement which says that the purpose of the convention is to protect women against any form of violence, that its provisions do not contain any obligation to introduce 'gender ideology' in Croatia's legal and education system, and that the convention is in line with Croatian constitutional provisions, notably those concerning protection of human rights and fundamentalfreedoms.SDP amendment against interpretive statement rejectedThe government and parliament rejected an amendment put forward by the Social Democratic Party (SDP) to ***delete*** Article 4 of the Act ratifying the Istanbul Convention, which contains the interpretive statement.International law provides for interpretive statements when an international treaty is signed or ratified and the content of that statement is necessary and important for the Croatian public and all social stakeholders, said Plenkovic.The fact that you are explaining the amendment bears witness to how serious the situation is, SDP MP Arsen Bauk responded, claiming that with the interpretive statement the government was unnecessarilycurrying favour with those who were against the convention and whom the interpretive statement would not satisfy.Economy minister survives no-confidence voteZAGREB, April 13(Hina) - The Croatian parliamentary ***Opposition*** on Friday failed to topple Economy Minister Martina Dalic and shewill continue to be a member of the Andrej Plenkovic government.The oppositionmotion to give Dalic a vote of no confidence was supported by 71 MPs while 76 voted against.Hrvoje Zekanovic of the HRAST party kept his promise of two days ago, when he left the ruling coalition over his disagreement with the government's plan to have the Istanbul Convention ratified, and withheld his support for Dalic.Italian minority MPFurio Radin, who is a member of the parliamentary majority, did not attend the vote.The motion to replace Dalic was signed by 37 members of six ***opposition*** parliamentary groups and independent MPs.They criticised Dalic over a scandal involving a consulting firm hired to provide services in the restructuring of the debt-laden Agrokor conglomerate by Agrokor's former emergency administrator Ante Ramljak, who, they said in a debate on Thursday, was her choice and her responsibility.Ramljak stepped down after it was revealed that he had hired his former employer, Texo Management company, to provide consulting services to Agrokor for almost one million kuna a month, and the scandal took on a new dimension after a document was leaked showing that until April 30, 2017 Ramljak was still formally an employee of Texo Management even though the government appointed him as Agrokor's emergency administrator on April 10, 2017.The government dismissed the ***Opposition***'s claims against Dalic as unfounded.14 of 55 HDZ MPs voted against Istanbul Convention, one abstained, two didn't voteZAGREB, April 13(Hina) - The Croatian parliament on Friday ratified the Council of Europe Conventionon preventing and combating violence against women and domestic violence, better known as the Istanbul Convention, with 30 MPs voting against the ratification, including 14 deputies of the ruling HDZ party, while HDZ MP Ivan Suker abstainedand two other HDZ MPs, Bozo Ljubic and Zeljko Raguz, did not vote even though they attended the session.This is the first time such a significant portion of the parliamentary majority opposed a government bill.Of the 55 HDZ MPs, 14 were against the ratification of the Convention - Ante Babic, Milijan Brkic, Stevo Culej, Ivan Celic, Marija Jelkovac, Anton Kliman, Miro Kovac, Tomislav Liposcak, Davor Loncar, Franjo Lucic, Davor Ivo Stier, Ivan Sipic, Petar Skoric andMiroslav Tudjman.Against were also the HDZ's coalition partners Goran Dodig and Branko Hrg of the Croatian Christian Democratic Party (HDS), Kazimir Varda of the BM 385 party, and independent MP Ivica Misic.HDZ MPs Bozo Ljubic and Zeljko Raguz were in the chamber but did not vote, and the three MPs of the Human Shieldand Ante Pranic (Bridge) did not either.Some of the MPs of the ***opposition*** Bridge party alsovoted against the ratification, namely Miro Bulj, Sonja Cikotic, Slaven Dobrovic, Nikola Grmoja, Tomislav Panenic, Bozo Petrov and Marko Sladoljev, as did Independents for Croatia MPs Bruna Esih, Zeljko Glasnovic and Zlatko Hasanbegovic, Ivan Lovrinovic of Let's Change Croatia, and HRAST MP Hrvoje Zekanovic, who parted ways with the HDZ over the Convention.Apart from Suker, independent MP Marin Skibola abstained from the vote.Independent MP Furio Radin, Nada Turina Djuric of the GLAS party and Social Democrat Sinisa Varga did not attend the session.Of the 151 parliament members, 142 attended the vote on the Istanbul Convention. It was ratified with 110 votes in favour, two abstentions and 30 votes against.PM says HDZ MPs who were against Istanbul Convention won't be penalisedZAGREB, April 13(Hina) - Prime Minister Andrej Plenkovic said on Friday that the fact that parliament ratified the Istanbul Convention was good in terms of protection of women from violence and domestic violence, reiterating that the 17 MPs of his HDZ party who did not vote for the ratification would not be punished because they were free to express their will.He told reporters the HDZdeputies who voted against the ratification or abstained did not makeany particular statement. "It may be that some MPs have some world view dilemmas and that some perhaps have another agenda. That'stheir business."As for the implementation of the Convention, he said all state institutions and the government would do their best to deal with the "negative social phenomenon" of violence against women. The interpretive statement accompanying the Convention "is a clear guide to all institutions on how to implement it," he added.Plenkovic said it was necessary to work on defusing the tensionand rifts the Convention had caused in Croatia. "The government and a convincingparliamentary majoritybelieve the goal of the Convention is to combat violence against women, and that was the only motive for putting the Convention on the agenda," he said, adding that the political and world view aspects were "subordinate" in this case.He said there had been no worrying tendencies inthe countries which enforced theConvention, contrary to what some people in Croatia's public sphere claimed due to pressure,campaigning, fears and insufficient knowledge of the document. "Time will tell that I'm saying the truth and we will continue to work inthe interest of all of Croatian society and respecting those who were against it."As for the messages addressed to him at a rally against the ratification of the Convention held in Split on Thursday, Plenkovic said any informed observer could clearly seethat the Convention was not the essence or thetopic of the protest. "They have another agenda and are within the 71 votes against" Economy Minister Martina Dalic,he said, referring to a motion for a no-confidence vote in Dalic which did not pass in parliament today.Plenkovic went on to say that he was faced with every possible problem in Croatian society and that he believed the government was dealing it very well in circumstances of a "negative, defeatist and pessimistic approach" to everything. He said the media contributed to that and that this was neither good nor healthy for society."I decided to run Croatia in such a waythat we are compatible with what we willingly joined and that, in doing so, webehave well, responsibly, to the country's benefit, and I will continue to do so," he said, adding, "I stand by every move I make and will do so in future."Asked if he would remain at the helm of the HDZ after this term as party president, he said, "Why not?"SDP whip says society has reached consensus on Istanbul ConventionZAGREB, April 13(Hina) - The head of the Social Democratic Party (SDP) parliamentary group, Arsen Bauk, said on Friday after a vote on the Istanbul Convention that the vote had confirmed his expectation that the Convention would be ratified with more than two-thirds majority support, which, he said, showed that the Croatian society had achieved a consensus of a constitutional character regarding the convention."This is good and I hope that there will be no further compromises with those who have used the Istanbul Convention as an instrument to exert influence on the government and on decision-making concerningindividual freedoms such as women's right to choose, the right to medically assisted reproduction, the rights of same-sex couples and other rights," Bauk told reporters.Commenting on differences within the HDZ on the Istanbul Convention, whichsurfaced during the parliamentary debate on the document, Bauk said that those differences were much deeper than differences in other big parties and that it was up to the HDZ to find a model to overcome them."Whether they will overcome them in such a way to continue together... or the party would do what it usually does - replace its leader, kick them out and treat them as if they were never party leaders - is up to them to decide," said Bauk.He expressed hope that the conflicts in the HDZ would not be compensated for with concessions on other laws, such as the Family Act, "to which we in the ***Opposition*** must react and warn about"."It is very important that the HDZ stops flirting and currying favour with the far right and to start defending human and individual rights like other moderate, Christian Democrat, conservative parties in Europe," said Bauk.Vote on Dalic shows ruling majority very thinAs for a vote of no-confidence in Economy Minister Martina Dalic, who survived the vote as 76 deputies of the parliamentary majority voted against the ***opposition***'s motion to replace her and 71 voted for, Bauk said that that vote, too, had confirmed his expectation that the ***opposition*** motion would be supported by 70-73 deputies.It has transpired that the ruling majority is very thin, Bauk said, adding that this made all ***opposition*** arguments seeking Dalic's replacement justified.HNS: Now we can concentrate on important problemsZAGREB, April 13 (Hina) - Ivan Vrdoljak, the leader of the Croatian People's Party (HNS), a junior partner in the ruling coalition, told a press conference on Friday that it was good that the vote on the Istanbul Convention was over and that now the focus should be on "important and greater problems."Asked whether dissenting views in the ruling Croatian Democratic Union (HDZ) about voting on the Istanbul Convention could destabilise that party and consequently the government, Vrdoljak said that he didn't think the government would be shaken."We can now concentrate on important matters. GDP is growing, foreign debt is decreasing, industrial production and exports are growing. We have many challenges ahead of us, so I don't expect any problems in the government," he added.Vrdoljak recalled that nine months ago, when it entered government, the HNS made a difficult but resolute decision to stabilise the political scene in the country. "Now it's obvious to everyone that that was a good move," he said.IDS: Ratification the only right decisionThe head of the ***opposition*** Istria Democratic Party (IDS) said on Friday that by ratifying the Istanbul Convention "despite unprecedented pressures," parliament made the only right decision."It's also the first concrete step so that we can provide women and all victims of violence with better protection, at the level of the most developed European Union countries," Boris Miletic said, adding that it was now up to state institutions to implement the Convention's provisions as comprehensively as possible.In Istria County, "all regional and local institutions will be an honest and good partner on that road," he said, adding that he was pleased that the Amsterdam Coalition, of which the IDS is part, was the first to insist that the ratification of the Convention be put on the agenda."Now we can turn to resolving the other amassed problems," Miletic said, adding that the most important thing was that the ratification of such an important document legitimised Croatia as a modern state and society.Council of Europe welcomes Croatia's ratification of Istanbul ConventionZAGREB, April 13(Hina) -Council of Europe Secretary General Thorbjorn Jagland on Friday welcomed the ratification of the Istanbul Convention by the Croatian Parliament, calling it "excellent news"."I welcome Croatia's ratification of the Council of Europe's Istanbul Convention with an impressive majority in Parliament today. This is excellent news before my visit next week," he said."Croatia's path towards European integration and EU membership has been impressive. Now Croatia will be taking over the Chairmanship of the Committee of Ministers of the 47-state Council of Europe at a crucial time. We will be discussing the current challenges in Europe and the priorities of Croatia's chairmanship. I am very much looking forward to this visit."The Croatian Parliament on Friday ratified the Council of Europe Convention on preventing and combating violence against women and domestic violence, better known as the Istanbul Convention, with 110 votes in favour, 30 against and two abstentions.Croatia is the 30th of the Council's 47 member states to ratify the Convention and the 18th European Union member state to do so.Police say Split protest against Istanbul Convention drew 15,000 peopleZAGREB, April 13(Hina) - The protest against the ratification of the Istanbul Convention that was held in Split on Thursdayevening drew 15,000 people, it was peaceful and no incidents were reported, Split-Dalmatia County Police chief Slobodan Marendic told a news conference on Friday."Around 6 pm, there were around 15,000 protesters, possibly their number rose to 18,000 by 7 pm, but our estimateis that there were 15,000 people," Marendic said, explaining that police did not want to go public with their estimate on Thursday as they first had to collect material to help them determine the actual number of protesters.PM responds to criticisms from parliamentary oppositionZAGREB, April 13(Hina) - During Friday's parliamentary debate on European Council conclusions presented by Prime Minister Andrej Plenkovic, Miro Bulj of the ***opposition*** Bridge party asked him when he would "start pursuing a sovereignist policy instead of being aBrussels clerk."Plenkovic said the government and he advocated Croatia's national interests, telling Bulj, "either you don't know what we are doing or you don't have a good sense of what Croatia's international position in 2018 means, or you have forgotten that the ***strategic*** goals of the state policy... were membership of both the EU and NATO, even the Council of Europe."Ivan Lovrinovic of Let's Change Croatia asked Plenkovic if thedraft settlement for the Agrokor company, in which he said Russian banks and a US investment fund played themain part, had anything to do "with the future of the energy sector in Croatia, the gas supply of the oil refinery in Bosanski Brod, the construction of the LNG terminal and the search for a ***strategic*** partner for INA."Plenkovic said Agrokor's ownership structure "depends first and foremost on the creditors and credit institutions from which the former owner and former management took loans." He said the draft settlement showed that "we have no prejudices against anyone, be they American funds or Russian banks. And that's an important message of running the economy."Bojan Glavasevc of the ***opposition*** Social Democrats said "this is definitely a sensitive moment given all that's going on in the Middle East," asking Plenkovic if he communicatedwith President Kolinda Grabar-Kitarovic, given that she invited Russia's President Vladimir Putin to Croatia at a time when Croatia was imposing sanctions against Russia."Of course we talked with the president. We very thoroughly examinedall the aspects and adopted joint decisions, given that such matters absolutely call for a consensus of all state institutions on matters which also have foreign policy repercussions. You see that the consequences haven't been dramatic at all," said Plenkovic.Branimir Bunjac of the ***opposition*** Human Shield said his group rejected Plenkovic's report on the Council of Europe conclusions and the government's entire policy."Croatia has expelled a Russian diplomat based on speculation that the Russians carried out a nerve agentattack on one of their citizens in Great Britain. We thusdefinitely showed that we are not a sovereign state whereas...our neighbours Slovenians didn't agree to such an ultimatum, andSlovakia rejected it," Bunjac said.He asked if Croatia was governed by Brussels, Washington or British secret services, adding that MPs of the ruling Croatian Democratic Union (HDZ) "will avoid going to war because they have serious medical conditions, some are anaemic, some have syncope."PM says has no ambition to run for office in EUZAGREB, April 13(Hina) - Prime Minister Andrej Plenkovic on Friday refuted media speculation that he had the ambition to take a senior position in the European Union.He was in parliament presenting the conclusions of the European Council reached on March 22 and 23.Asked after a discussion to clearly comment on media reports that his ambition was to take a senior position in the EU, Plenkovic said his "ambition is to be Croatia's prime minister and fulfilwhat is set out in the party's programme."Speaking of Croatia's recent activities within the EU, he mentioned his speechof February 6 in whichhe said that Croatia "advocates the equality of all member states, the equality of our citizens within the EU, equal opportunities."He said he also underlined "our joint achievements inshowing, within democratically legitimate European institutions, that European policies and budgets should have the biggest benefit possible for our citizens."Plenkovic said the College of Commissioners held a meeting in February at which Croatia presented its priorities in the EU - making the country ready by 2020 tojointhe Schengen Area, and joining the euro area. There was also talk of building the Peljesac bridge and the importance of EU enlargement to Southeast Europe, he added.He said that in March the Council also discussedenergy. The EU's goal is building an integrated energy market, he added.Hementioned Croatia's activities to build an LNG terminal, saying it should meet the highest ecology standards and that it would ensure Croatia's gas supplies in the long term.Hewent on to say that Croatia supported the continuation of EU negotiations with Mercosur and Mexico and the conclusion of agreements with Japan and Singapore.Plenkovic said the Council also discussed the attack in Salisbury and the response to it, migration, and relations with Turkey.He said the Council discussed the Central Mediterranean migration route and that a meeting was held in February with Sahel countries. "Those five countries currently have 77 million inhabitants and, according to projections, there will be 130 million of them in 15 years," he said, adding that Croatia, because of its ***geographical*** position, must keep an eye on those demographic trends.The Council also discussed the continuation of the reform of theDublin Regulation, with emphasis on prevention and the establishment of a common European asylum system.Plenkovic said current EU chair Bulgaria decided to hold asummit in Sofia on May 17, bringing togetherEU member states and the countries of Southeast Europe, to "send a message of support for reforms."He said it was important that the EU stand by the refugee agreement with Turkey, complying with its financial obligations to Ankara.Speaking of enlargement, Plenkovic said he expected the European Commission to support the accession candidates at the Sofia summit. During its presidency over the EU in 2020, Croatia wants to hold a summit to stimulate reform and compliance with accession requirements, he added.Plenkovic meets with EC Vice-President Katainen and Commissioners Mimica and KingZAGREB, April 13 (Hina) - Croatian Prime Minister Andrej Plenkovic met in Zagreb on Friday withEuropean Commission Vice-President for Jobs, Growth, Investment and CompetitivenessJyrki Katainen, Commissioner for International Cooperation and Development Neven Mimica and Commissioner for the Security Union Julian King.They discussed several topics relating to the future of the European Union, notably priorities of the next Multiannual Financial Framework, as well as implementation of projects, absorption of funding and its effectiveness. In that context, Plenkovic spoke of his government's plans to strengthen the Croatian economy and outlined the priorities of the National Reform Programme, a government press release said.Also discussed was progress in the Permanent Structural Cooperation (PESCO) in defence and security, which Croatia has joined along with 24 other member states. Plenkovic said this was one of the examples where Croatia was sending a strong message that it wanted to be among the members seeking deeper integration. The issue of migration was also discussed in that context.The meeting was also attended by Minister of Economy, Entrepreneurship and Crafts Martina Dalic, Minister of Foreign and European Affairs Marija Pejcinovic Buric, Minister of the Interior Davor Bozinovic, Minister of Finance Zdravko Maric, and Minister of Regional Development and EU Funds Gabrijela Zalac.Croatian president receives EC vice-presidentZAGREB, April 13 (Hina) - President KolindaGrabar-Kitarovic on Friday receivedEuropean Commission Vice-President for Jobs, Growth, Investment and CompetitivenessJyrki Katainenand discussed structural reforms, the Juncker plan and European defence policy, the President's Office said in a press release.Katainen, who is currently on an official visit to Croatia, and Grabar-Kitarovic agreed that this favourable period in the economy was ideal to implement structural reforms and that investing in a quality education system was a long-term investment.Katainen mentioned the EC's projects stimulating investmentand in that context he emphasised the Investment Plan for Europe, known as the Juncker Plan.With financing from the European Investment Bank, this plan promotes investmentinthe private sector through the European Fund for ***Strategic*** Investments with a view to creating a greater social and economic value.Croatia too has benefits from that funding, Katainen underscored.The growth and competitiveness of the EU are the main priorities and their achievement requires solidarity and cohesion, the two officials agreed.They also discussed the priorities and challenges of Europe's defence policy, with Katainen highlighting defence cooperation between the EU member states and cooperation with NATO.Emphasis was put on the European Defence Fund as a financial mechanism from which member states will be able to implementresearch and development projects. This fund should be interesting to Croatia too, the press release said.Grabar-Kitarovic informed her guest of the Three Seas Initiative and the summit meetings held so far within the Initiative. She expressed hope that a strong EC delegation would attend the next summit of the Initiative, to be held in Bucharest.FM meets European int'l cooperation and development commissionerZAGREB, April 13(Hina) - Croatia's development policy and its complementarity with the goals and activities ofthe European Union's development and humanitarian policy were the topics of a meeting between Foreign Minister Marija Pejcinovic Buric and European International Cooperation and Development CommissionerNeven Mimica in Zagreb on Friday.They underlined the importance of the nextmultiannual financial framework for the development policy of the EU as the world's biggest donor, the Foreign Ministry said in a press release.The two officials also underlined the importance of implementing the UN's2030 Agenda for Sustainable Development and finding models for a more efficient use of new and small donors' capacities in the EU's development policy.Theyunderscored the importance of cooperation with the European Commission in informing citizens about development cooperation, saying it is necessary to encourage stronger inclusion of Croatian companies in projects financed through theEU External Investment Plan.Pejcinovic Buric highlighted the importance of including stakeholders from the private sector, civil society and the academic community in the EU's development policy.Bozinovic: Croatia to meet technical criteria for Schengen Area by year's endZAGREB, April 13 (Hina) - After meeting with the European Commissioner for the Security Union, Julian King, in Zagreb on Friday, Interior Minister Davor Bozinovic said that Croatia would meet the technical criteriato enter the Schengen Area by the end of the year.Bozinovic discussed several security topics with King, including border surveillance and the implementation of the European directiveon the use of passenger name record (PNR) data for the prevention, detection, investigation and prosecution of terrorist offences and serious crime.Bozinovic expects that the motion in second reading, which was adopted by the government on Thursday, would be passed by parliament in a week or so.He assessed the directive as important in the joint fight against terrorism, organised crime, money laundering and access to substances for home-made explosive devices.Joint efforts are important to establish and apply IT systems, Bozinovic said and added that the Schengen Information System has shown that it was justified to apply it in Croatia, which has recorded 168 million views over the past seven months with 8,000 'hits' identifying vehicles and people that are interesting from a security aspect.Croatia is known as a tourist destination and has nine international airports that need to be subjected to the directive, he said.All this is sending a clear message that Croatia is on the right track to achieve a higher standard in protecting citizens and achieving the government's ***strategic*** objectives, like entering the Schengen Area before the end of the year, Bozinovic said.King,one of three European Commissioners on a visit toCroatia today, said that the directivewas a concrete example of cooperation which brings security benefits for all interested parties. Passenger tracking enables strengthening the security aspect throughout the European Union, direct information exchange of passenger details, better prevention, detecting and investigating terrorism and other serious forms of crime, such as drug smuggling, people trafficking and sexual abuse of children.I have seen that an excellent job has been done in implementing the directive, King said.Croatia, Canada mark 25 yrs of diplomatic relationsZAGREB, April 13 (Hina) - Croatia and Canada are friends and partnerslooking forward to growing commercial ties, dedicated to advancing the fundamental values that theyshare, and facing the challenges of the future together, the two countries' ambassadors said in Zagreb on Friday.Croatian Ambassador Marica Matkovic and Canadian Ambassador Daniel Maksymiuk issued a joint statement on the occasion of 25 years of diplomatic relations between the two countries."Today, our countries are Allies in NATO, committed to our collective security and to promoting peace around the world. This commitment is all the more profound given the challenges Croatia faced during the 1990's and Canada's peacekeeping efforts in Southeastern Europe," the statement said."Canada and Croatia are champions of open markets, open economies, and trading relations that advance the values of transparency and sustainability. We are partners in CETA, the most ambitious and progressive trade agreement ever, which the Republic of Croatia was one of the first EU members to ratify," said the diplomats."Our excellent bilateral relations are enriched by a vibrant and dynamic community of Croatian-Canadians, many of whom are professionally active in both countries, who contribute to Canada's diversity and connect our two countries even more closely," the statement said."The past quarter-century of cooperation has seen many other achievements; in multilateral diplomacy, security and defense, trade and investment, research and innovation, culture and the arts", it added.Conference on European Fund for ***Strategic*** Investments held in ZagrebZAGREB, April 13 (Hina) - To ensure more successful use of the European Fund for ***Strategic*** Investments (EFSI), also known as the Juncker Plan, it is necessary to increase its visibility and improve the provision of information to end users, a conference was told in Zagreb on Friday.The conference, entitled "TheEuropean Fund for ***Strategic*** Investments - Advantages and Opportunities for Enterprisesand Local Communities," was organised by the European Commission Representation, Croatian MEP Ivana Maletic and the Hanza Media company.Economy Minister Martina Dalic said that the new EU member states cannotbe happy with the distribution of projects and the structure of the use of the Juncker Plan per member state. She said that the largest number of projects and the most valuable investments were contracted in the most developed member states, stressing that additional efforts should be made in promoting investment opportunities under this plan.The conference heard that the old member states use 88.5 percent of the funds from the Juncker Plan, while the new members account for only 11.5 percent.Twelve projects worth 219 million euros in total have been approved for Croatia so far and they should generate 836 million worth of investment. Of this number, five have been granted by the European Investment Bank for small and medium enterprises, tourism and energy.Jyrki Katainen, European Commission Vice-President forJobs, Growth, Investment and Competitiveness, emphasised the importance of implementing reforms.We need to focus on structural reforms. If we want societies to be richer, we need to implement reforms, Katainen said. He added that Croatia should speed up reforms, especially at this stage of economic ascendancy, and that money from EU funds could play a major role.MEP Ivana Maletic said that sources of funding were available, but that it was important to prepare projects and link up with investors. She said that the EFSU issues guarantees for financing riskier projects which without a guarantee would not be able to get funding. She noted that the aim was to mobilise as many private sources of funding as possible and investment in small and medium businesses.Finance Minister Zdravko Maric said that improvement and acceleration of the project preparation processes was an example of the most painless structural reforms, adding that all authorities should do their best to simplify these procedures to facilitate the use of EU funding.Maric said that for countries like Croatia the key problem was the visibility of the plan itself and that it was necessary to acquaint all the stakeholders with its possibilities.Gabrijela Zalac, Minister of Regional Development and EU Funds, also highlighted the importance of information dissemination and training, saying that efforts had been stepped up in that regard.The European Investment Bank (EIB) and the Croatian Bank for Reconstruction and Development (HBOR) are coordinating points for investing under the EFSI.Zalac cited the Valamar hotel company, which signed a loan agreement with the HBOR last month, saying that it was the first direct loan granted to a private sector company with the support of an EU budget guarantee through the EFSI.The head of the EIB office in Croatia, Anton Kovacev, said that the EIB Group had 12 projects approved under the EFSI, worth 219 million euros in total. He said that these projects would generate about 840 million euros in investment, and added that 15 new projects had been nominated.Kovacev said that in terms of the proportion of EFSI funding in the Gross Domestic Product, Croatia ranks seventh among the member states and that it can be satisfiedwith that.Ministers say Aldott's departure should not impact talks with MOLZAGREB, April 13(Hina) - The departure of Zoltan Aldott from the post of INA Management Board chair should not impact talks between the Croatian government and INA's other owner, the Hungarian oil company MOL,on the possible purchase of MOL's stake in INA by the government, Economy Minister Martina Dalic and Finance Minister Zdravko Maric said on Friday.Asked what Aldott's departure from INA would mean for the process of negotiations with MOL,Dalic said that MOL was the government's interlocutor."The government's interlocutor in talks concerning the co-ownership of INA is MOL. I expect representatives of MOL, which is INA's co-owner, to be our interlocutors in those talks, and what I expect of INA and its management, including the new management board chair, is for INA to develop as a vertically integrated oil company, which means that it should develop evenly all segments of its business," Dalic said on the margins of a business conference in Zagreb.Finance Minister Zdravko Maric, too, said that the change inINA's management board would not change anything about Croatia's plans with the company."We have an advisor and a plan as to how to proceed in the weeks and months ahead," said Maric.When asked if this was a change in MOL's strategy, Maric said that it was too early for any conclusions.When asked if Aldott's departure would slow down the process which the government planned to implement with regard to INA, Maric said that he did not think that this would happen."We are expecting that process to happen anyway. It will not be simple... and will require a lot of effort and energy," Maric said, noting that the government was ready for it.MOL said on Thursday that it would propose Sandor Fasimon for the post of INA Management Board chair to replace Zoltan Aldott, who has been appointed a member of MOL Group's Supervisory Board and has said that he will leave INA after a meeting ofits shareholders' assembly in June.Aldott was appointed INA Management Board chair in April 2010.The Croatian government on Tuesday chose a consortium consisting ofMorgan Stanley, Intesa Sanpaolo Group andPrivredna Banka Zagreb to be its investment advisor on INA's possible buyout and possible subsequent sale of the stake to be bought back from MOLto a new ***strategic*** partner in INA.The bid by the consortium amounts to eight million euros.Spinraza to be included on HZZO list next week, says health ministerZAGREB, April 13 (Hina) -Spinraza, a drugused in treating spinal muscular atrophy (SMA), will be put on the list of medicines provided by the Croatian Health Insurance Fund (HZZO) next week while clinical trials with this new medicine will begin in Zagreb's KBC Hospital on April 17 and will include 23 SMA patients, Health Minister Milan Kujundzic announced on Friday."Spinraza has been put into procedure after the company applied and we accelerated the procedure. I think that it could be put on the HZZO list of medicines next week," the minister said.With regard to Roche's SMA medication, the management at the KBC Hospital confirmed that they would begin treating young patients as of April 17,Kujunzdic said.He addedthat the hospital had records of which patients met the criteria to be included in a clinical study to test Roche's medication andthat it would include patients up to the age of 25 and that some patients over the age of 18 would be included."The study will continue for a year and then after that if we see that it has a positive effect, treatment with the medication will be free of charge over the following four years," Kujundzic explained.Four children have already been put on the treatment with Spinraza and they will continue with therapy. Other patients who won't be included in the clinical study for Roche's medication will be treated with Spinraza if they meet the relevant criteria.State secretary Josipa Rimac fined for conflict of interestZAGREB, April 13(Hina) - The Conflict of Interest Commission on Friday fined Josipa Rimanc (HDZ), state-secretary at the Ministry of Administration, HRK 4,000 for giving false information inher declarationof assets.Rimac listed a house owned by her husband which is actually divided into three separate flats and cannot be treated as a single unit of real estate.In the case of Matko Gluncic, state secretary at the Ministry of Science and Education, who granted funds to an NGO despite the fact that he was a member of that NGO and to the periodical it published, the Commission decided that this was a violation of principle and that he did not take account of his own credibility and objectivity.However, there is no penalty prescribed in cases like this.The Commission did not continue proceedings against Deputy Parliament Speaker Zeljko Reiner (HDZ) on two complaints which note that he was knighted by the Order of the Holy Sepulchre which meansthat he is accountable to the Holy Father. The complainantsasked whether Reiner was in conflict of interest because, as deputy speaker in the highest legislative body of a sovereign state, hewas directly subordinate to the sovereign of another country.Crodux rejects responsibility for water pollution in Slavonski BrodZAGREB, April 13 (Hina) - The Crodux oil company, at a press conference in Zagreb on Friday, dismissed responsibility for water pollution in the eastern town of Slavonski Brod, saying it was not possible that the petrol spill could have reached water wells and water pipes 48 hours after a leak in the oil pipeline.The company rejected all insinuation and incorrect information in the media that tens of thousands of litres of oil had been transported from the area after the incident and that the repair work had been carried out irresponsibly and against the rules.The company denied claims that it had tried to cover up the leak, saying that authorities had been promptly notified and were already at the site half an hour after the incident. It stressed that the repair work had been done professionally and safely, without causing harm to people,property and the environment, and that this was documented.Crodux said that the cause of the leak was damage to the pipe that was several decades old.The leak occurred on March 28 in an area where the soil is clay, 2.6 kilometres away from the nearest water well, and the company claims there is no way that the pollutant could have affected the Jelas water supply plant within 48 hours. Inspectors identified the pollutant that leaked out of the pipeline as motor petrol containing 2.7 percent of benzene, which was not found in any of the water samples, Crodux said.Hydrogeologist Darko Mayer said that the pollution came from under the ground, adding that it appeared suddenly and disappeared suddenly.The company said it had taken legal action to prove its innocence.Croatia strongly condemns threats made by war criminal Vojislav SeseljZAGREB, April 13 (Hina) - The Croatian Ministry of Foreign and European Affairs on Friday strongly condemned threats which Serbian convicted war criminal Vojislav Seselj had made against Tomislav Zigmanov, president of the Democratic Alliance of Croats in Vojvodina and a member of the Serbian parliament, and Nenad Canak, president of the League of Social Democrats of Vojvodina, urging Serbia to take legal action against such outbursts of hatred and threats.The ministry noted in a statement that Seselj had repeated threats against the leaders of the Croatian community in Vojvodina only 24 hours after the appeals chamber of the Mechanism for International Criminal Tribunals, the successor to the International Criminal Tribunal for the former Yugoslavia in The Hague, sentenced him to ten years' imprisonment for crimes against humanity, including his inflammatory speech in the predominantly Croat village of Hrtkovci on 6 May 1992, which resulted in the deportation, persecution, forced resettlement and other inhumane acts against Croats in Vojvodina."I am making intensive preparations to repeat my war crimes and I am going to start with Tomislav Zigmanov and Nenad Canak," Seselj told the Blic newspaper on Thursday. He repeated the statement he had made on Wednesday that he was proud of the war crimes attributed to him and was planning on repeating them.The Croatian ministry voiced serious concern that the Serbian authorities had remained silent on Seselj's repeated threats, saying it "demands and expects an appropriate legal reaction from the relevant authorities of Serbia to these repeated outbursts of hatred and direct threats targeting the members of the same minority community in Vojvodina that was the object of brutal ethnically-motivated violence in the 1990s and whose wounds are still fresh."The ministry also called on Serbia to "prevent any form of physical and verbal violence and intolerance against members of the Croatian minority in Serbia."Vucic says Serbia has Germany's full understandingZAGREB, April 13(Hina) - German Chancellor Angela Merkel said on Friday Serbia was playing a key role in resolving problems in the Western Balkans, while Serbian President AleksandarVucic said after visiting her that Serbia had Germany's full understanding andsupport on its European Union journey.We made it our job to conduct a very intensive dialogue on the Western Balkans, notably in the first half of this year, Merkel said, pointing to activities under Bulgaria's presidency over the EU.Speaking ahead of talks with Vucic, who visited Berlin for the second time this year, Merkel underlined Serbia's importance as a political and economic stakeholder in the Western Balkans.If we consider Kosovo and Bosnia and Herzegovina, Serbia plays a key role here and it's therefore important that we maintain close and intensive contact, she said."Angela Merkel listened to our arguments and showed understanding and respect for Serbia," Vucic said after a working lunch with her, adding that they talked about bilateral matters, the situation in the Western Balkans and "mostly about Kosovo.""We concluded that it's necessary to avoid any possible act of provocation that could strain the situation in Kosovo."Vucic said he had believed Belgrade and Pristina could reach a direct agreement on the normalisation of Serbia-Kosovo relations. "Now I see it's also necessary to consider the interests of the European Union, Russia, the US, and that China must be notified about everything, which additionally complicates matters."Before the meeting, Vucic thanked Merkel by saying "there would have been more conflicts in the region" without her.He said that despite the announcement that itwould not attend an EU-Western Balkans summit in Sofia in May becauseKosovo representatives would, Serbia"will be present" at the event.Serbian interior minister claims situation in Kosovo "very serious"ZAGREB, April 13 (Hina) - The Serbian Minister of the Interior, Nebojsa Stefanovic, said on Friday during talks with UN officials in Belgrade, that the overall security situation in Kosovo was "very serious."Stefanovic met with the UNAssistant Secretary-General for Rule of Law and Security Institutions in the Department of Peacekeeping Operations, Alexander Zuev, and reiterated that Serbia's position was that the UNMIK mission was still absolutely necessary in Kosovo.Recalling that UNMIK was responsible for the rule of law and security, Stefanovic underscored that the murderof a Serbian policeman and leader of a civil initiative group, Oliver Ivanovic, has still not been solved.Zuev invited Stefanovic to attend a meeting of interior ministers at the UN headquarters in June, which will be chaired by UN Secretary-General Antonio Guterres.Tension between Belgrade and Pristina has been rising for more than two weeks after the head of the Serbian government's Kosovo office, Marko Djuric, was arrested and then expelled from Kosovo.Relations are further complicated by the fact that Belgrade is under constant pressure from the West and EU to resolve relations with Pristina as a precondition to progress on its path toward European integration as well as by Serbia's insistence that Pristina meet its commitments under the Brussels agreement to establish an associationof Serb municipalities in Kosovo.In other news:Croatia among EU countries with highest increases in industrial outputZAGREB, April 13(Hina) - Croatia was one of the three EU countries that saw the highest monthly increases in industrial production in February 2018, the other two countries being Latvia and the Netherlands, shows a report by the EU's statistical office Eurostat.Seasonally adjusted industrial output in the EU28 dropped in February by 0.7% from January, when it went down 0.3%.The decrease was due to production of capital goods falling by 2.7%, durable consumer goodsby 1.6% andintermediate goods by 1.0%. Production of energy roseby 5.1%.Industrial production in the euro area dropped by0.8% compared with January, when it went down by 0.6%.The February decrease was due to the production of capital goods falling by 3.6%, durable consumer goods by 2.1% andintermediate goods by 0.8%. Production of energy rose,by as much as 6.8%.Among member states for which data are available, the highest increases were registered in Latvia and the Netherlands (both +3.9%), and Croatia (+2.1%).The largest decreases in industrial production were registeredin Lithuania (-3.9%), Estonia (-2.7%), and Malta and Portugal (both -2.3%).Annual growth of industrial production slows downOn the year, industrial production in the EU28 rose 3.1%, after a 3.7% increase in January.The increase of 3.1% is due to production of energy rising by 4.6% andcapital goods by 3.2%.The increase of 2.9% in industrial production in the euro area in February 2018, compared with February 2017, is due to production of energy rising by 5.7%, intermediate goods by 2.9% andnon-durable consumer goods by 2.4%, said Eurostat.Among member states for which data are available, the highest increases in industrial production were registered in Latvia (+8.7%), Poland (+7.5%) and Slovenia (+7.2%). Decreases were observed in Malta (-7.7%), Greece (-1.9%) and Bulgaria (-1.0%), Eurostat said.Industrial production in Croatia in February 2018 was 3.3% higher than in February 2017, while in January it was 0.4% down on the year.ZSE indices continue downward movementZAGREB, April 13 (Hina) - The main Zagreb Stock Exchange (ZSE) indices on Friday fell to their lowest levels in the last 20 months.The Crobex had been falling for the third consecutive day, losing 0.35% to 1,782.45 points, its lowest level since 8 August 2016 when it closed at 1,780.90 points.The Crobex10 had been on the decline for four straight days, sliding by 0.35% to 1,033.69 points, its lowest level since 16 August 2016 when it ended at 1,032 points.Trading was marked by a low turnover, of merely 1.92 million. The most traded stock was that of Zagrebacka Banka, which turned over HRK 374,700. Its price rose by 1.38% to HRK 58.80 per share.(EUR 1 = HRK 7.421465)THIS BULLETIN INCLUDES ITEMS RELEASED BY 2100 HOURS FRIDAY. (Hina) vm Masthead Brief News Bulletin is published by the Croatian News Agency HINA Marulicev trg 1610 000 ZagrebCroatia web:[*www.hina.hr*](http://www.hina.hr) mail: [*hina@hina.hr*](mailto:hina@hina.hr) phone: (+385 1) 48 08 660; fax (+385 1) 48 08 822 Publisher: Branka Gabriela Valentic, DirectorEditor in Chief: Serdo Obratov Bulletin Editor: Marija Sestan

ZAGREB, April 13(Hina) - The Croatian parliament on Friday ratified the Council of EuropeConvention on preventing and combating violence against women and domestic violence, better known as theIstanbul Convention, with 110 votes in favour, 30 against and two abstentions.

ZAGREB, April 13(Hina) - The Croatian parliament on Friday ratified the Council of Europe Conventionon preventing and combating violence against women and domestic violence, better known as the Istanbul Convention, with 30 MPs voting against the ratification, including 14 deputies of the ruling HDZ party, while HDZ MP Ivan Suker abstainedand two other HDZ MPs, Bozo Ljubic and Zeljko Raguz, did not vote even though they attended the session.

ZAGREB, April 13(Hina) - Prime Minister Andrej Plenkovic said on Friday that the fact that parliament ratified the Istanbul Convention was good in terms of protection of women from violence and domestic violence, reiterating that the 17 MPs of his HDZ party who did not vote for the ratification would not be punished because they were free to express their will.

ZAGREB, April 13(Hina) - The head of the Social Democratic Party (SDP) parliamentary group, Arsen Bauk, said on Friday after a vote on the Istanbul Convention that the vote had confirmed his expectation that the Convention would be ratified with more than two-thirds majority support, which, he said, showed that the Croatian society had achieved a consensus of a constitutional character regarding the convention.

ZAGREB, April 13(Hina) -Council of Europe Secretary General Thorbjorn Jagland on Friday welcomed the ratification of the Istanbul Convention by the Croatian Parliament, calling it "excellent news".

ZAGREB, April 13(Hina) - The protest against the ratification of the Istanbul Convention that was held in Split on Thursdayevening drew 15,000 people, it was peaceful and no incidents were reported, Split-Dalmatia County Police chief Slobodan Marendic told a news conference on Friday.

ZAGREB, April 13(Hina) - During Friday's parliamentary debate on European Council conclusions presented by Prime Minister Andrej Plenkovic, Miro Bulj of the ***opposition*** Bridge party asked him when he would "start pursuing a sovereignist policy instead of being aBrussels clerk."

ZAGREB, April 13(Hina) - Prime Minister Andrej Plenkovic on Friday refuted media speculation that he had the ambition to take a senior position in the European Union.

ZAGREB, April 13 (Hina) - Croatian Prime Minister Andrej Plenkovic met in Zagreb on Friday withEuropean Commission Vice-President for Jobs, Growth, Investment and CompetitivenessJyrki Katainen, Commissioner for International Cooperation and Development Neven Mimica and Commissioner for the Security Union Julian King.

ZAGREB, April 13 (Hina) - President KolindaGrabar-Kitarovic on Friday receivedEuropean Commission Vice-President for Jobs, Growth, Investment and CompetitivenessJyrki Katainenand discussed structural reforms, the Juncker plan and European defence policy, the President's Office said in a press release.

ZAGREB, April 13(Hina) - Croatia's development policy and its complementarity with the goals and activities ofthe European Union's development and humanitarian policy were the topics of a meeting between Foreign Minister Marija Pejcinovic Buric and European International Cooperation and Development CommissionerNeven Mimica in Zagreb on Friday.

ZAGREB, April 13 (Hina) - After meeting with the European Commissioner for the Security Union, Julian King, in Zagreb on Friday, Interior Minister Davor Bozinovic said that Croatia would meet the technical criteriato enter the Schengen Area by the end of the year.

ZAGREB, April 13 (Hina) - Croatia and Canada are friends and partnerslooking forward to growing commercial ties, dedicated to advancing the fundamental values that theyshare, and facing the challenges of the future together, the two countries' ambassadors said in Zagreb on Friday.

ZAGREB, April 13 (Hina) - To ensure more successful use of the European Fund for ***Strategic*** Investments (EFSI), also known as the Juncker Plan, it is necessary to increase its visibility and improve the provision of information to end users, a conference was told in Zagreb on Friday.

ZAGREB, April 13(Hina) - The departure of Zoltan Aldott from the post of INA Management Board chair should not impact talks between the Croatian government and INA's other owner, the Hungarian oil company MOL,on the possible purchase of MOL's stake in INA by the government, Economy Minister Martina Dalic and Finance Minister Zdravko Maric said on Friday.

ZAGREB, April 13 (Hina) -Spinraza, a drugused in treating spinal muscular atrophy (SMA), will be put on the list of medicines provided by the Croatian Health Insurance Fund (HZZO) next week while clinical trials with this new medicine will begin in Zagreb's KBC Hospital on April 17 and will include 23 SMA patients, Health Minister Milan Kujundzic announced on Friday.

ZAGREB, April 13(Hina) - The Conflict of Interest Commission on Friday fined Josipa Rimanc (HDZ), state-secretary at the Ministry of Administration, HRK 4,000 for giving false information inher declarationof assets.

ZAGREB, April 13 (Hina) - The Crodux oil company, at a press conference in Zagreb on Friday, dismissed responsibility for water pollution in the eastern town of Slavonski Brod, saying it was not possible that the petrol spill could have reached water wells and water pipes 48 hours after a leak in the oil pipeline.

ZAGREB, April 13(Hina) - German Chancellor Angela Merkel said on Friday Serbia was playing a key role in resolving problems in the Western Balkans, while Serbian President AleksandarVucic said after visiting her that Serbia had Germany's full understanding andsupport on its European Union journey.

ZAGREB, April 13 (Hina) - The Serbian Minister of the Interior, Nebojsa Stefanovic, said on Friday during talks with UN officials in Belgrade, that the overall security situation in Kosovo was "very serious."

ZAGREB, April 13(Hina) - Croatia was one of the three EU countries that saw the highest monthly increases in industrial production in February 2018, the other two countries being Latvia and the Netherlands, shows a report by the EU's statistical office Eurostat.

ZAGREB, April 13 (Hina) - The main Zagreb Stock Exchange (ZSE) indices on Friday fell to their lowest levels in the last 20 months.

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[***Brand tribalism in technology and sport: determinants and outcomes***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:673K-K021-JCWX-C02X-00000-00&context=1516831)

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**Body**

Marketing success stems from robust brand relationships. Such consumer-brand rapport resembles that of an interpersonal relationship (Fournier ), characterized as distinctively engaging (Sprott et al. ), personality-laden (Aaker ), and peerlessly expressive (Brakus et al. ). Moreover, the relationships between consumers and their beloved brands have been regarded as brand communities (McAlexander et al. ; Muniz and O’Guinn ) and brand tribes (Cova and Cova ; Cova and Pace ; Taute and Sierra ), where these transitory (Goulding et al. ), heterogenous sub-tribes may be many within a community (Özbölük and Dursun ). For example, the Apple brand represents a brand community and iPhone, iPad, and iWatch users are brand tribes within this community. Among diverse marketplaces such as sports, technology, transportation, dog agility competitions, footwear, organic food, confectioneries, soft drinks, and apparel, consumers exhibit a penchant for brand community and tribe association; behavior in such circles includes inimitable rituals, brand appreciation, communal beliefs, and responsibility to the community and its members (e.g., Husemann et al. ; McAlexander et al. ; Muniz and O’Guinn ; Närvänen et al. ; Syrjälä ; Thomas et al. ).

Research has directed its attention more on the positive outcomes of brand communities and tribes and less on brand relationship attributes. In this regard, the data show that the nurturing of, and involvement with brand communities or tribes lead to beneficial outcomes for firms, including ideas for product innovation, brand advocacy, increased sales, new product adoption, word of mouth, brand loyalty, and consumer recruitment (Badrinarayanan et al. ; Gruner et al. ; Füller et al. ; Madupu and Cooley ). In the context of sports, such involvement produces ideas of collectivism and utopianism among community/tribe members, leading to self-realization through related consumption (Torchia ). Therefore, understanding consumer behavior in brand tribes is a profitable area of study for researchers of marketing (e.g., Gruner et al. ; Taute et al. ) and sports branding (Watkins ).

Not confined by geographic location, brand communities are unique social structures fixated on a brand (Muniz and O’Guinn ), evidenced by the World Series of Beer Pong (O’Sullivan ); these circles possess character and hierarchical features, while sharing symbols, language, responsibility, and rituals (Muniz and O’Guinn ; Schouten and McAlexander ; Relling et al. ). Brand communities have social structure, share a philosophy, and constitute a ubiquitous culture (Schouten and McAlexander ); they are identifiable through brand use, community engagement, social networking, and impression management (Black and Veloutsou ; Schau et al. ; Swenson ). Such communities have been identified in a range of contexts, including films (Kozinets ), politics (Black and Veloutsou ), war games (Cova et al. ), automobiles (McAlexander et al. ), bikers (Schouten and McAlexander ), and charity organizations (de la Peña et al. ).

In consumers’ everyday lives, the global importance of smartphones and sport fandom is well known, both of which lead to profitable outcomes for constituents. Akin to collegiate football fans (Taute et al. ), iPhone and Android users represent sundry social networks with a shared zeal for their venerated brands; thus, they are suitably classified as tribes (Dionisio et al. ; Taute and Sierra ). Further, tribe principles such as sustained brand admiration, shared knowledge and kinship, established traditions and rituals, and moral obligation to each other and the brand (Henry and Caldwell ) are palpable within these brand clusters; accordingly, self-fulfillment, self-expression, and shared experiences are experienced by smartphone and collegiate football tribe members (Cova and Cova ).

Even as collegiate football fans (Taute et al. ) and smartphone users have been categorized as brand tribes (Jurisic and Azevedo ; Taute and Sierra ), determinants and outcomes of such consumers’ brand tribalism warrants further inspection. For example, understanding community/tribe development and related influences of fan behavior is an important (Yoshida et al. ), yet under-researched (Watkins ) topic for sports marketers. Uncovering such paths will benefit (1) brand managers as they seek effective strategy implementation in growing their brand’s following and (2) marketing theorists in their efforts to develop explanatory frameworks and robust predictive models of consumer behavior. To help close this research gap and offer acuity to the brand tribalism literature, two studies are developed.

In a smartphone context, Study 1 conjectures that positive affect (PosAFF) antecedes both components of brand tribalism (i.e., defense of the tribal brand—DEFENSE and positive response toward the tribal brand—TribePOS). In turn, these tribe dimensions lead to individuals’ motivational need for power (NPOWER) and need for achievement (NACHIEVE). In a collegiate football context, Study 2 posits (PLEASURE–AROUSAL–DOMINANCE) emotional factors (i.e., the PAD framework) antecede both components of brand tribalism, which in turn influence brand pride (PRIDE). Subsequently, intentions to purchase team apparel (APPAREL) and attend games (ATTEND) are positively affected. In the following section, we review relevant literature to this research. Next, we outline the hypotheses, describe the data collection and analysis procedures, and report the results for Study 1 and Study 2. In closing, we discuss the findings, implications, study limitations, and directions for future research.

Background literature

Emotional response: positive affect and the PAD framework

Emotions are precursors, involved in, and outcomes of buyer behavior (MacInnis and de Mello ; Richins ). For example, both donors and recipients experience positive and negative emotions before, during, and after the gifting event (Ruth ). Researchers argue that all important decisions have emotional consequences (Elster ); in this vein, emotions inform decision making (Pham ; Schwarz and Clore , ) or alternatively, may interfere with or postpone decisions involving trade-offs (Luce et al. ). Arguments suggest that compared to cognition, affect is more effectual at predicting behavior (Allen et al. ). Consumers have been shown to use emotions in responding to advertising content (Taute et al. ), while other findings show the strengthening of brand relationships via emotional rather than factual advertising content (Heath et al. ). Further, consumers may scrutinize feelings for indicators as to whether to approach or avoid (Adaval ; Brehm et al. ; Pham ). Emotions too, have been examined as a discrete but continuous, multi-dimensional process (Havlena and Holbrook ). Mehrabian and Russell’s () seminal PAD (pleasure–arousal–dominance) framework is a fitting example. Here, emotional response includes pleasure (i.e., the valence of the felt emotion), arousal (i.e., the action-orientation of the emotion, where circumstance leads to experienced emotion), and dominance (i.e., the emotion’s control over a person’s thoughts and behaviors for the duration of the emotion).

Brand tribalism

Members of a brand tribe are fixed in a hearty emotional bond to such an entity, whether product or brand (Jurisic and Azevedo ). Importantly, brand tribes are differentiated from brand communities in that tribes (1) do not control consumers’ lives, (2) are playful rather than stanch, (3) are ephemeral, and (4) are entrepreneurial (Goulding et al. ). In the postmodern sense, the brand becomes venerated for its ability to fuse consumers with some sense of social hierarchy, thus a tribe (Cova ; Maffesoli ). The idiom ‘tribe’ therefore denotes a person’s return to the religious values of elfin bucolic communities, a collective value system, a sense of fitting in, and an ethnocentric perspective of us versus them (Cova ; Cova and Cova ). With dyadic communication and emotional exchange as central components of the brand tribal relationship (Veloutsou ), tribal consumption is based more on social connecting, hedonic-based value than utilitarian equity (Cova and Cova ). To illustrate, online social network influence and a predilection for interpersonal influence antecede brand tribalism; beguilingly, consumers may in fact show more loyalty to the tribe they belong to than the brand it represents (Ruane and Wallace ).

Motivational needs: power and achievement

McClelland’s () seminal work on motivational influences, including need for achievement, has been examined in organizational behavior and marketing contexts. Together, need for power and need for achievement relate positively to successful political behaviors, including organizational politics (Liu et al. ) and innovative managerial practices (Kunz and Linder ). Within organizations, need for achievement and need power influence group composition with respect to task conflict and status conflict, respectively (Chun and Choi ). Notably, researchers continue to call for empirical query on the need for power and the need for achievement, in relation to consumer behavior (e.g., Schroth and McCormack ; Zou et al. ) and, a lack of research exploring the interdependency of motivational needs continues (Schroth ). Furthering these areas of study and heeding such research calls, the current research posits that consumers pursue brand tribe membership in furtherance of their motivational needs, specifically need for power and need for achievement; these literatures are succinctly reviewed.

Need for power

With an emphasis on prestige and status attainment (Winter ), individuals with a need for power are motivated by the potential to influence affairs (Schoemaker ). In the management literature, employees’ need for power is boosted by a charismatic leader’s empowerment practices (Choi ). Individuals with high need for power display greater political skill when they exhibited strong collective identity or orientation toward others rather than pursuit of self-gain (Randel and Wu ). Also, bureaucratic culture mixed with high need for power positively influences job satisfaction and involvement, and negatively affects penchant to leave, whereas innovative culture amalgamated with high need for achievement positively affects job satisfaction and inversely influences proclivity to leave (Koberg and Chusmir ). Linked to marketing, Chinese consumers’ need for power relates positively to uniqueness seeking in the marketplace (Zou et al. ), while intention to use applications associated with human computation games is directly influenced by users’ need for achievement and need for power (Goh and Lee ).

Need for achievement

Considered self-regulatory in the pursuit of goal attainment or failure avoidance (Elliot and Church ), need for achievement is related to workplace commitment and improved performance (McHenry et al. ; Steers and Spencer ). Further, reasoned by McClelland () as ardently planning for the future, not giving up, and generating economic success, need for achievement helps explain admirable work ethic (Hon and Rensvold ), graded accomplishment in the classroom (Elliot and Church ), and entrepreneurial achievement (Babalola ). McClelland and Burnham () propose managers’ high need for achievement may in fact be counterproductive to organizational goals. Researchers have also maintained that promising entrepreneurs require a high need for achievement to be successful (Zhao and Wu ). For computer operating systems and smartphones, need for achievement correlates positively with brand attitude and resulting purchase intentions (Taute et al. ). Enigmatically, Amyx and Alford () found that salespersons’ need for achievement improves performance but does not necessarily lead to organization loyalty. Along this counterintuitive sense, House, Spangler and Woycke () show that need for achievement relates inversely to U.S. Presidential charisma, direct action, and performance in international relations. Additional findings suggest that subordinates low in need for achievement fancy supportive leadership roles, while those high in need for achievement favor prominent leadership roles (Mathieu ).

Study 1 hypotheses

Positive affect and brand tribalism

Ardent brand relationships have been expressed as communities or tribes (Cova ), where community or tribe formation stems from an emotional bond to the brand (Jurisic and Azevedo ). Brand tribes are supportive of their members (Luedicke and Giesler ) and are united through shared interpersonal and social experiences (Cova ), palpable with a group of smartphone brand users assembled at a storefront waiting for the release of a new device. Sahlins () offers an anthropological view of tribalism consisting of segmentary lineage (kinship binding tribe members together), social structure (tribe members’ perceived sense of unison), sense of community (tribe members’ ability to harmonically coexist), and defense of the tribe (tribe members’ emotionally charged enmity toward opposing tribes). As being a smartphone user/owner is likely to make consumers feel good about being a member of this brand community, we focus on the favorable emotive aspects of brand tribalism (i.e., positive response toward the tribal brand), namely segmentary lineage, social structure, and sense of community; and as such, users are likely to be protective of their technological brand, we therefore, investigate defense of the tribal brand (Taute and Sierra ; Taute et al. ). Because brand relationships are augmented through favorable affect (Heath et al. ; Taute et al. ) and positive emotions help drive consumers’ brand approach behaviors (Adaval ; Brehm et al. ), we posit that favorable emotional responses toward a smartphone brand will have a direct positive influence on both dimensions of brand tribalism. Thus,

Positive affect toward users’ smartphone relates positively to defense of the tribal brand

Positive affect toward users’ smartphone relates positively to positive response toward the tribal brand

Brand tribalism and motivational needs

Behaviorally and attitudinally, employees and consumers are shaped by their motivational needs (Jones et al. ; Kerr and Das ; Mathieu ; McClelland and Burnham ; Orth and Gal ). Specifically, innovative managerial practices are impacted by the need for power (Kunz and Linder ) and for consumers, need for power relates positively to uniqueness seeking in the marketplace (Zou et al. ). Along these lines, for South Korean smartphone consumers, need for achievement is shown as a positive correlate and outcome of purchase intent (Sierra et al. ). Also, the need for achievement influences workplace performance and commitment (McHenry et al. ; Steers and Spencer ) and affects employee and consumer behavior in diverse sales and purchase contexts (Amyx and Alford ; Babalola ; Elliot and Church ).

Being part of a brand tribe is valued by consumers, as is the pursuit and attainment of motivational needs. In this regard, research shows a direct relationship between social contribution and need for power (Ruf and Chusmir ) and orientation toward others, as evidenced in the social structure and sense of community components of brand tribalism, mixed with a high need for power produces robust political skill (Randel and Wu ); such tribe involvement and its link to motivational needs warrants exploration. Additionally, and as supported by Michaelidou () where motivational needs relate well with each other and, where need for achievement relates positively to power dimensions such as status, professional fulfillment, and contribution to society (Parker and Chusmir ; Ruf and Chusmir ), we surmise a positive correlation between the need for achievement and the need for power. In this sense, those motivated by life achievement are apt to seek power positions and their associated benefits. Thus, the following hypotheses are tested:

Defense of the tribal brand relates positively to need for power

Defense of the tribal brand relates positively to need for achievement

Positive response toward the tribal brand relates positively to need for power

Positive response toward the tribal brand relates positively to need for achievement

Need for achievement relates positively to need for power

Methodology

Scale descriptions

The questionnaire contained tailored items from five, seven-point rating scales: positive affect (PosAFF; 9 items), defense of the tribal brand (DEFENSE; 6 items), positive response toward the tribal brand (TribePOS; 10 items), need for power (NPOWER; 4 items), and need for achievement (NACHIEVE; 5 items). Each of these scale sources is noted; complete scale items are provided in the "".

Positive affect was assessed with items from the PANAS scale (Watson et al. ). To evaluate the positive (i.e., segmentary lineage, social structure, and sense of community) and negative (i.e., defense of the tribal brand) affect-laden components of brand tribalism, items developed in Taute and Sierra () were employed as a two-factor solution. Lastly, need for power and need for achievement were evaluated with items adapted from Steers and Braunstein’s () Manifest Needs Questionnaire.

Data collection procedure

Undergraduate students at a southwestern U.S. university completed the questionnaire during a regularly scheduled class session. This consumer-type has been used as study participants in previous smartphone brand tribalism research (e.g., Taute et al. ); thus, they were employed here. While maintaining response anonymity, respondents were first asked to indicate their smartphone, how long they have owned/used this phone, and subsequently, to respond to rating-scaled statements regarding this hand-held device.

Sample profile

The mean age of study participants (N = 190) is 21.63 years (SD = 1.60), with women (55%) outnumbering men. Sixty-five percent of the sample is employed, working an average of 28.64 h (SD = 9.54) per week. Regarding ethnicity, Whites (60%), Hispanics (28%), and Blacks (7%) are most represented. In terms of their smartphone, iPhone (74%) and Droid (23%) are noted most by respondents, with an average of 4.49 years (SD = 1.98) of ownership.

Results

Common method bias

To curb common method bias (CMB), surveys with uncommon acquiescence bias were ***deleted*** and item intermixing was avoided (Podsakoff et al. ). Furthermore, Harman’s single-factor test was used to assess CMB. The unrotated EFA solution (for PCA and MLE) reveals a multi-factor solution and a first-factor explained variance of 34.87%; these data, along with low intra-respondent variance (Hyman and Sierra ), suggest CMB was not problematic.

Data pooling

Independent samples t tests were run to examine mean scores for iPhone (N = 141) and Droid (N = 44) users for each item used to measure the studied constructs. Aside from four items (i.e., SOCIAL2 − MiPhone = 3.71, MDROID = 4.44, t = 2.55; DEFENSE2 − MiPhone = 3.16, MDROID = 3.81, t = 2.01; DEFENSE9 − MiPhone = 3.48, MDROID = 4.25, t = 2.45, and PosAFF5 − MiPhone = 4.73, MDROID = 5.29, t = 1.98), results indicate non-significant mean differences at the P < 0.05 level for each item; thus, the data were pooled for analysis.

Factor structure

A measurement model was estimated with LISREL 9.20 and the 34 items comprising the five scales. Average variance extracted (AVE) for each construct exceeds 0.50 (see Table ), providing evidence for convergent validity; also, AVE for the constructs is greater than the squared correlations between each construct and the other constructs, aside from DEFENSE and PosAFF (Phi2 = 0.7396), offering evidence for discriminant validity (Fornell and Larcker ). Estimation of the measurement model produced the following GOF statistics: χ2(517df) = 1989.08 (P = 0.00), CFI = 0.90, RMSEA = 0.123, and SRMR = 0.071.

Measurement model results (Study 1)

| **Construct** | **Indicators** | **Standardized loading (*?*)** | **Reliability** | **AVE** |
| --- | --- | --- | --- | --- |
| Positive affect | POSAFF1 | 0.8 | 0.948 | 0.721 |
| POSAFF2 | 0.8 |  |  |  |
| POSAFF3 | 0.86 |  |  |  |
| POSAFF4 | 0.86 |  |  |  |
| POSAFF5 | 0.87 |  |  |  |
| POSAFF6 | 0.89 |  |  |  |
| POSAFF7 | 0.85 |  |  |  |
| POSAFF8 | 0.88 |  |  |  |
| POSAFF9 | 0.83 |  |  |  |
| Defense of the tribal brand | DEFENSE1 | 0.8 | 0.911 | 0.663 |
| DEFENSE2 | 0.85 |  |  |  |
| DEFENSE3 | 0.72 |  |  |  |
| DEFENSE4 | 0.87 |  |  |  |
| DEFENSE5 | 0.83 |  |  |  |
| DEFENSE6 | 0.81 |  |  |  |
| Positive response toward the tribal brand | TRIBEPOS1 | 0.6 | 0.921 | 0.574 |
| TRIBEPOS2 | 0.56 |  |  |  |
| TRIBEPOS3 | 0.66 |  |  |  |
| TRIBEPOS4 | 0.55 |  |  |  |
| TRIBEPOS5 | 0.77 |  |  |  |
| TRIBEPOS6 | 0.81 |  |  |  |
| TRIBEPOS7 | 0.83 |  |  |  |
| TRIBEPOS8 | 0.89 |  |  |  |
| TRIBEPOS9 | 0.87 |  |  |  |
| TRIBEPOS10 | 0.92 |  |  |  |
| Need for power | NPOWER1 | 0.69 | 0.885 | 0.726 |
| NPOWER2 | 0.92 |  |  |  |
| NPOWER3 | 0.89 |  |  |  |
| NPOWER4 | 0.89 |  |  |  |
| Need for achievement | NACHIEVE1 | 0.82 | 0.882 | 0.625 |
| NACHIEVE2 | 0.82 |  |  |  |
| NACHIEVE3 | 0.74 |  |  |  |
| NACHEIVE4 | 0.81 |  |  |  |
| NACHIEVE5 | 0.76 |  |  |  |

Structural equation model

The relationships displayed in Fig.  were tested using a structural equation model with LISREL 9.20. A COV matrix and MLE were used to estimate model parameters. Missing data were handled via pairwise ***deletion***. Two additional parameters that are consistent with the measurement theory and capture significant error covariance between items within the PosAFF factor, beyond that explained by the common factor, are included in the model. Model estimation produced the following GOF statistics: χ2(518df) = 1889.51 (P = 0.00), CFI = 0.90, RMSEA = 0.118, and SRMR = 0.14. Although these fit indices are subpar (Hu and Bentler ), the statistical power associated with the RMSEA statistic approximates 1.0, so the goodness-of-fit statistics are assumed conservative (McQuitty ).

Path model (Study 1). Note In the parentheses, the t statistic is provided. The underlined t statistic is statistically significant but ***opposite*** the predicted direction. \*Not significant at the P < 0.05 level (dashed line). \*\*Significant at the P < 0.05 level. \*\*\*Significant at the P < 0.01 level

The path coefficients (PC) are used to evaluate the posited relationships. The t statistic associated with six of the seven PC is significant at the P < 0.05 level or better (see Fig. ). Specifically, PosAFF relates positively to DEFENSE (H1; PC = 0.54, t = 7.02) and TribePOS (H2; PC = 0.57, t = 6.40). In turn, DEFENSE relates positively to NPOWER (H3; PC = 0.26, t = 3.55) and negatively to NACHIEVE (H4; PC = −0.18, t = −2.21), while TribePOS is unrelated to NPOWER (H5; PC = −0.09, t = −1.35), but positively affects NACHIEVE (H6; PC = 0.19, t = 2.24). Lastly, NACHIEVE relates positively to NPOWER (H7; PC = 0.65, t = 7.30).

Study 2 hypotheses

PAD emotional dimensions and brand tribalism

Whether at the venue or viewing from afar, fans readily experience emotions before, during, and after sporting events (e.g., Goldstein and Iso-Ahola ; Jun Woo et al. ; Raynaud and Bolos ). Such emotions influence fans’ attitudinal and behavioral responses toward the team and/or sport brand (e.g., Swanson et al. ). In harmony with Holbrook et al. (), the PAD three-dimensional (pleasure–arousal–dominance) measure of emotions (Mehrabian and Russell ) may help explain fans’ brand-response behaviors. Illustratively, emotions linked to pleasure (e.g., admiring a favorite team), arousal (e.g., being excited during a favorite team’s season), and dominance (e.g., being emotionally influenced by a rival game approaching) spark team-based brand tribalism. Here, a sense of community among fellow fans, responsibility in defending the adored team, and a strengthening of the bond shared among zealous aficionados, to name a few, are ever-present among passionate enthusiasts. Therefore, with the following set of hypotheses, we examine each of the three PAD emotional dimensions as antecedents of collegiate football fans’ brand tribalism toward their favorite team:

Fans’ pleasure emotional response toward their favorite team relates positively to defense of the tribal brand.

Fans’ pleasure emotional response toward their favorite team relates positively to positive response toward the tribal brand.

Fans’ arousal emotional response toward their favorite team relates positively to defense of the tribal brand.

Fans’ arousal emotional response toward their favorite team relates positively to positive response toward the tribal brand.

Fans’ dominance emotional response toward their favorite team relates positively to defense of the tribal brand.

Fans’ dominance emotional response toward their favorite team relates positively to positive response toward the tribal brand.

Brand tribalism and brand pride

Defined as experienced pleasure of being associated with a brand (Helm et al. ), brand pride is conceptually linked to brand tribalism, as contagious pride (i.e., collective-expression), vicarious pride (i.e., creation of the collective self), conspicuous pride (i.e., self-expression), and introspective pride (i.e., creation of the individual self) are unremittingly paraded in such brand circles (Decrop and Derbaix ). These brand pride elements are on display among fans at sporting events, especially across collegiate football venues on gameday. Although considered a significant influencer of consumer behavior, determinants and outcomes of brand pride have been under-examined in marketing (Decrop and Derbaix ; Taute et al. ). Of value here, understanding factors that bolster fans’ team-related brand pride is an important topic for sports marketers (Chang et al. ).

There is pride in being a fan of a collegiate football team, which brand tribalism components (e.g., sense of community, defense of the tribal brand) may intensify. In general, the literature related to brand tribalism reveals favorable pecuniary outcomes of brand tribe membership. For example, such affiliation increases purchase intentions and brand value (Bagozzi and Dholakia ; Schau et al. ). Brand tribe elements also boost consumers’/fans’ pride in their beloved brand (Decrop and Derbaix ). As Helm et al. () found, brand identification, which is linked to defense of the tribal brand, relates positively to brand pride. Also, brand love, captured within the brand pride measure (Taute et al. ), is explained by sense of community, affective brand experience, and brand identification (Albert and Merunka ; Batra et al. ; Bergkvist and Bech-Larsen ). Accordingly, the two dimensions of brand tribalism measured in this research are modeled as determinants of brand pride with the following hypotheses:

Defense of the tribal brand relates positively to fan’s brand pride toward their favorite team.

Positive response toward the tribal brand relates positively to fans’ brand pride toward their favorite team.

Brand pride and purchase intentions

As the brand literature indicates, the relationship between consumers and their adored brands produces favorable marketing outcomes; and, it is brand pride that helps explain the connection between consumer identification with the brand and consumers’ personal connection to the brand (Taute et al. ), producing long-standing, robust consumer-brand relationships. Accordingly, brand pride and brand image prestige relate positively (Bellezza and Keinan ). Regarding favorable outcomes, brand pride is linked to positive word-of-mouth, intent to buy, and customer loyalty (Holt ; Soscia ). Germane to the context here, brand importance, evident in brand pride, positively influences game/team-related purchase intentions (Yoshida et al. ). Furthermore, parasocial or interpersonal brand love leads to brand commitment, brand loyalty, and favorable word-of-mouth (Carroll and Ahuvia ; Fetscherin ; Thomson et al. ). Thus, sport team-related brand pride should relate positively to behavioral intentions of the esteemed brand, which we test with the following:

Fans’ brand pride toward their favorite team relates positively to their intention to buy this team’s apparel.

Fans’ brand pride toward their favorite team relates positively to their intention to attend this team’s games.

Methodology

Scale descriptions

The questionnaire contained tailored items from eight, seven-point rating scales: PAD framework [(PLEASURE; 8 items), (AROUSAL; 4 items), and (DOMINANCE; 4 items)], defense of the tribal brand (DEFENSE; 6 items), positive response toward the tribal brand (TribePOS; 10 items), brand pride (PRIDE; 4 items), intention to purchase team apparel (APPAREL; 5 items), and intention to attend games (ATTEND; 5 items). Each of these scale sources is noted; complete scale items are provided in the "".

A 16-item, three-dimensional scale was used to measure the emotions (i.e., pleasure–arousal–dominance) in the PAD framework (Mehrabian and Russell ). To assess pleasure, respondents were asked to indicate how they feel toward their favorite collegiate football team (e.g., annoyed/pleased). For arousal, respondents were asked to indicate the level of intensity they feel toward their favorite collegiate football team (e.g., sluggish/frenzied). For dominance, respondents were asked to indicate the level in which their emotions control their thoughts and/or behaviors about their favorite collegiate football team (e.g., guided/autonomous). Further, the items in Study 1 used to measure brand tribalism, were employed. Brand pride was assessed with the scale in Taute et al. (), while intention to purchase team apparel and intention to attend games were measured with items borrowed from Holmes and Crocker () and MacKenzie, Lutz and Belch ().

Data collection procedure

With collegiate football passion unrivaled in the region, students enrolled in marketing courses at a southwestern U.S. university were recruited to complete a questionnaire during regularly scheduled classes. Initially, respondents were asked to indicate their favorite collegiate football team and when this team became their favorite. Subsequently, participants replied to rating-scaled statements pertaining to this team.

Sample profile

The mean age of the sample (N = 188) is 22.71 (SD = 4.06), with men (65%) outnumbering women. A range of ethnicities (i.e., 73% White, 21% Hispanic, and 5% Black) and class levels (i.e., 56% senior, 25% junior, and 14% MBA) are represented. Regarding the favorite team noted, Texas (31%), Texas State (21%), Texas A&M (12%), Oregon (4%), Alabama (4%), and Louisiana State (2%) comprise the bulk of the sample; respondents indicated 9.44 (SD = 6.81) mean years of revering their team.

Results

Common method bias

Study 1’s methods to curtail CMB were reused. Again, CMB was assessed with Harman’s single-factor test. The unrotated (PCA and MLE) EFA showed a multi-factor solution and a first-factor explained variance of 37.12%; these data along with low intra-respondent variance (Hyman and Sierra ) indicate CMB was not an issue.

Factor structure

A measurement model was estimated with LISREL 9.20 and the 46 items comprising the eight scales. Aside from TribePOS (0.41), AVE for each construct exceeds 0.50 (see Table ); also, AVE for majority of constructs is greater than the squared correlations between each construct and the other constructs. Estimation of the measurement model produced the following GOF statistics: χ2(961df) = 1656.95 (P = 0.00), CFI = 0.892, RMSEA = 0.063, and SRMR = 0.061.

Measurement model results (Study 2)

| **Construct** | **Indicators** | **Standardized loading (?)** | **Reliability** | **AVE** |
| --- | --- | --- | --- | --- |
| Pleasure | PLEASURE1 | 0.76 | 0.943 | 0.681 |
| PLEASURE2 | 0.7 |  |  |  |
| PLEASURE3 | 0.91 |  |  |  |
| PLEASURE4 | 0.91 |  |  |  |
| PLEASURE5 | 0.88 |  |  |  |
| PLEASURE6 | 0.84 |  |  |  |
| PLEASURE7 | 0.79 |  |  |  |
| PLEASURE8 | 0.79 |  |  |  |
| Arousal | AROUSAL1 | 0.8 | 0.894 | 0.695 |
| AROUSAL2 | 0.91 |  |  |  |
| AROUSAL3 | 0.91 |  |  |  |
| AROUSAL4 | 0.69 |  |  |  |
| Dominance | DOMIN1 | 0.81 | 0.87 | 0.64 |
| DOMIN2 | 0.76 |  |  |  |
| DOMIN3 | 0.78 |  |  |  |
| DOMIN4 | 0.84 |  |  |  |
| Defense of the tribal brand | DEFENSE1 | 0.7 | 0.886 | 0.573 |
| DEFENSE2 | 0.81 |  |  |  |
| DEFENSE3 | 0.69 |  |  |  |
| DEFENSE4 | 0.85 |  |  |  |
| DEFENSE5 | 0.75 |  |  |  |
| DEFENSE6 | 0.73 |  |  |  |
| Positive response toward the tribal brand | TRIBEPOS1 | 0.46 | 0.873 | 0.408 |
| TRIBEPOS2 | 0.57 |  |  |  |
| TRIBEPOS3 | 0.65 |  |  |  |
| TRIBEPOS4 | 0.48 |  |  |  |
| TRIBEPOS5 | 0.77 |  |  |  |
| TRIBEPOS6 | 0.74 |  |  |  |
| TRIBEPOS7 | 0.72 |  |  |  |
| TRIBEPOS8 | 0.69 |  |  |  |
| TRIBEPOS9 | 0.55 |  |  |  |
| TRIBEPOS10 | 0.68 |  |  |  |
| Brand pride | PRIDE1 | 0.81 | 0.841 | 0.593 |
| PRIDE2 | 0.69 |  |  |  |
| PRIDE3 | 0.8 |  |  |  |
| PRIDE4 | 0.77 |  |  |  |
| Intention to purchase team apparel | APPAREL1 | 0.91 | 0.965 | 0.846 |
| APPAREL2 | 0.96 |  |  |  |
| APPAREL3 | 0.96 |  |  |  |
| APPAREL4 | 0.88 |  |  |  |
| APPAREL5 | 0.89 |  |  |  |
| Intention to attend games | ATTEND1 | 0.86 | 0.933 | 0.744 |
| ATTEND2 | 0.92 |  |  |  |
| ATTEND3 | 0.92 |  |  |  |
| ATTEND4 | 0.82 |  |  |  |
| ATTEND5 | 0.78 |  |  |  |

Structure equation model

The relationships displayed in Fig.  were tested using structural equations modeling with LISREL 9.20. A COV matrix and MLE were used to estimate model parameters. Missing data were handled via pairwise ***deletion***. Model estimation produced the following GOF statistics: χ2(976df) = 1815.70 (P = 0.00), CFI = 0.869, RMSEA = 0.069, and SRMR = 0.089.

Path model (Study 2). Note: In the parentheses, the t statistic is provided. The underlined t statistic is statistically significant but ***opposite*** the predicted direction. \*Not significant at the P < 0.05 level (dashed line). \*\*\*Significant at the P < 0.01 level

The path coefficients (PC) are used to evaluate the posited relationships. The t statistic associated with six of the ten PC is significant at the P < 0.05 level or better (see Fig. ). Specifically, PLEASURE relates inversely to DEFENSE (H1; PC = −0.29, t = −3.19) and is unrelated to TribePOS (H2; PC = −0.08, t = −0.93); AROUSAL relates positively to both DEFENSE (H3; PC = 0.85, t = 6.84) and TribePOS (H4; PC = 0.81, t = 5.01); and, DOMINANCE is unrelated to both DEFENSE (H5; PC = 0.12, t = 1.57) and TribePOS (H6; PC = −0.01, t = −0.18). In turn, DEFENSE is unrelated to PRIDE (H7; PC = 0.11, t = 1.58), while TribePOS relates positively to PRIDE (H8; PC = 0.78, t = 5.48). Subsequently, PRIDE relates positively to both APPAREL (H9; PC = 0.77, t = 10.20) and ATTEND (H10; PC = 0.66, t = 8.50).

Discussion and implications

Across sundry settings, belonging to a brand tribe(s) is an aspect of consumers’ lives that they cherish, are proud of, boosts self-worth, and contributes to identity construction (e.g., Badrinarayanan et al. ; Sierra et al. ; Taute et al. ). Therefore, exhaustively investigating determinants and outcomes of brand tribalism is of value to marketing methodologists and practitioners. As these paths are not fully known, two studies using pooled, multi-brand data were developed to help advance knowledge in this milieu. Using a smartphone context, Study 1 suggests that emotions antecede brand tribalism dimensions, which in turn, influence consumers’ motivational needs. Specifically, the positive affect associated smartphone ownership relates positively to both components of brand tribalism (i.e., defense of the tribal brand and positive response toward the tribal brand). Subsequently, defense of the tribal brand relates positively to need for power, while positive response toward the tribal brand positively influences need for achievement. Beguilingly, Study 1 proffers that being a member of a brand tribe is but a platform in the development and progression of the motivational need for power and need for achievement. Additionally, the data suggest that consumer’s need for achievement and need for power relate positively.

As motivational needs are paramount in consumer’ lives, brand managers can use these data to help satisfy such needs via the formation of brand tribes within brand communities. For example, strategies may lean on social media to drive the creation of brand tribes through contests, live feeds, and/or special events, to name few. As brand enthusiasts follow and share such content, brand tribes within this brand community will bourgeon accordingly. In doing so, consumers will find their motivational needs being met through brand tribalism (i.e., defending the tribe, responding positively toward the tribe), leading to economic favor for related constituents.

Using a collegiate football setting, Study 2 models the PAD framework’s emotional components as brand tribalism antecedents. The data indicate that pleasure and defense of the tribal brand relate inversely and, arousal relates positively to both defense of the tribal brand and positive response toward the tribal brand. Therefore, brand managers, seeking to grow their brand’s tribal following should emphasize heightened states of elation in their communicative efforts, evident in arousal emotions; such ploys are seen in print images and interactive ads for casino visits, family vacations, and sporting events. Also, to increase brand defense behavior among tribe members, strategists should stress important upcoming dates and events, as these tend to dominate consumers’ thoughts and behaviors (e.g., rivalry week in sports, Black Friday shopping sprees, monumental occasions like weddings or turning 40 years old).

Study 2 also reveals a positive relationship between positive response toward the tribal brand and brand pride; thus, to boost pride in product ownership, brand strategies and advertising communications should emphasize segmentary lineage, social consensus, and sense of community aspects of brand tribalism more so than defense of the tribal brand elements. These findings resemble that of other brand tribalism research where the positive response elements of brand tribalism explain more variance in brand pride than defense of the tribal brand (Sierra et al. ). In turn the data show that strengthening brand pride generates a positive effect on sport-related purchase intentions for both goods (i.e., apparel) and services (i.e., attending games).

Overall, the results here provide acumen about smartphone users’ and collegiate football fans’ brand-related emotive and cognitive responses and the role these factors play in influencing motivational needs and purchase intentions, respectively. As such, effect size benchmarks for this sequential process, across two diverse settings, are established, which help facilitate research stream growth and theoretical understanding (Peterson and Jolibert ). Brand managers and consumer behavior researchers thereby profit, as online/offline brand tribal-based choice models can be readily compared, leading to productive strategies to increase firms’ brand tribe membership and to offer more lucid methodological roadmaps to investigate determinants and outcomes of brand tribalism.

Illustratively, as Study 1 indicates, defense of the tribal brand has a positive effect on need for power; thus, marketers may opt to pursue more rivalry-based (i.e., “us” versus “them”) advertising campaigns, especially when linking brand tribe membership with life motivations such as power or dominant roles. These ***strategic*** ploys are evident in contemporary communicative efforts regarding Google Pixel versus iPhone. This campaign suggests a decayed stigma associated with iPhone, while Pixel is depicted as the innovative, more versatile technology, suggesting a sense of power or dominance in owning a Pixel. Further, positive response toward the tribal brand relates positively to need for achievement; as such, marketers should pursue life achievement campaigns for example, whereby being a member of a brand tribe helps in attaining such goals, seen readily in automobile and education promotional materials.

Limitations and future research directions

Our research is not without limitations. For example, the data used to explain determinants and outcomes of brand tribalism were collected from U.S. southwest consumers focusing on a specific technology or sport. To help ascertain external validity of the results, additional data from ***geographically*** spread, diverse samples, across technology and sport contexts are warranted (Winer ). Further, the scales used to evaluate the model constructs may not be equally valid across brand tribal settings, which may shape their measurement properties and interrelationships.

Future investigation may use causal and/or interpretive methods to explain determinants and outcomes of brand tribalism; in doing so, attitudinal-based constructs could be explored including brand involvement, brand love, brand hate, need for cognition, self-esteem, brand loyalty, and schadenfreude directed at rival brands. As brand tribes within brand communities lack homogeneity, segmentation strategies must be modified appropriately (Özbölük and Dursun ); thus, brand tribalism differences between demographic factors such income categories or ethnic groups necessitate examination. The situational context may provide an insightfully robust research platform for longitudinal inquiry. For example, while at community events (e.g., professional sports, brand conventions, and cause-related rallies) versus non-event days, tribe members could be questioned to inspect if differences exist in their tribal tendencies, thereby offering marketers a clearer path to strategy success via opportune implementation of promotional materials.

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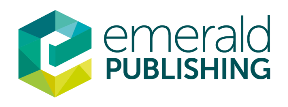


[***Acquirer-to-target relatedness and target country unfamiliarity in acquisitions***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5V6X-0HW1-JB00-310G-00000-00&context=1516831)

Management Decision

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**Body**

**ABSTRACT**

Purpose

The purpose of this paper is to analyze corporate scope decisions in acquisitions with a focus on the relationship between target country unfamiliarity and acquirer-to-target relatedness and on the moderating effects played by product diversification and international experience.

Design/methodology/approach

Using a dataset of 689 acquisitions completed in the period 2007-2013 by acquirers located in 60 countries, this paper utilizes an ordered logistic regression analysis.

Findings

With greater target country unfamiliarity, acquirers are encouraged to pursue greater acquirer-to-target relatedness. This finding suggests that acquirers tend to seek a balance between product and international diversification to reduce the sources of uncertainty in their acquisition moves. While past international experience strengthens this relationship, diversification experience has a negative moderating effect and hence encourages acquirers to reduce relatedness at increasing market unfamiliarity.

Originality/value

The originality of this paper is twofold. First, the authors extend the traditional internationalization-diversification framework to an unfamiliarity-relatedness relationship in the context of acquisitions. Second, the authors propose a construct of target country unfamiliarity in acquisitions that goes beyond the traditional domestic vs cross-border dichotomy by including previous experience in the target country.

**Introduction**

International and product diversification represent key ***strategic*** decisions for corporate scope growth (Hitt et al., 1994; Qian, 2002; Chang and Wang, 2007; Kumar, 2009; Mayer et al., 2015) that over years have raised increasing academic interest. With an extensive body of literature converging upon the factors that influence a firm’s scope expansion along each of these two directions separately, extant research has gradually shifted the focus on their interrelationship, examining both their joint impact on firm performance (e.g. Sambharya, 1995; Hitt et al., 1997; Lampel and Giachetti, 2013) and their antecedents (e.g. Kumar, 2009; Hashai and Delios, 2012; Mayer et al., 2015), with substantially mixed findings on whether they represent substitute or complementary growth strategies.

Empirical evidence on the relationship between international diversification and product diversification is controversial and reveals complex and multifaceted interlinkages (Kling et al., 2014). Due to constraints deriving from the limited stock of available resources (Wiersema and Bowen, 2008; Levinthal and Wu, 2010), hampered transfer of knowledge (Kumar, 2009), along with managerial complexity and increased governance costs (Penrose, 1959; Teece, 1982), international and product diversification may represent mutually exclusive development paths. Observing a sample of 1,299 firms in the period 1993-1997, Kumar (2009) tests competing hypotheses and identifies a negative association between the two trajectories of growth. Indeed, both product diversification and internationalization have traditionally been considered as expressions of explorative behavior (Lavie et al., 2010). Because firms feel more comfortable when acting within the boundaries of what they already know (Nohria and Garcia-Pont, 1991), they may pursue “alternative forms of balance” (Lavie and Rosenkopf, 2006, p. 84) by counterbalancing unfamiliarity in one dimension of growth with familiarity in the other. However, both the resource-based view and transaction cost economics theories propose that these two directions of corporate scope expansion share similar underlying mechanisms and may hence be complementary (Hitt et al., 1997, 2006; Buckley and Casson, 2009). Indeed, although in the short-term coordination costs may possibly outweigh the benefits of expanding along both market and product scope simultaneously, concurrent growth may eventually occur motivated by the pursuit of scope economies and catalyzed by firm-level factors (Hitt et al., 1997; Geringer et al., 2000), including prior experience (Mayer et al., 2015). Extending the analysis by Kumar (2009), Mayer et al. (2015) have recently found evidence of simultaneous growth for firms with a high product diversification, while a mutually exclusive growth is observed in those firms having low levels of product diversification.

***Strategic*** management research extensively supports the view that acquisitions are the prevalent mode of product diversification and foreign market entry, especially when departing from current products and markets (Chang and Rosenzweig, 2001; Lee and Lieberman, 2010; Kling et al., 2014), because theoretically there are nearly no constraints to the extent to which resources to be acquired can differ from existing ones (Krishnan et al., 2004; Eschen and Bresser, 2005). Despite this flexibility, the integration of new resources poses challenges: the greater the divergence among resources to be combined, the more the pitfalls that the acquiring firm may encounter. However, little attention has been placed on the specificities of the product diversification – internationalization link when these strategies are implemented through acquisitions, a context in which experience has long been acknowledged as a crucial determinant of changes in a firm’s scope (e.g. Baum et al., 2000; Nadolska and Barkema, 2007). Interest in how the two expansion strategies combine through mergers and acquisitions (M&A) is indeed very recent (Kling et al., 2014) and provides potential for additional contributions. For example, building on a sample of 478 listed MNEs from both USA and European countries, Kling et al. (2014) investigate the impact of international and product diversification through acquisitions and divestitures on the firm’s risk-return profile in relation to its global vs regional strategy and find support for the hypothesis that cross-border acquisitions create more value in global firms if compared to home-region oriented MNEs.

Most studies examining the geographic scope of acquisitions distinguish between cross-border and domestic acquisitions (e.g. Shimizu et al., 2004; Collins et al., 2009; Kling et al., 2014). Cross-border acquisitions inherently involve additional challenges if compared to domestic deals, due to the different sources of distance with the target environment (e.g. institutional, linguistic, cultural, economic, legislative). For this reason, knowledge of the critical characteristics of the target country can prove beneficial for firms engaging in cross-border acquisitions (Collins et al., 2009) and, more broadly, in any international expansion project (Zaheer, 1995), as it reduces the firm’s liability of foreignness. To account for the significant role played by previous experience in the target country, in this paper we overcome the traditional clear-cut dichotomy between cross-border and domestic acquisitions as suggested by Anand et al. (2005). We propose a construct of target country unfamiliarity that allows to unbundle acquisitions into: domestic acquisitions; cross-border acquisitions in which the acquirer enjoys prior experience in the host country, labeled as cross-border acquisitions for foreign country re-entry; and cross-border acquisitions in which the acquirer does not have any previous experience in the target country, labeled as cross-border acquisitions for foreign country entry.

This paper contributes to the ongoing conversations on the antecedents of corporate scope expansion along the product and market dimensions with a specific focus on acquisitions. First, building on the resource-based view and liability of foreignness, we extend previous studies on the diversification-internationalization link to analyze how the degree of product acquirer-to-target relatedness is affected by the level of acquirer’s unfamiliarity with the target country. Consistent with previous findings that a substitution effect exists between the two directions of corporate growth, our results show that, when faced with increasing unfamiliarity with the target country, acquiring firms tend to prefer target firms with greater product relatedness. Second, following Kumar’s (2009) proposition about the role played by firm-level factors in determining a firm’s growth along the product and the international dimension and extending the recent analysis by Mayer et al. (2015) to the specific context of acquisitions, we explore whether and how past analogous experiences, i.e. product diversification experience and international experience, shape the unfamiliarity-relatedness relationship. Our analysis suggests that previous experience in product diversification creates the conditions for simultaneous growth along the product and the market dimensions. International experience, on the contrary, intensifies the positive relationship between unfamiliarity and relatedness, thus suggesting that this type of experience, as ***opposite*** to diversification experience, is not ***geographically*** fungible. As such, we answer calls in the literature for the consideration of the contingency factors that may alter the relationship between product and international diversification (Kumar, 2009). Finally, by unbundling the market scope of acquisitions into domestic, foreign country re-entry, and foreign country entry, we offer a more nuanced picture of the role of market unfamiliarity in acquisition decisions that takes into account the additional challenges that firms experience when straying from their markets.

This paper is organized as follows: next section presents the theoretical background of our study on the basis of which three testable hypotheses are developed. Then, a description of the methodology and of the variables used in the study is provided. After presenting our empirical findings, results are discussed. Finally, some conclusions are drawn and suggestions for future research are provided.

**Theoretical background and hypotheses**

Over years, an escalating interest among ***strategic*** management scholars has been devoted to the impact of relatedness on post-acquisition performance and mixed findings have been obtained concerning whether and how the degree of relatedness affects value creation following an acquisition (e.g. Seth, 1990; Datta, 1991; Park, 2002).

Research extensively supports the view that the degree of relatedness between acquirer and target drives the synergistic potential in an acquisition (Chatterjee, 1986; Singh and Montgomery, 1987; Seth, 1990; Datta, 1991; Larsson and Finkelstein, 1999; Haleblian and Finkelstein, 1999; Zaheer et al., 2013). As suggested by several studies, relatedness involves both similarity and complementarity (e.g. Penrose, 1959; Larsson and Finkelstein, 1999; Zaheer et al., 2013), whereby similarity has been defined as a high degree of overlapping resources between acquirer and target, while complementarity occurs when “different but potentially mutually enhancing” (Zaheer et al., 2013, p. 606) characteristics of the acquiring and target firms generate value creation. Similarity can create the potential for increased profitability thanks to high post-acquisition integration levels, which lead to scale and scope economies, reduced costs, and increased operational efficiency (Larsson and Finkelstein, 1999; Zollo and Singh, 2004; Zaheer et al., 2013). Benefits deriving from the combination of similar resources, however, may be threatened by the fact that in order to achieve such efficiencies, structural unification through rationalization of resources and consolidation of functional activities needs to be accomplished (e.g. Datta, 1991; Wang and Zajac, 2007; Puranam et al., 2009; Zaheer et al., 2013). Complementarity, on the contrary, fosters value-creating synergies based on mutually supportive resources and competencies (Bauer and Matzler, 2014) and avoids the need to eliminate the redundancies typically arising from the combination of overlapping resources (Harrison et al., 2001; Wang and Zajac, 2007). The synergistic benefits of complementarity may, however, be jeopardized by the complexity driven by the increased unfamiliar interdependencies across the wide variety of functions and products involved (Harrison et al., 1991; Larsson and Finkelstein, 1999; Ellis et al., 2011). Indeed, at increasing complementarity, the two firms involved in the deal are more exposed to information asymmetry: they are more likely unfamiliar with each other’s businesses and may ultimately not be able to successfully integrate (Wang and Zajac, 2007).

When considering the geographic dimension of acquisitions, research has pointed out that acquisitions occurring across national boundaries are perceived as more unfamiliar and uncertain vis-à-vis acquisitions in the domestic market (Shimizu et al., 2004): geographic heterogeneity increases information asymmetries and dilates both the dispersion of activities and the exposure to diverse business contexts and cultures (Teerikangas and Very, 2006), which further challenges the whole acquisition process due to the different accounting standards, control mechanisms, and managerial practices implemented (Calori et al., 1994; Lubatkin et al., 1998; Child et al., 2001).

The degree of unfamiliarity with a target market is driven by liability of foreignness, intended as “all additional costs a firm operating in a market overseas incurs that a local firm would not incur” (Zaheer, 1995, p. 343), and is magnified by double-layered acculturation, i.e. the necessity to both adapt to a foreign national culture and integrate the target’s corporate culture (Barkema et al., 1996; Shimizu et al., 2004). Liability of foreignness and double-layered acculturation imply uncertainty, demand intricate interdependencies, and generate costs in terms of exchange risk, unequal market access, and lack of knowledge of the foreign market (Hymer, 1960). Zaheer (1995, 2002) identified four main sources of liability of foreignness: costs associated with spatial distance (e.g. transportation, travel); firm-specific costs deriving from the lack of familiarity with the local environment; costs generated by the host country environment in terms of lack of legitimacy of foreign firms; and costs deriving from the home country environment (e.g. restrictions on sales to some specific countries). Liability of foreignness hence mainly arises from the unfamiliarity with the environment and results in weak or absent linkages with local actors, poor access to local information and resources, and ultimately in a lower legitimacy and acceptance of the foreign entrant if compared to local firms (Petersen and Pedersen, 2002). Liability of foreignness, however, is not a static cost, as it tends to decline as firms progressively gain more knowledge of the local environment: as the acquirer extends its experience, develops linkages, aligns with the external institutional environment, and engages in learning activities, its liability of foreignness will reduce, or even disappear (Petersen and Pedersen, 2002; Zaheer, 2002).

In light of the shrinking liability of foreignness as long as firms consolidate their knowledge of the local market (Zaheer, 1995; Barkema et al., 1996; Petersen and Pedersen, 2002), we expect uncertainty in cross-border acquisitions to differ depending on previous firm-level experience in the target country. Prior research has considered the effects of learning stemming from experience in the target country as a motivator of subsequent acquisitions in that same country (e.g. Collins et al., 2009), as a factor influencing the choice of the entry mode (e.g. Barkema and Vermeulen, 1998; Slangen and Hennart, 2008), and as a factor affecting performance (e.g. Very and Schweiger, 2001; Uhlenbruck, 2004). The common underlying argument is that because organizational experience is not isolated from the external context and rather interacts with it to create knowledge (Argote and Miron-Spektor, 2011), previous acquisition experience in a particular country provides “a more salient vehicle for learning” if compared to past experience in other countries (Collins et al., 2009, p. 1331). Past acquisition experience in a certain target country results in a location-bound experience (Johanson and Vahlne, 1977; Very and Schweiger, 2001; Clarke et al., 2012) that reduces the disadvantages of foreignness, while also leading to scale economies and learning benefits that may reduce uncertainty and facilitate negotiation and integration thanks to local knowledge (Very and Schweiger, 2001). From a risk perspective, acquirers may hence perceive cross-border acquisitions in known foreign countries as less uncertain if compared to cross-border acquisitions aimed at entering a new foreign market.

Because pre-entry experience provides the firm with relevant resources and knowledge (Qian et al., 2012), the traditional clear-cut dichotomy between domestic and cross-border acquisitions, although established in the literature (Shimizu et al., 2004), may lead to ambiguous results (Anand et al., 2005) as it neglects the crucial role played by experience in the target country. For this reason, we overcome the conventional distinction between domestic and cross-border acquisitions and propose a construct of target country unfamiliarity that disentangles acquisitions into: domestic acquisitions, cross-border acquisitions for foreign country re-entry, and cross-border acquisitions for foreign country entry. This allows to bring into the picture the intermediate case of those deals which, although occurring across national boundaries, are made in countries where acquirers had previously established their presence through subsidiaries. These deals are hence characterized by a lower unfamiliarity in the eyes of the acquirers. It is worth noting that we are not suggesting that entry into new foreign markets is necessarily associated with high levels of liability of foreignness as similarities between a firm’s home country and foreign target countries in terms of economic conditions, culture, and institutional environment may dramatically reduce managers’ perception of market unfamiliarity (Buckley et al., 2007; Kang and Jiang, 2012). Rather, we argue that, if compared to entry into foreign markets in which a firm has already established its own subsidiaries, entry into a country for the first time entails greater uncertainty and challenges. Our conceptualization of unfamiliarity is shown in Figure 1.

**The unfamiliarity-relatedness relationship**

Several studies have highlighted that because both international and product diversification are risky strategies as they generate market and financial risks, respectively, it is very unlikely for firms to be willing to pursue both of them simultaneously as they would incur in both risks at the same time (e.g. Sambharya, 1995).

Resource-based view scholars have contended that the exploitation of scope economies in both tangible – e.g. plant and equipment – and intangible resources – e.g. technical and marketing know-how – is the main reason motivating diversification (Teece, 1982) and simultaneous growth along the product and the geographic dimension is stimulated to the extent that these resources are fungible (Kumar, 2009). However, constraints in terms of transfer of knowledge and absorption of new knowledge may force a trade-off decision between the two dimensions of growth (Kumar, 2009). Such constraints are generated by the tacit component that is inherently implied in intangible resources (Kogut and Zander, 1992).

The importance of learning for successfully executing strategy has been extensively recognized in both the international business literature (e.g. Zaheer, 1995; Delios and Beamish, 1999) and in the context of product diversification (e.g. Markides and Williamson, 1994). In a study on a sample of 1,299 US firms in the manufacturing sector over the period 1993-1997, Kumar (2009) investigates whether or not constraints are more influential than incentives in the joint pursuit of international and product diversification and finds a negative relationship between the two expansion paths, thus suggesting that constraints to growth are more powerful if compared to incentives in determining ***strategic*** choices.

Simultaneous growth along the product and the market dimensions hence implies additional complexity if compared to growth in one individual dimension at a time: bounded rationality (Zahra and George, 2002), increased governance and coordination costs and managerial complexity (Geringer et al., 2000; Kumar, 2009; Lampel and Giachetti, 2013) may indeed pose constraints to the transferability of knowledge and absorptive capacity (Kumar, 2009), possibly compromising the synergistic benefits of synchronic scope expansion (Zhou, 2011). In the specific context of acquisitions, we therefore expect acquirers to pursue a balance between sources of unfamiliarity, thereby extending their corporate scope boundaries in one dimension individually: when moving into markets characterized by increasing liability of foreignness, acquirers may be encouraged to remain in the neighborhood of what they already know, keeping a higher product relatedness with the target firm (Nohria and Garcia-Pont, 1991; Lavie and Rosenkopf, 2006). Although evidence has been found that business similarity does not necessarily imply cultural similarity (Greenwood et al., 1994), recent studies suggest that with greater similarity much of the knowledge required to manage the target business already lies in the acquiring firm (Zaheer et al., 2013), as similarity “naturally generates knowledge about each other” (Wang and Zajac, 2007, p. 1295). Based on these arguments, we posit the following:H1. There is a positive relationship between an acquirer’s unfamiliarity with the country of the target firm and the acquirer-to-target relatedness.

**The effects of experience**

The prominent role of experience in determining the trajectory of decisions and the performance of subsequent ***strategic*** actions has been highlighted in several studies (e.g. Geringer et al., 2000; Haleblian et al., 2006; Kumar, 2009; Mayer et al., 2015). Building on Kumar’s (2009) study and using a sample of 767 firms between 1993 and 2007 located in the USA and in the three largest European economies, i.e. France, Germany, and the UK, Mayer et al. (2015) find a positive relationship between product and international growth at increasing levels of product diversification. The authors also find support for the hypothesis that, because diversification experience is ***geographically*** fungible while international experience is not, the former is a more influential determinant of simultaneous growth if compared to the latter. Extant research, however, has not examined the interrelationship between these strategies when implemented through acquisitions, a domain in which experience substantially affects scope changes (e.g. Baum et al., 2000; Nadolska and Barkema, 2007).

Research suggests that, due to organizational inertia, a firm’s repertoire of routines makes future behavior repetitive and path-dependent (Amburgey and Miner, 1992; Lavie and Rosenkopf, 2006): experience in geographic and product diversification may hence affect a firm’s future moves in both directions because over time firms tend to reproduce their strategies, anchoring their ***strategic*** decisions to past actions (Amburgey and Miner, 1992; Hashai and Delios, 2012). The main argument behind studies suggesting complementarity between product and geographic growth is that both strategies share similar underlying mechanisms (Mayer et al., 2015) and build on common dynamic capabilities (Hitt et al., 1994; Kumar, 2009). Hence, as “the challenges will not be identical when entering a new product or a new geographic market but sufficiently similar for firms to benefit from their experience in the other dimension of growth” (Mayer et al., 2015, p. 1460), experience in product and international diversification may reduce the pressures to trade-off one growth path for the other (Kumar, 2009; Mayer et al., 2015).

**The moderating effect of product diversification experience**

Product diversification generates scale and scope economies along with exposure to diverse learning opportunities and provides the firm with managerial capabilities that may help to deal with some of the challenges associated with internationalization: while single-business firms have no or limited experience in managing the internal diversity and the complexity generated by product diversification, multi-business firms can capitalize on this experience not just for further diversification but also when internationalizing (Hitt et al., 1994, 1997; Geringer et al., 2000). Diversified firms possess management capabilities and better governance structures (Hitt et al., 1997), may reap cost advantages thanks to operational synergies in terms of cost complementarities and shared input facilities, and are able to efficiently transfer firm-specific capital across the different sub-units and businesses, especially under conditions of uncertainty (Barney, 1997; Benito-Osorio et al., 2012). Some scholars have also suggested that a higher degree of product diversification enables firms to gain more from international diversification (Hitt et al., 1997) as synergistic opportunities, bargaining power and competitive advantages become greater as product-diversified firms expand into multiple markets (Chang and Wang, 2007). Past experience in product diversification may therefore provide the acquirer with a repository of routines and capabilities that can be leveraged to embark on deal projects characterized by low acquirer-to-target relatedness at increasing unfamiliarity with the target country of the acquisition. These arguments lead to the following:H2. Product diversification experience negatively moderates the relationship between an acquirer’s unfamiliarity with the country of the target firm and the acquirer-to-target relatedness.

**The moderating effect of international experience**

The importance of “discovering” the critical characteristics of the target market has been recognized in several studies (e.g. Markides and Williamson, 1994; Zaheer, 1995; Winter and Szulanski, 2001; Kumar, 2009): prior experience in the target country of the focal acquisition has indeed been acknowledged as a crucial factor affecting both behavior (e.g. Collins et al., 2009; Alessandri et al., 2014) and performance (e.g. Singh and Montgomery, 1987; Haleblian and Finkelstein, 1999). While this argument lies at the basis of our conceptualization of target country unfamiliarity, we follow previous studies (e.g. Mayer et al., 2015) in examining the role played by international experience, which is inherently general and non-location-bound, as it is accrued by operating in the international arena rather than in any specific country (Clarke et al., 2012). Such experience is highly related to the ability to adapt to the local institutional environment (Petersen and Pedersen, 2002): internationally experienced acquirers have developed knowledge and competencies that are not context-specific and that can hence be transversally applied to other contexts (Anand et al., 2005).

The possibility to extend the knowledge bases accrued from experience in international operations may substantially affect the decision about the product-market profile: because the cost of internationalization is also a function of organizational and managerial competencies in handling foreign market efforts (Eriksson et al., 2000), international experience may reduce the magnitude of unfamiliarity. Internationally experienced acquirers are exposed to diverse opportunities to accumulate general knowledge, gain access to a variety of environments and capabilities that would not be accessible in the context of their home country (Qian et al., 2010). Thanks to this, they may reach greater operational efficiency and capitalize on interrelationships among the diverse geographic areas thereby reaching scale and scope economies (Riahi-Belkaoui, 1996). Because this type of experience is not restricted within the boundaries of any specific location and creates a repertoire of cross-applicable routines and capabilities, the experience gathered in terms of how to adapt to foreign institutional contexts may substantially reduce liability of foreignness and may encourage acquirers to increase their product scope, pursuing a lower degree of relatedness as the unfamiliarity with the target country increases. We therefore posit:H3. International experience negatively moderates the relationship between an acquirer’s unfamiliarity with the country of the target firm and the acquirer-to-target relatedness.

Conceptual model and hypotheses are reported in Figure 2.

**Method**

**Sample and data**

The initial dataset consisted of 826 acquisitions completed in the period 2007-2013. Data on deals were collected from Zephyr, a database of M&A included in ORBIS and produced by Bureau van Dijk Electronic Publishing. ORBIS includes financial data on over 50 million corporations worldwide and is largely used in management and finance research (e.g. Banalieva and Dhanaraj, 2013; Bollaert and Delanghe, 2015).

Additional data on target countries of acquisitions were collected from the yearly reports on global competitiveness issued by the World Economic Forum (WEF). As suggested by Kling et al. (2014), we identified the ultimate acquirer and target in order to avoid any misclassification in case a subsidiary initiates an acquisition.

While including target firms from a variety of industries in our sample, we imposed a limitation to provide an element of homogeneity: the acquiring firm should be active in the food and beverage sector, either as its primary business or as one of secondary businesses. Because the timeframe observed covers the years of the global financial crisis, the food and beverage sector has been selected for its non-cyclical nature which makes it less subject to economic and financial downturns. In order to examine corporate scope growth choices through acquisitions, we considered only completed transactions, thus leaving out from the sample any announcements, rumors, and withdrawals. In line with previous studies (Rossi and Volpin, 2004; Very et al., 2012), we included in the sample only those deals in which acquirers gain majority ownership of the target firm, i.e. >50 percent of target shares. Following previous studies, duplicated deals were ***deleted*** and we kept only those deals with disclosed values (Kling et al., 2014). In addition, from the initial dataset, 137 observations were cut due to missing values. Our model is hence tested on a final dataset of 689 acquisitions completed by 464 acquirers located in 60 different countries.

**Variables**

**Dependent variable**

Because “conceptually, relatedness is a matter of degree” (Lien and Klein, 2006, p. 13), we measured acquirer-to-target relatedness through the weighted variable proposed by Haleblian and Finkelstein (1999) and later re-used in Finkelstein and Haleblian (2002). Although most studies base their measures of relatedness on the Standard Industrial Classification (SIC) codes of the two firms involved, we use the North American Industrial Classification System (NAICS), the latter being argued as a more precise measure if compared to the former as it captures more subtleties than the SIC, identifies emerging industries, and groups together industries that share similar production processes. Our measure of acquirer-to-target relatedness has hence been built according to the following grading scheme (Haleblian and Finkelstein, 1999; Finkelstein and Haleblian, 2002). We first examined matches between the primary NAICS codes of acquirer and target using values 2, 4, 6 to identify increasing levels of relatedness. We thus assigned 6 to a four-digit match, 4 to a three-digit match, and 2 in case of a two-digit match. We also took into account that relatedness may involve secondary businesses. Hence, if no match was found at primary business level, we graded relatedness considering NAICS codes corresponding to secondary businesses. Specifically, we used values 1, 2, 3 according to the following scheme: we assigned a 3 to matches at four-digit level, a 2 to three-digit level matches, and a 1 in case of match at two-digit level. Acquisitions not showing any match in any of the NAICS codes were assigned 0, i.e. unrelated acquisitions. As a result of this operationalization method, our acquirer-to-target relatedness scale ranges from 0 to 6[[1]](#footnote-2)1.

**Independent variables**

In our conceptual framework target country unfamiliarity involves three different levels. The case of a domestic acquisition is qualified by the lowest unfamiliarity with any critical contextual trait of the target country as the acquirer does not suffer from any liability of foreignness. Among cross-border acquisitions, those aimed at re-entering a foreign country in which the acquirer already operates are expectably characterized by a greater level of unfamiliarity if compared to domestic acquisitions as they go beyond national boundaries, but by a lower level of unfamiliarity if compared to cross-border acquisitions for foreign market entry, as in the first case acquiring firms can leverage on past experience in the target country. By comparing the country ISO codes of each acquirer’s subsidiaries with that of the target firm, we identified whether the geographic location of the target represents or not a new destination for the acquirer. Those acquisitions showing a match between the target’s country and one or more of the acquirer’s subsidiaries were labeled as cross-border acquisitions for foreign country re-entry, as acquirers can benefit from previous location-bound experience. Those acquisitions not showing any match, being those characterized by the greatest level of unfamiliarity with the target country, are identified as the case of cross-border acquisitions for foreign country entry. In our empirical model, the three levels of unfamiliarity have been operationalized through two binary variables: one for cross-border acquisitions for foreign country re-entry and one for cross-border acquisitions for foreign country entry, each of which captures differences with respect to the baseline category of domestic acquisitions.

We operationalize diversification experience as a continuous variable based on the number of different businesses at three-digit level in which the acquirer is active at the moment of the acquisition (Hashai and Delios, 2012). International experience is measured as the acquirer’s total number of foreign subsidiaries. This measure is in line with the intensity dimension proposed by Clarke et al. (2012), according to which equity-based experience provides opportunities for a more radical learning if compared to non-equity-based experience.

A number of control variables are included to account for additional factors that may influence the relatedness-unfamiliarity relationship.

**Firm-level control variables**

Consistent with literature arguing that acquisition experience affects acquisition behavior (e.g. Haleblian et al., 2006), we control for acquisition experience: in line with previous studies, past experience in acquisitions is measured as the number of acquisitions performed by the acquirer in the four years preceding the focal deal (Fowler and Schmidt, 1989; Porrini, 2004; Ellis et al., 2011). We control for acquirer’s pre-deal performance to account for acquirers rewarded by positive past performance being more willing to take risks. This variable is measured as the return on assets one year prior to the deal. Acquirer size is typically considered as a proxy of resource endowments that may eventually be invested in the post-acquisition phase. We therefore control for the size of the acquiring firm, which is operationalized as the log-transformed total assets in the year preceding the focal acquisition (Wang and Zajac, 2007).

**Acquisition-level control variables**

Because large acquisitions are usually perceived as more complex than small acquisitions (Haunschild, 1994; Ellis et al., 2011), we also control for the size of the acquisition, measured as the value paid for the acquired stakes as provided by the database ORBIS. To control for time and industry effects, we created binary variables for each of the seven years in our sample and for the four macro-industries of the acquirers (i.e. agriculture, utilities, manufacturing, and services).

**Country-level control variables**

As acquisitions in our dataset involve 60 different target countries, we control for several country-level variables. The data source of all target country control variables is the Global Competitiveness Report developed by the WEF. First, because more efficient countries may be more attractive, we include a variable of government efficiency of the target country in the year preceding the focal event. This variable ranks countries as a result of several dimensions: wastefulness of government spending, burden of government regulation, efficiency of legal framework in settling disputes, efficiency of legal framework in challenging regulations, and transparency. Second, as healthy competition is a significant driver of market efficiency, we control for characteristics of both domestic and foreign competition in the target country. We hence include a variable capturing the intensity of local competition, which is a country ranking based on the degree to which competition is limited vs intense, as well as a variable of openness to foreign ownership to capture the extent to which the target country is open to foreign investors. Because the size of the market is an important factor affecting the potential for scale economies, we control for the target market size by including a variable developed by the WEF that involves two components: the size of the domestic market (computed as the natural log of the sum of the purchase power parity-adjusted GDP plus the total value of imports of goods and services minus the total value of exports of goods and services) and the size of the foreign market (computed as the natural log of the total value of exports of goods and services). Finally, we control for the target country stage of development. This variable ranges from 1 to 5 based on the WEF classification, according to which five different stages of development are identified: factor-driven stage, efficiency-driven stage, innovation-driven stage, and two stages of transition, i.e. one from factor-driven to efficiency-driven and one from efficiency-driven to innovation-driven.

Consistent with other studies, all acquirer-related variables are lagged with respect to the year of the focal deal to ensure proper inference of causality. Variables and measures are summarized in Table I.

**Empirical findings**

Table II provides the distribution of the sample. In total, 251 acquisitions out of 689 involve diversification (36 percent) and a decreasing tendency to diversify is found at increasing levels of unfamiliarity: while 79 percent of diversified acquisitions occur in the domestic market, 17 percent occur in a foreign country where the acquirer already has experience and only 4 percent involves entry in a new foreign country.

Consistent with the nature of our dependent variable as an ordered factor response variable with levels corresponding to the response categories, an ordered logistic regression has been used as estimation method. Since in our sample multiple acquisitions are carried out by the same acquirers, error terms may not be independent from one another. To control for cases of repeated acquirers, we “clusterize” the error terms by acquirer. Table III displays means, standard deviations, and correlations. While correlation coefficients are low for almost all of the variables, they are relatively high among country-level variables, namely foreign ownership, intensity of local competition, and government efficiency. To ensure that multicollinearity was not an issue, as a post-regression test, we examined the VIFs – variance inflation factors (using the collin.ado program in STATA). In all models, the VIFs were largely below the recommended threshold of 10, thus suggesting that multicollinearity did not bias our results.

In Table IV we report the ordered logistic regression results.

Model 1 is the baseline model, including all firm-level, acquisition-level, and country-level control variables. In Model 2 we add the two variables of cross-border acquisitions for foreign country re-entry and cross-border acquisitions for foreign country entry to capture the effects of different levels of target country unfamiliarity on the degree of acquirer-to-target relatedness, while also including the main effects of product diversification experience and international experience. The inclusion of these variables leads to an increase in the explanatory power of the model (pseudo-R2=0.06 in Model 2). Models 3 and 4 incorporate the interaction terms capturing the moderating effect of acquirer’s product diversification experience and international experience, respectively. Model 5 displays our complete results with all interaction terms simultaneously (pseudo-R2=0.07).

In line with studies suggesting that product and market growth tend to be mutually exclusive paths (Wiersema and Bowen, 2008; Kumar, 2009), H1 predicts a positive relationship between the level of target country unfamiliarity and the degree of product relatedness in the acquisition. This hypothesis is supported only for greater levels of unfamiliarity, i.e., in the case of cross-border acquisitions for foreign country entry (β=2.11, p<0.01), while no support is provided in the case of cross-border acquisitions for foreign country re-entry. Differences in the degree of acquirer-to-target-relatedness are not statistically significant when comparing domestic acquisitions and cross-border acquisitions if the acquirer is already familiar with the foreign country, while those differences become statistically significant when acquisitions take place in foreign countries in which the acquirers had not previously settled any activities. We computed the marginal effect (at the point of means) corresponding to the coefficient of cross-border acquisitions for entry in Table IV, Model 5. This effect indicates that, if compared with domestic acquisitions, cross-border acquisitions for foreign country entry are associated with a 22.7 percent increase of the probability of higher acquirer-to-target relatedness[[2]](#footnote-3)2. This result corroborates our prediction that acquirers tend to seek product-market combinations whereby corporate scope growth along one dimension is counterbalanced by the choice to remain within familiar boundaries in the other dimension.

H2 and H3 investigate whether the relatedness-unfamiliarity relationship is affected by, respectively, product diversification and international experiences. Specifically, H2 posits the existence of a negative moderating effect played by diversification experience. Such effect is supported in the case of cross-border acquisitions for foreign country entry (β=−0.86, p<0.01 in Model 5). Based on our coefficient in Model 5, we computed the marginal effect of cross-border acquisitions for entry associated with “low” and “high” levels of diversification experience, identified, respectively, as the levels corresponding to the 10th and 90th percentiles of the distribution of such variable (holding other variables at means). The marginal effects indicate that, when diversification experience is low, cross-border acquisitions for foreign market entry have a 44.2 percent greater probability (compared to domestic acquisitions) of being associated with a higher level of acquirer-to-target relatedness. Such probability decreases at 5.3 percent for high levels of diversification experience. Specifically, the marginal effect becomes zero for diversification experience equal to 3.34 and turns negative for higher levels of diversification experience, thus confirming that the “substitution” effect between international and product diversification is mitigated for more experienced diversified firms.

The significant moderating effect of product diversification experience is shown in Figure 3. It is worth noting that, since our independent variable is binary, the function plotted in Figure 3 is defined only when the independent variable is equal to 1 and 0. To make the interpretation of results easier and the plot more readable, each line depicted in Figure 3 links the “pairs” of predicted logit values corresponding to cross-border acquisitions for foreign country entry equal to 0 and 1 for each possible value of diversification experience in our sample.

The interaction term of cross-border acquisitions for foreign country re-entry and product diversification experience is not statistically significant, thus failing to support the hypothesized moderating effect played by diversification experience in the case of cross-border acquisitions for foreign country re-entry. H2 therefore receives partial support.

As to H3, which posits a negative moderating effect played by international experience, our results provide evidence of two main findings. First, the direct effect of cross-border acquisitions for re-entry is not significant in Model 5, thus preventing a sound interpretation of the barely significant coefficient of the interaction term cross-border acquisitions for re-entry×international experience (β=0.01, p-value<0.1, in Model 5). Second, a statistically significant moderating effect of international experience is found in the case of cross-border acquisitions for foreign country entry (β=0.03, p-value<0.01), but the coefficient shows a direction that is ***opposite*** to H3: international experience intensifies the substitution effect between product diversification and target country unfamiliarity in the context of high levels of unfamiliarity. We computed the marginal effect of cross-border acquisitions for entry associated with “low” and “high” levels of international experience, identified as the levels corresponding to the 10th and 90th percentiles of the distribution of such variable. The marginal effect confirms that the moderating role of international experience is significant in the case of high levels of target market unfamiliarity: when international experience is low, cross-border acquisitions for foreign market entry have only a 6.6 percent greater probability (compared to domestic acquisitions) of being associated with a higher level of acquirer-to-target-relatedness, while such probability raises to 44.1 percent when international experience is high.

Figure 4 plots the predicted logit values corresponding to the binary independent variable cross-border acquisition for foreign country entry equal to 0 and 1 for varying levels of international experience, evenly distributed between the 10th and the 90th percentiles. Such plot shows that, as international experience increases, cross-border acquisitions for foreign country entry have an increasingly higher probability of being associated with greater relatedness (compared with domestic acquisitions). The graph therefore confirms the reinforcing effect of international experience on the likelihood of acquirers pursuing acquisitions of firms characterized by greater similarities in terms of business scope. These results offer interesting insights, which we discuss in the next section.

**Robustness test**

We conducted a further analysis to test the robustness of our results. We created a dichotomous dependent variable that takes value 1 for diversifying acquisitions (corresponding to those deals coded as 0 in our models shown in Table IV) and takes value 0 in all the other cases (corresponding to the levels from 1 to 6 of acquirer-to-target relatedness). Because this dependent variable represents the reverse of acquirer-to-target relatedness, we expect coefficients to have ***opposite*** signs if compared to the findings that we obtained in our models in Table IV. The results obtained in the robustness test prove to be fully consistent with this expectation and hence confirm our findings. The first hypothesis is supported, thus confirming the existence of a substitution effect between diversification and target country unfamiliarity in the context of acquisitions. H2 is supported as well: previous diversification experience mitigates the substitution effect and increases the likelihood of diversification at high levels of unfamiliarity. Similarly, results for the third hypothesis are consistent with those in our main model: previous international experience intensifies the substitution effect. Full results are available from the authors upon request.

**Discussion and conclusions**

In this paper we examined the relationship between unfamiliarity with the target country of an acquisition and the degree of acquirer-to-target relatedness. Results provide support to theories suggesting the existence of a substitution effect between growth along the product and market dimensions (Wiersema and Bowen, 2008; Levinthal and Wu, 2010). Indeed, cross-border acquisitions for foreign country entry imply a greater acquirer-to-target relatedness if compared to domestic acquisitions; a result in line with our prediction that corporate scope growth in one dimension tends to be counterbalanced by the choice to remain within familiar boundaries in the other dimension (Lavie and Rosenkopf, 2006). In other words, when the liability of foreignness is high, the unfamiliarity stemming from the environment encourages acquirers to pursue greater relatedness and, hence, those sources of value creation that derive from the combination of similar resources. On the contrary, no significant effect is provided for intermediate levels of target country unfamiliarity. The lack of significance of the coefficient of cross-border acquisitions for foreign country re-entry suggests that acquirers benefiting from prior experience in the target country may not seek greater acquirer-to-target relatedness if compared to acquirers realizing a domestic acquisition. This result is consistent with the literature arguing that the liability of foreignness significantly reduces or even disappears as long as firms gain knowledge of and get more embedded in the local environment (Petersen and Pedersen, 2002; Zaheer, 2002).

However, as suggested by Kumar (2009), the nature of the relationship between product and market dimensions is affected by the balance between those factors that allow to exploit resources and capabilities across product and market boundaries and those factors that limit such exploitation, whereby past product diversification and international experience have been argued to play a key role in shaping corporate scope expansion decisions (Kumar, 2009; Mayer et al., 2015). Results for H2 provide evidence of a negative moderating effect, which suggests that increasing diversification experience, being the result of past exploration of new product lines, confers experiential knowledge that can be leveraged and can thus encourage to acquire in a less related business when entering a new foreign country.

In a recent study by Mayer et al. (2015), international experience was found to have a weaker moderating effect if compared to diversification experience, explained by the fact that while the repertoire of routines and capabilities derived by diversification may be ***geographically*** fungible (Anand and Delios, 2002), resources accumulated from international experience tend to be related to the process of internationalization itself. Differently from the findings of Mayer et al. (2015), results for H3 show that international experience is not just less impacting than diversification experience, but rather intensifies the tendency to grow along one dimension at a time. Therefore, these two experiences actually play ***opposite*** effects. In particular, the negative moderating effect of international experience, although departing from our predictions, is consistent with path-dependency theories. Indeed, because high international experience is the result of previous commitment of resources and efforts in realizing a process of internationalization, acquirers may be more willing to pursue geographic expansion within the core business or related businesses if compared to growth along both scope dimensions. Hence, when corporate scope growth occurs through acquisitions, international experience strengthens the likelihood of expanding asynchronously.

This paper provides several contributions. From a theoretical point of view, we contribute to the existing literature on product-market diversification choices and extend this perspective to an unfamiliarity-relatedness relationship in the context of acquisitions, showing that acquirers seek a balance between the sources of unfamiliarity in their acquisition moves. We contribute to the extant conversation on the role of past experience in shaping corporate scope growth decisions (Kumar, 2009; Mayer et al., 2015) by focusing on how such experiences act within the specific context of acquisitions. In line with Mayer et al. (2015), our findings suggest that product diversification experience encourages simultaneous growth also in the context of acquisitions, while a substantially different effect is found for international experience. Indeed, internationally experienced acquirers tend to deepen their commitment along the market dimension thereby preferring the benefits of synergistic gains derived by similarity rather than those arising from complementarity. Our partially different findings could be interpreted in the light of our focus on acquisitions as research context. These findings call for more research on the mechanisms through which experience affects corporate scope decisions for other ways of executing strategy.

An additional contribution stems from our conceptualization of target country unfamiliarity in acquisitions, which, following the suggestion of Anand et al. (2005), allows to go beyond the traditional domestic vs cross-border comparison by taking into account the role played by past experience in the target country. Our results demonstrate that our threefold classification of country unfamiliarity provides a richer understanding of firm acquisition behavior across varying national environments.

This paper also has some interesting managerial implications. Managers, being decision makers, are subject to uncertainty which discourages ***strategic*** decisions that are perceived as highly risky; however, past analogous experience may reduce unfamiliarity and may spur decisions otherwise rejected. Although coordination costs may possibly outweigh the benefits of expanding along both dimensions of scope simultaneously (Mayer et al., 2015), experience may lead managers to overcome unfamiliarity and to pursue simultaneous growth, especially to maximize the utilization of the firm’s proprietary assets (Delios and Beamish, 1999; Davies et al., 2001). In particular, product diversification experience becomes especially relevant for firms seeking flexibility as it enables to grow along both directions. Internationally experienced acquirers, on the contrary, may be able to better seize opportunities for geographic growth if compared to firms with a locally oriented strategy. However, as theories on ***strategic*** inertia (Haleblian and Finkelstein, 1999; Finkelstein and Haleblian, 2002) have well underlined, past experience and the continued use of existing ***strategic*** routines may generate inertia, thus possibly leading managers to stick to current strategies instead of adjusting firm geographic and product market scope to varying environmental conditions. Managers should therefore also carefully scrutinize ***strategic*** alternatives trying to assess both similarities and differences with previous ***strategic*** moves.

This study has some limitations, which suggest interesting avenues for future research. First, target firm-specific characteristics are not included: firm-level factors of the target may affect preferences of acquiring companies; for instance, positive historical performance of target firms may strengthen the desirability profile of the acquisition leading managers to navigate the deal for both operating and competitive performance reasons. In addition, although we controlled for several target country-level variables, further research may investigate whether and how distance between the target’s and the acquirer’s country moderate the unfamiliarity-relatedness relationship as lower distance may reduce the challenges of entering a new and unfamiliar country. In addition, our concept of unfamiliarity has been built based on past equity-based experience through subsidiaries in the target country of the acquisition and therefore does not account for alternative types of experience either equity-based, e.g. joint ventures, and non-equity-based, e.g. export activities. Although providing the acquirer with a lower embeddedness in the local context if compared to wholly owned subsidiaries, experience based on other foreign country entry modes may still play a role in reducing the liability of foreignness. Future research may hence explore whether and how different types of country-specific experience affect the unfamiliarity-relatedness relationship in acquisitions.

Link to PDF file

**Notes**

**Load-Date:** January 17, 2019

**End of Document**



[***P8\_TA(2015)0410 Prevention of radicalisation and recruitment of European citizens by terrorist organisations European Parliament resolution of 25 November 2015 on the prevention of radicalisation and recruitment of European citizens by terrorist organisations (2015/2063(INI))***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5PX3-MST1-JDG9-Y281-00000-00&context=1516831)

Impact News Service

November 4, 2017 Saturday

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**Length:** 11106 words

**Body**

Brussels: Official Journal of the European Union has issued the following notice:

P8\_TA(2015)0410

Prevention of radicalisation and recruitment of European citizens by terrorist organisations

European Parliament resolution of 25 November 2015 on the prevention of radicalisation and recruitment of European citizens by terrorist organisations (2015/2063(INI))

(2017/C 366/08)

The European Parliament,

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| ? | having regard to Articles 2, 3, 5, 6, 7, 8, 10 and 21 of the Treaty on European Union and to Articles 4, 8, 10, 16, 67, 68, 70, 71, 72, 75, 82, 83, 84, 85, 86, 87 and 88 of the Treaty on the Functioning of the European Union, |

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| ? | having regard to the publications ?European Union Minorities and Discrimination Survey Data ? Focus Report 2: Muslims? and ?FRA survey on Jewish people's experiences and perceptions of hate crime and discrimination in European Union Member States?, both published by the European Union Agency for Fundamental Rights (FRA), |

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| ? | having regard to the resolution adopted by the UN Security Council on 8 October 2004 on ?Threats to International Peace and Security Caused by Terrorism?, |

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| ? | having regard to the Charter of Fundamental Rights of the European Union, in particular Articles 6, 7, 8, 10(1), 11, 12, 21, 48, 49, 50 and 52 thereof, |

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| ? | having regard to the EU Internal Security Strategy as adopted by the Council on 25 February 2010, |

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| ? | having regard to the Commission communication of 22 November 2010 entitled ?The EU Internal Security Strategy in Action: Five steps towards a more secure Europe? (COM(2010)0673) and creating the European Radicalisation Awareness Network (RAN), |

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| ? | having regard to its resolution of 12 September 2013 on the second report on the implementation of the EU Internal Security Strategy (1), |

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| ? | having regard to the Commission communication of 15 January 2014 entitled ?Preventing radicalisation to terrorism and violent extremism: Strengthening the EU's Response? (COM(2013)0941), |

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| ? | having regard to the Revised EU Strategy for Combating Radicalisation and Recruitment to Terrorism, adopted by the Justice and Home Affairs Council at its meeting on 19 May 2014 and approved by the Council at its meeting of 5 and 6 June 2014 (9956/14), |

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| ? | having regard to the Commission communication of 20 June 2014 on the final implementation report of the EU Internal Security Strategy 2010-2014 (COM(2014)0365), |

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| ? | having regard to Europol?s EU Terrorism Situation and Trend Report (TE-SAT) for 2014, |

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| ? | having regard to the resolution adopted by the UN Security Council on 24 September 2014 on threats to international peace and security caused by terrorist acts (Resolution 2178 (2014)), |

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| ? | having regard to the report of the EU Counter-Terrorism Coordinator to the European Council of 24 November 2014 (15799/14), |

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| ? | having regard to its resolution of 17 December 2014 on renewing the EU Internal Security Strategy (2), |

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| ? | having regard to the conclusions of the Justice and Home Affairs (JHA) Council of 9 October and 5 December 2014, |

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| ? | having regard to the statement of the informal JHA Council of 11 January 2015, |

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| ? | having regard to its plenary debate of 28 January 2015 on anti-terrorism measures, |

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| ? | having regard to its resolution of 11 February 2015 on anti-terrorism measures (3), |

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| ? | having regard to the informal JHA Council held in Riga on 29 and 30 January 2015, |

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| ? | having regard to the conclusions of the Justice and Home Affairs Council of 12 and 13 March 2015, |

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| ? | having regard to the Commission communication of 28 April 2015 on the European Security Agenda (COM(2015)0185), |

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| ? | having regard to the ECJ ruling on the Data Retention Directive, |

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| ? | having regard to the additional protocol to the Council of Europe Convention on the Prevention of Terrorism and the Council of Europe?s action plan on the fight against violent extremism and radicalisation leading to terrorism adopted on 19 May 2015, |

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| ? | having regard to the Commission Green Paper entitled ?Strengthening mutual trust in the European judicial area ? A Green Paper on the application of EU criminal justice legislation in the field of detention?(COM(2011)0327), |

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| ? | having regard to Rule 52 of its Rules of Procedure, |

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| ? | having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs and the opinions of the Committee on Foreign Affairs and the Committee on Culture and Education (A8-0316/2015), |

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| A. | whereas more than 5 000 European citizens have joined terrorist organisations and other military formations, particularly ISIS (Da?esh), Jahbat al-Nusra and others outside the European Union, especially in the Middle East and North Africa (MENA) region; whereas this phenomenon is speeding up and taking on significant proportions; |

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| B. | whereas radicalisation has become a term used to describe the phenomenon of people embracing intolerant opinions, views and ideas which could lead to violent extremism; |

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| C. | whereas the recent terrorist attacks in France, Belgium, Tunisia and Copenhagen highlight the security threat which is posed by the presence and movement of these ?foreign? fighters who are often EU nationals, in Europe and in its neighbourhood; whereas the EU has condemned these attacks in the strongest terms and has committed itself to combating terrorism alongside the Member States, inside and outside EU territory; |

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| D. | whereas the terrible terrorist attacks that killed and wounded hundreds of people in Paris on 13 November 2015 have highlighted once more the urgent need for coordinated action by the Member States and the European Union to prevent radicalisation and fight against terrorism; |

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| E. | whereas the terrorist threat is significant in the EU, particularly in those Member States that have been or still are militarily engaged in overseas operations in the Middle East and Africa; |

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| F. | whereas the radicalisation of these ?European fighters? is a complex and dynamic phenomenon that is based on a series of global, sociological and political factors; whereas it does not correspond to one single profile, and affects men, women, and particularly young European citizens of all social origins, who share the common trait of feeling at odds with society; whereas the causes of radicalisation may equally be socio-economic, ideological, personal or psychological, and, for that reason, it has to be understood in the light of the background of each individual concerned; |

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| G. | whereas, because of terrorism and radicalisation, there is much stereotyping of religions, which in turn is bringing about renewed upsurges of hate crimes and hate speech motivated by racism, xenophobia or intolerance of opinions, beliefs or religions; whereas it must be pointed out that it is the perverse misuse of religion, and not religion per se, that is one of the causes of radicalisation; |

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| H. | whereas radicalisation is not to be associated with any one ideology or faith but may occur within any of them; |

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| I. | whereas one of the arguments used by violent extremists in recruiting young people is that islamophobia is increasing, following years of war on terror, and that Europe is no longer a place where Muslims are welcome or can live in equality and practise their faith without discrimination and stigmatisation; whereas this can lead to a feeling of vulnerability, aggressive anger, frustration, loneliness and isolation from society; |

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| J. | whereas combating radicalisation cannot be limited to Islamic radicalisation; whereas religious radicalisation and violent extremism also affect the entire African continent; whereas political radicalisation also affected Europe in 2011, in Norway with the attacks perpetrated by Anders Behring Breivik; |

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| K. | whereas the vast majority of terrorist attacks in EU countries have for years been perpetrated by separatist organisations; |

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| L. | whereas, according to Europol in 2013 there were 152 terrorist attacks in the EU, of which two were ?religiously motivated? and 84 were motivated by ethno-nationalist or separatist beliefs, while in 2012 there were 219 terrorist attacks in the EU, of which six were ?religiously motivated?; |

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| M. | whereas combating terrorism and preventing the radicalisation and recruitment of European citizens by terrorist organisations still falls essentially within the sphere of competence of the Member States, but European cooperation is essential for the efficient and effective exchange of information between law enforcement agencies in order to combat the cross-border nature of the threat posed by terrorists; whereas a concerted European approach is thus necessary and will provide added value in terms of coordinating or harmonising where appropriate the legislation applying in an area in which European citizens are free to move, and of making prevention and counterterrorism effective; whereas combating trafficking in firearms should be a priority for the EU in fighting serious and organised international crime; |

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| N. | whereas human rights must be at the core of the Union?s policies on counterterrorism and prevention of radicalisation, while it must be ensured that the right balance is struck between public safety and respect for fundamental rights, including the rights to security, privacy, and freedom of expression, religion, and association; |

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| O. | whereas Jewish communities are the target of terrorist and anti-Semitic attacks, leading to an increasing perception of insecurity and fear within those communities in Europe; |

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| P. | whereas the rise of terrorism and foreign fighters has increased intolerance towards ethnic and religious communities in several countries in Europe; considering that a holistic approach to fighting discrimination in general and Islamophobia and anti-Semitism in particular, are complementary in relation to working for the specific prevention of terrorist extremism; |

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| Q. | whereas a number of instruments already exist in Europe to address the radicalisation of European citizens and whereas the EU and its Member States should make full use of these tools and look to enhancing them in order to reflect the current challenges the EU and Member States face; whereas there remains a reluctance on the part of Member States to cooperate in sensitive areas, such as information and intelligence sharing; whereas, given the increasing significance of terrorist radicalisation, which is in total contradiction with European values, new means must be implemented, and this must take place in compliance with the Charter of Fundamental Rights; |

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| R. | whereas it is essential that in all measures undertaken by the Member States and the EU fundamental rights and civil liberties are respected, namely the right to private life, the right to security, the right to data protection, the presumption of innocence, the right to a fair trial and due process, freedom of expression and freedom of religion; whereas the security of European citizens must preserve their rights and liberties; whereas, indeed, these two principles are two sides of the same coin; |

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| S. | whereas the extent to which Member States assume responsibility to counteract the risk of radicalisation and the prevention of recruitment by terrorist organisations can vary greatly from one Member State to another; whereas, while some Member States have already taken effective measures, others are lagging behind in their action to tackle this phenomenon; |

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| T. | whereas concerted European action is required as a matter of urgency to prevent the radicalisation and recruitment of European citizens by terrorist organisations in order to contain this growing phenomenon and thus stem the flow of departures by European citizens to conflict zones, deradicalise the home-stayers, and prevent other terrorist acts from being committed; |

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| U. | whereas this is an international phenomenon and lessons may be learned from many parts of the world; |

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| V. | whereas the important thing now is to put greater emphasis on and invest in preventive rather than reactive measures to address the radicalisation of European citizens and their recruitment by terrorist organisations; whereas a strategy to counter extremism, radicalisation and terrorist recruitment within the EU can only work if it is developed in parallel to a strategy of integration and social inclusion and of reintegration and deradicalisation of so-called ?foreign fighters? who are returnees; |

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| W. | whereas certain forms of internet use is conducive to radicalisation, enabling fanatics throughout the world to connect with each other and recruit vulnerable individuals without any physical contact whatsoever and in a manner that is difficult to trace; |

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| X. | whereas it is essential to clearly distinguish behaviour aimed at preparing and/or supporting terrorist attacks or acts by or opinions of extremists that lack the mens rea and actus reus; |

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| Y. | whereas terrorist radicalisation appears to be attributable to factors that are both internal and external to the Union; |

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| Z. | whereas combating terrorist radicalisation must form part of a global approach that aims to ensure an open Europe and is based on a set of common values; |

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| AA. | whereas youth radicalisation should not be disconnected from its social and political context and must be investigated within the broader scope of sociology of conflict and violence studies; |

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| AB. | whereas the causes of terrorist radicalisation have not been studied to a sufficient extent; whereas lack of integration cannot be perceived as the primary cause of terrorist radicalisation; |

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| AC. | whereas, according to the European Court of Justice, the fact that a person has been a member of an organisation which, because of its involvement in terrorist acts, is on the list forming the Annex to Common Position 2001/931/CFSP and that the person has actively supported the armed struggle waged by that organisation does not automatically constitute a serious reason for considering that the person concerned has committed a ?serious non-political crime? or ?acts contrary to the purposes and principles of the United Nations?; on the other hand, where there are serious reasons for considering that a person has committed such a crime or has been guilty of such acts this is conditional on an assessment on a case-by-case basis of the specific facts and on whether individual responsibility for carrying out those acts can be attributed to the person concerned; |

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| AD. | whereas in order to be able to revoke a residence permit granted to a refugee on the ground that the refugee supports such a terrorist organisation, the competent authorities are nevertheless obliged to carry out, under the supervision of the national courts, an individual assessment of the specific facts concerning the actions of both the organisation and the refugee in question; |

I.    European added value in the prevention of terrorism

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|  | 1. | In the light of the dramatic events in Paris, condemns the murderous attacks, and expresses its condolences to and solidarity with the victims and their families, while reaffirming the need to take a stand against violence; condemns also the use of stereotypes and xenophobic and racist discourse and practices by individuals and collective authorities which, directly or indirectly, link the terrorist attacks to the refugees who are currently fleeing their countries in search of a safer place, escaping from war and acts of violence which occur in their home countries on a daily basis; |

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|  | 2. | Emphasises that terrorism cannot and should not be associated with any specific religion, nationality or civilisation; |

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|  | 3. | Expresses its concern that, unless the conditions conducive to the spread of terrorism are addressed, the phenomenon of EU citizens travelling to other countries to join jihadist or other extremist groups, as well as the specific security risk they present when returning to the EU and the neighbouring countries, is likely to worsen in the years ahead, especially given the ongoing military escalation in the MENA region; calls for a comprehensive study on the effectiveness of national and EU measures aimed at preventing and combating terrorism; |

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|  | 4. | Calls on the Commission to establish as a priority an action plan to implement and evaluate the EU strategy for combating radicalisation and recruitment to terrorism, on the basis of the exchange of best practice and the pooling of skills within the European Union, the evaluation of measures undertaken in the Member States and cooperation with third countries and international organisations, on a basis of full respect for international human rights conventions and through a multistakeholder and multisectoral participative and consultative approach; takes the view that the Commission should contribute to and support the development by Member States of an effective and intensive communication strategy on preventing the radicalisation and recruitment of European citizens and of non-EU nationals residing in the EU by terrorist organisations; |

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|  | 5. | Calls on the Member States to coordinate their strategies and share the information and experience at their disposal, to implement good practices at both national and European level, to cooperate with a view to taking new steps in combating radicalisation and recruitment to terrorism by updating national prevention policies and putting networks of practitioners in place on the basis of the ten priority areas for action as identified in the EU strategy for combating radicalisation and recruitment to terrorism; stresses the importance of fostering and strengthening crossborder cooperation among law enforcement authorities to this regard, and highlights the crucial importance of providing adequate resources and training to police forces working on the ground; |

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|  | 6. | Requests the full disclosure of the Council?s action plans and guidelines regarding the ongoing EU Strategy for Combating Radicalisation and Recruitment to Terrorism; |

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|  | 7. | Considers that the additional protocol to the Council of Europe Convention on the Prevention of Terrorism, as well as resolution 2178 of the UN Security Council, should be made use of by the Member States and the European institutions with a view to agreeing on a common definition for the criminalisation of persons to be considered as ?foreign fighters?; calls on the Commission to carry out in-depth studies of the primary causes, the process, and the various influences and factors which lead to radicalisation with the support of the new Centre of Excellence of the Radicalisation Awareness Network (RAN); |

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|  | 8. | Calls on the Commission to prepare, in close cooperation with Europol and the counterterrorism coordinator, an annual report on the state of security in Europe, including with regard to the risks of radicalisation and the consequences for the safety of people?s lives and physical integrity in the EU, and to report back to Parliament on an annual basis; |

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|  | 9. | Stresses the importance of making the fullest use of existing instruments to prevent and combat the radicalisation and recruitment of European citizens by terrorist organisations; highlights the importance of using all relevant internal and external instruments in a holistic and comprehensive manner; recommends that the Commission and the Member States make use of available means, particularly under the Internal Security Fund (ISF), via the ISF Police instrument, in order to support projects and measures aimed at preventing radicalisation; stresses the major role which can be played by the RAN and its Centre of Excellence in taking on this objective of counteracting the radicalisation of European citizens in a comprehensive way; requests that this network receive better publicity and visibility among players combating radicalisation; |

II.    Preventing violent extremism and terrorist radicalisation in prisons

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|  | 10. | Stresses that prisons remain one of several environments which are a breeding ground for the spread of radical and violent ideologies and terrorist radicalisation; calls on the Commission to encourage the exchange of best practices among the Member States in order to counter the increase of terrorist radicalisation in Europe?s prisons; encourages Member States to take immediate action against prison overcrowding, which is an acute problem in many Member States which significantly increases the risk of radicalisation and reduces the opportunities for rehabilitation; recalls that public youth protection institutions or detention or rehabilitation centres may also become places of radicalisation for minors, who constitute a particularly vulnerable target; |

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|  | 11. | Calls on the Commission to propose guidelines based on best practices on measures to be implemented in European prisons aimed at the prevention of radicalisation and of violent extremism, with full respect for human rights; points out that the separation of inmates who are found to have adhered to violent extremism or have already been recruited by terrorist organisations from other inmates as a possible measure to prevent terrorist radicalisation from being imposed on others through intimidation and to contain radicalisation in prisons; warns, however, that any such measures should be imposed on a case-by-case basis only and be based on a judicial decision and subject to review by the competent judicial authorities; further recommends that the Commission and Member States examine the evidence and experience concerning the practice of separation in prisons with the objective of containing the spread of radicalisation; is of the view that this assessment must feed into the development of practices in national prison systems; recalls, however, that these measures should be proportionate and in full compliance with the fundamental rights of the inmate; |

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|  | 12. | Supports the introduction of specialised training for all prison staff, as well as partners operating in the penal system, religious staff and NGO personnel who interact with prisoners, in order to teach them to detect at an early stage, prevent and deal with behaviour tending to radical and extremist behaviour; stresses the importance of appropriately training and recruiting religious, philosophical and secular representatives so that they can not only adequately meet prisoners? cultural and spiritual needs in prisons, but also contribute to countering potential radical discourse; |

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|  | 13. | Encourages the establishment of educational programmes with adequate funding in European prisons in order to promote critical thinking, religious tolerance, and reintegration into society of inmates, but also to offer special assistance to those who are young, vulnerable or more susceptible to radicalisation and recruitment by terrorist organisations, and thus on a basis of the utmost respect for the human rights of inmates; considers that accompanying measures should also be offered subsequently to release from prison; |

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|  | 14. | Recognizes that central to such efforts is a prison environment which fully respects the human rights of inmates and complies with international and regional standards, including the UN Standard Minimum Rules for the Treatment of Prisoners; |

III.    Preventing online terrorist radicalisation

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|  | 15. | Notes that the internet generates specific challenges given its global and cross-border nature, thus giving rise to legal gaps and jurisdictional conflicts and allowing recruiters and those who are radicalised to communicate remotely and easily from all corners of the world with no physical borders, no need to establish a base, and no need to seek sanctuary in a particular country; recalls that the internet and social networks are significant platforms for the fuelling of radicalisation and fundamentalism, as they facilitate the rapid and large-scale global distribution of hate messages and praise for terrorism; expresses concern at the impact that such messages praising terrorism have especially on younger people, who are particularly vulnerable; underlines the role of education and public awareness campaigns in preventing radicalisation online; affirms its attachment to freedom of expression not only offline but also online, and believes this should underpin all regulatory action regarding the prevention of radicalisation via the internet and social media; notes the dialogue launched at European level with internet companies with a view to preventing the online distribution of illegal content and erasing such content swiftly, in line with EU law and national legislation and in strict compliance with freedom of expression; calls for an effective strategy for the detection and removal of illegal content inciting to violent extremism, while respecting fundamental rights and freedom of expression, and in particular for contributing to the dissemination of effective discourse to counter terrorist propaganda; |

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|  | 16. | Recalls that internet and social media companies and service providers have a legal responsibility to cooperate with Member State authorities by ***deleting*** any illegal content that spreads violent extremism, expeditiously and with full respect for the rule of law and fundamental rights, including freedom of expression; believes that Member States should consider legal actions, including criminal prosecutions, against internet and social media companies and service providers which refuse to comply with an administrative or judicial request to ***delete*** illegal content or content praising terrorism on their internet platforms; believes that refusal or deliberate failure by internet platforms to cooperate, thus allowing such illegal content to circulate, should be considered an act of complicity that can be equated to criminal intent or neglect and that those responsible should in such cases be brought to justice; |

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|  | 17. | Calls on the competent authorities to ensure that websites that incite hatred are monitored more strictly; |

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|  | 18. | Is convinced that the internet is an effective platform for spreading the discourse of respect of human rights and ***opposition*** to violence; considers that the internet industry and service providers should cooperate with Member State authorities and civil society to promote powerful and attractive narratives to counter hate speech and radicalisation online, which should be based on the Charter of Fundamental Rights of the European Union; calls on the digital platforms to cooperate with the Member States, civil society and organisations whose fields of expertise are terrorist deradicalisation or evaluation of hate speech, in order to take part in spreading prevention messages calling for the development of critical thinking and for a process of deradicalisation, as well as identifying innovative legal ways to counter praise of terrorism and hate speech, thereby making online radicalisation more difficult; calls on the Commission and the Member States to encourage the development of such counter-narratives online, and to work closely with civil society organisations for the purposes of reinforcing the channels for distributing and promoting democratic and non-violent discourse; |

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|  | 19. | Supports the implementation of youth awareness programmes concerning online hate speech and the risks that it represents, and of programmes promoting media and internet education; supports the implementation of training programmes with a view to mobilising, training and creating networks of young activists to defend human rights online; |

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|  | 20. | Takes the view that building a counter-narrative, including in third countries, is one of the keys to combating the appeal of terrorist groups in the MENA region; calls on the EU to increase its support for initiatives such as the SSCAT (Syria ***Strategic*** Communication Advisory Team) and to promote the deployment and financing of projects of this kind in third countries; |

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|  | 21. | Considers that the internet industry and service providers must henceforth make it possible to promote radicalisation prevention messages aimed at countering messages that praise terrorism; believes that a special European cooperation unit should be created within Europol with a view to sharing good practices in the Member States, while also permanently cooperating with internet operators, in order to highlight messages that oppose hate speech and praise for terrorism, thereby making online radicalisation more difficult; calls on the Commission and the Member States to support the effective use of counter-narratives and mitigation measures via the internet; |

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|  | 22. | Supports the introduction of measures enabling all internet users to easily and quickly flag illegal content circulating on the internet and on social media networks and to report it to the competent authorities, including through hotlines, while respecting human rights, especially freedom of expression, and EU and national legislation; |

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|  | 23. | Raises serious concerns over the increasing use of encryption technologies by terrorist organisations that make their communications and their radicalisation propaganda impossible for law enforcement to detect and read, even with a court order; calls on the Commission to urgently address these concerns in its dialogue with internet and IT companies; |

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|  | 24. | Considers that every Member State should set up a special unit tasked with flagging illegal content on the internet and with facilitating the detection and removal of such content; welcomes the creation by Europol of the Internet Referral Unit (IRU), to be responsible for detecting illegal content and supporting Member States in this regard, while fully respecting the fundamental rights of all parties involved; recommends that such units should also cooperate with the EU anti-terrorism coordinator and the European Counter Terrorist Centre within Europol, and with civil society organisations active in this field; further encourages Member States to cooperate with each other and with the relevant EU agencies on these matters; |

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|  | 25. | Welcomes the establishment with effect from 1 January 2016 of the European Counter-Terrorism Centre (ECTC), of which the European unit tasked with flagging content will be a part; stresses the need to provide the financial resources required to deliver the additional tasks conferred on Europol in connection with the establishment of the European Counter Terrorist Centre; calls for Parliament to be duly involved in the creation of this centre and in its terms of reference, tasks and finance; |

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|  | 26. | Believes that online radicalisation cannot be stamped out without reinforcing the tools available to the EU to combat cybercrime; recommends that the mandate and resources of the European Cybercrime Centre (EC3) should be strengthened alongside those of Europol and Eurojust, so that the EC3 can play an effective role in better detecting and tackling online threats and better identifying the means used by terrorist organisations; recalls the need to have properly trained experts at Europol as well as in the Member States in order to respond to this specific threat; calls on the VP/HR to reorganise the EU Situation Centre (SitCen) and the Intelligence Centre (IntCen) and ensure their coordination with the Anti-Terrorism Coordinator in order to better track online criminal activities and the spread of hate speech related to radicalisation and terrorism; urges the Member States to significantly increase information sharing among themselves and with the relevant EU structures and agencies; |

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|  | 27. | Considers that all EU and national measures aimed at preventing the spread of violent extremism among European citizens and their recruitment by terrorist organisations should respect EU fundamental rights and the relevant case law of the European Court of Justice and European Court of Human Rights, including respect for the principle of the presumption of innocence, the principle of legal certainty, the right to a fair and impartial trial, the right of appeal and the principle of non-discrimination; |

IV.    Preventing radicalisation through education and social inclusion

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|  | 28. | Stresses that schools and education have an important role to play in preventing radicalisation; recalls the crucial role that schools play in helping to promote integration within society and develop critical thinking, and to promote non-discrimination; calls on the Member States to encourage educational establishments to provide courses and academic programmes aimed at strengthening understanding and tolerance, especially with regard to different religions, the history of religions, philosophies and ideologies; stresses the need to teach fundamental values and democratic principles of the Union such as human rights; highlights that it is Member States' duty to guarantee that their education systems respect and promote EU values and principles and that their functioning does not contradict the principles of non-discrimination and integration; |

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|  | 29. | Urges the Member States to ensure that educational programmes on internet use exist in every school (at both primary and secondary level), aimed at educating and training responsible, critical and law-abiding internet users; |

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|  | 30. | Stresses the importance of empowering teachers to take an active stand against all forms of discrimination and racism; emphasises the essential role of education and of competent and supportive teachers, not only in strengthening social ties, encouraging a sense of belonging, developing knowledge, skills and competences, embedding fundamental values, and enhancing social, civic and intercultural competences, critical thinking and media literacy, but also in helping young people ? in close cooperation with their parents and families ? to become active, responsible and open-minded members of society; emphasises that schools can build students? resilience to radicalisation by providing a safe environment and time for debating and exploring controversial and sensitive issues; points out that adolescents are a particularly vulnerable group, as they are at a difficult stage in their lives when they are developing their value system and seeking meaning, and are at the same time highly impressionable and easily manipulated; recalls that groups as well as individuals can be radicalised, and recognises that the development of response to individual and to group radicalisation can be different; emphasises the role society has to play in giving young people better prospects and a purpose in life, in particular by means of high-quality education and training; underlines the role of educational institutions in teaching youth to recognise and manage risks and make safer choices, and in promoting a strong sense of belonging, shared community, care support and responsibility for others; stresses the need to use the various opportunities that vocational education and academic courses offer in order to expose young people to the diverse national, regional, religious and ethnic identities existing in Europe; |

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|  | 31. | Emphasises that Europe?s diversity and its multicultural communities are integral to its social fabric and are an essential cultural asset; considers that any policy for tackling radicalisation must be sensitive and proportionate in order to respect and strengthen the diverse social fabric of communities; |

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|  | 32. | Highlights the importance of combining deradicalisation programs with measures such as establishing partnerships with community representatives, investment in social and neighbourhood projects aimed at disrupting economic and ***geographical*** marginalisation, and mentoring schemes for alienated and excluded young people considered at risk of radicalisation; recalls that all Member States are obliged to diligently implement EU anti-discrimination instruments and to take effective measures to address discrimination, hate speech and hate crimes as part of the counter-radicalisation strategy; |

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|  | 33. | Calls on the Commission to support Member States in carrying out a communication campaign to raise the awareness of young people and of supervisory staff as regards issues of radicalisation; stresses that training and awareness-raising campaigns should give priority to early intervention, in order to protect individuals and avoid any risk of radicalisation; calls on the Member States to provide educational staff with special training and appropriate tools enabling them to detect any worrying changes in behaviour, identify circles of complicity which amplify the phenomenon of radicalisation through imitation, and properly supervise young people who are at risk of being recruited by terrorist organisations; further encourages the Member States to invest in and financially support specialised facilities in the proximity of schools that serve as contact points enabling young people, but also their families and teachers and relevant experts, to engage in extracurricular activities open to families, including psychological counselling; stresses the importance of there being clear guidance in this area so as not to compromise the primary role of teachers, youth workers and others for whom the wellbeing of the individual is the primary concern, since excessive intervention by public authorities could be counterproductive; |

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|  | 34. | Points out the opportunities offered to Member States and to media education experts by the ?Creative Europe? programme; notes that the EU?s programmes in the areas of education, culture, social activities and sport constitute essential pillars of support for the actions taken by Member States to tackle inequalities and prevent marginalisation; stresses the importance of developing new actions to promote European values in education, as part of the European ***strategic*** framework for cooperation in education and training; insists therefore, among other things, on targeting the transmission and practice of civic values throughout the programmes Europe for citizens, Erasmus + and Creative Europe; |

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|  | 35. | Stresses that it is vital to engage in an intercultural dialogue with the various communities, leaders and experts, with a view to helping achieve better understanding and prevention of radicalisation; stresses the responsibility and the important role of all religious communities in countering fundamentalism, hate speech and terrorist propaganda; draws the Member States? attention to the issue of the training of religious leaders ? which ought, where possible, to take place in Europe ? with regard to preventing incitement to hatred and violent extremism in places of worship in Europe, and to ensure that those leaders share European values, and also of training the representatives of religions, philosophies and secular society working inside correctional facilities; notes however, that while places of worship may provide contact points, much of the indoctrination and recruitment process takes place in more informal settings or on the internet; |

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|  | 36. | Highlights the crucial importance of making all actors aware of their responsibility to prevent radicalisation, whether at local, national, European or international level; encourages the establishment of close cooperation between all civil society actors at national and local level, and of greater cooperation between actors on the ground, such as associations and NGOs, in order to support victims of terrorism and their families, as well as individuals who have been radicalised and their families; calls, in this regard, for the introduction of training adapted to those actors on the ground and for additional financial support for them; stresses, however, that funding for NGOs and other civil society actors should be separate from financial support for counterterrorism programmes; |

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|  | 37. | Considers that civil society and local actors have a crucial role to play in the development of projects adapted to their localities or organisations, in addition to their role as an integrating factor for those European citizens who feel at odds with society and are tempted by terrorist radicalisation; believes it essential to raise awareness among and inform and train frontline workers (teachers, educationalists, police officers, child protection workers and workers in the healthcare sector) in order to strengthen local capacity to combat radicalisation; feels that the Member States should support the establishment of structures facilitating, in particular, the guidance of young people, as well as exchanges with families, schools, hospitals, universities, etc.; recalls that such measures can only be implemented through long-term social investment programmes; notes that associations and organisations in this field, which do not bear the mark of governments, can achieve excellent results in the reintegration into society of citizens who had been on the path to radicalisation; |

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|  | 38. | Considers it vital to set up an alert system for assistance and guidance in every Member State which would allow families and community members to obtain support or to easily and swiftly flag the development of sudden behavioural change that might signal a process of terrorist radicalisation or an individual?s departure to join a terrorist organisation; notes that in this regard, ?hotlines? have been successful and are enabling the reporting of persons among friends and families suspected of being radicalised, but are also helping friends and families to deal with this destabilising situation; calls on the Member States to look into the possibility of establishing such a system; |

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|  | 39. | Recalls that the rise of Islamophobia in the European Union contributes to the exclusion of Muslims from society, which could create fertile ground for vulnerable individuals to join violent extremist organisations; considers that Islamophobia in Europe is in turn manipulated by organisations such as Da?esh for propaganda and recruitment purposes; recommends, therefore, the adoption of a European framework for the adoption of national strategies to combat Islamophobia, in order also to tackle discrimination that hinders access to education, employment and housing; |

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|  | 40. | Stresses that recent research points to the growing number of young women who have been radicalised and recruited by terrorist organisations, providing evidence of their role in violent extremism; considers that the EU and the Member States should take gender into account at least to some extent in developing strategies for the prevention of radicalisation; calls on the Commission to support generalised programmes aiming to engage young women in their endeavours for greater equality and to provide support networks through which they can safely have their voices heard; |

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|  | 41. | Stresses the importance of the role of women in the prevention of radicalisation; |

V.    Stepping up the exchange of information on terrorist radicalisation in Europe

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|  | 42. | Reiterates its commitment to work towards the finalisation of an EU directive on passenger name records (PNR) by the end of 2015 and to guarantee that such a directive will be compliant with fundamental rights and free from any discriminatory practices based on ideological, religious or ethnic stigmatisation, and will fully respect the data protection rights of EU citizens; recalls, however, that the EU PNR directive will be just one measure in the fight against terrorism, and that a holistic, ambitious and comprehensive strategy on counterterrorism and the fight against organised crime, involving foreign policy, social policy, education policy, law enforcement and justice, is required to prevent the recruitment of European citizens by terrorist organisations; |

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|  | 43. | Calls on the Commission to enhance the EU's expertise regarding the prevention of radicalisation by establishing a European network that incorporates the information provided by RAN and by the Policy Planner's Network on Polarisation and Radicalisation (PPN), as well as that provided by experts specialised in a wide array of disciplines across the social sciences; |

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|  | 44. | Insists on the absolute necessity of stepping up the expedient and effective exchange of relevant information between the law enforcement authorities in the Member States and between Member States and the relevant agencies, in particular by optimising the use of and contributions to the Schengen Information System (SIS) and Visa Information System (VIS), Europol?s secure information exchange network application (SIENA) and Europol's ?Focal Point Travellers? on European citizens who have been radicalised; stresses that stepping up the exchange of information between law enforcement authorities will entail increasing trust between Member States, as well as reinforcing the role and the effective resourcing of EU entities such as Europol, Eurojust and the European Police College (Cepol); |

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|  | 45. | Calls for the EU to include the issue of terrorist radicalisation in the training provided by Cepol; |

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|  | 46. | Stresses the importance of implementing a specialised European training programme for those working in the justice system, to raise their awareness of the different forms of radicalisation; |

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|  | 47. | Stresses that improved cooperation between Member States aimed at countering the radicalisation and recruitment of European citizens is also characterised by intensive exchanges and cooperation between their judicial authorities and with Eurojust; notes that better reporting at European level on the criminal records of terrorist suspects would help speed up their detection and make it easier for them to be properly monitored, either when they leave or when they return to the EU; encourages, therefore, the reform and better use of the European Criminal Records Information System (ECRIS); urges the Commission to assess the feasibility and added value of establishing a European Police Records Index System (EPRIS); underlines that international treaties and the EU law, as well as fundamental rights, and in particular the protection of personal data, must be respected in such information exchanges and that effective democratic oversight of security measures is essential; |

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|  | 48. | Considers that combating the trafficking of weapons should be a priority for the EU in fighting serious and organised international crime; believes, in particular, that cooperation needs to be strengthened further as regards information exchange mechanisms and the traceability and destruction of prohibited weapons; |

VI.    Strengthening deterrents against terrorist radicalisation

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|  | 49. | Believes that measures aimed at preventing the radicalisation of European citizens and their recruitment by terrorist organisations will not be fully effective until they are accompanied by an effective, dissuasive and articulated range of criminal justice measures in all Member States; considers that through effectively criminalising terrorist acts carried out abroad with terrorist organisations the Member States will equip themselves with the tools needed to eliminate terrorist radicalisation among European citizens while making full use of the existing EU police and judicial cooperation tools in criminal matters; considers that law enforcement and justice authorities (judges and prosecutors) should have sufficient capacity to prevent, detect and prosecute those acts, and should be adequately and continuously trained on terrorism-related crimes; |

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|  | 50. | Calls for reinforced capacities for Eurojust's Coordination Centre, which should play a critical role in promoting the joint action of Member States? judicial authorities in the collection of evidence and enhance the effectiveness of prosecutions of crimes related to terrorism; is, in this regard, of the view that more use should be made of the Joint Investigation Teams instrument, both among Member States and between Member States and third countries with which Eurojust has established cooperation agreements; |

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|  | 51. | Notes that prosecuting terrorist acts carried out in third countries by European citizens or by non-EU nationals residing in the EU requires that the collection of evidence in third countries should be possible, on a basis of full compliance with human rights; calls, therefore for the EU to work on the setting-up of judicial and law enforcement cooperation agreements with third countries to facilitate the collection of evidence in said countries, provided that strict legal standards and procedures, the rule of law, international law and fundamental rights are safeguarded by all parties and under judicial control; recalls, therefore, that the collection of evidence, interrogation and other such investigative techniques must be carried out subject to strict legal standards and must comply with EU laws, principles and values and international human rights standards; warns, in this connection, that the use of cruel, inhuman and degrading treatment, torture, extra-judicial renditions and kidnapping is prohibited under international law and may not take place for the purpose of collecting evidence of criminal offences committed inside the territory of the EU or outside its territory by EU nationals; |

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|  | 52. | Welcomes the deployment of security/counterterrorism experts in a number of key EU delegations, with a view to strengthening their capacity to contribute to European counterterrorism efforts and to liaising more effectively with relevant local authorities, while further building up counterterrorism capacity within the European External Action Service (EEAS); |

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|  | 53. | Encourages, therefore, the establishment of cooperation agreements between Eurojust and third countries, on the lines of those already established with the US, Norway and Switzerland, while stressing nevertheless the need to ensure full compliance with international human rights law and EU data protection and privacy rules; points out that priority in establishing such agreements should be given to countries that are also particularly hit by terrorism, such as MENA countries; additionally, is of the view that the deployment of Eurojust liaison prosecutors in the relevant countries, especially in the southern neighbourhood, would promote more exchange of information and would enable better cooperation in order to effectively fight terrorism while respecting human rights; |

VII.    Preventing the departure and anticipating the return of radicalised European citizens recruited by terrorist organisations

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|  | 54. | Reiterates that the EU must step up its external border controls as a matter of urgency, on a basis of full compliance with fundamental rights; stresses that it will be impossible to effectively track entry and exit in the EU unless Member States implement the mandatory and systematic controls foreseen at the EU?s external borders; calls on the Member States to make good use of existing instruments such as the SIS and the VIS, including with reference to stolen, lost and falsified passports; also considers that, to this end, one of the EU?s priorities must be to better enforce the Schengen Code; |

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|  | 55. | Invites the Member States to give their border guards systematic access to the Europol information system, which may contain information on people suspected of terrorism, foreign fighters and preachers of hate; |

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|  | 56. | Calls on the Member States to share good practices with regard to exit and return checks and the freezing of financial assets of citizens, in the context of preventing citizens from taking part in terrorist activities in conflict areas in third countries and of how to manage their return to the EU; stresses in particular that Member States should be enabled to confiscate the passports of their citizens planning to join terrorist organisations, at the request of the competent judicial authority, according to their national laws and in full compliance with the principle of proportionality; considers that the restriction of someone's freedom of movement, which is a fundamental right, can only be decided if the necessity and proportionality of the measure are properly evaluated by a judicial authority; further supports criminal proceedings against suspects of terrorism who become involved in terrorist activities on their return to Europe; |

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|  | 57. | Calls for international contributions to the funding mechanism endorsed by the United Nations Development Programme (UNDP) to facilitate the immediate stabilisation of areas cleared of Da?esh; |

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|  | 58. | Calls on the VP/HR and the Council to find a clear language of condemnation for the decade-long financial and ideological support provided by some governments and influential individuals in the Gulf countries for extremist Islamist movements; calls on the Commission to review the EU?s relations with third countries in order to more effectively combat material and immaterial support for terrorism; recalls that, in the context of the current revision of the European Neighhbourhood Policy (ENP), the security dimension and the capacity of ENP tools to contribute to improving partners? resilience and their capabilities to provide for their own security, on a basis of respect for the rule of law, must be strengthened; |

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|  | 59. | Reiterates that making good use of existing instruments such as the SIS, SIS II and VIS systems, Interpol?s SLTD system, and Europol's Focal Point TRAVELLERS constitutes the first step in stepping up external border security in order to identify EU citizens and foreigners residing in the EU who may be leaving or returning from a conflict area for the purpose of committing terrorist acts or may receive terrorist training or take part in non-conventional armed conflict on behalf of terrorist organisations; urges Member States to improve cooperation and sharing of information regarding suspected ?foreign fighters? with Member States at the EU?s external borders; |

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|  | 60. | Calls on the Member States to ensure that any foreign fighters are put under judicial control and, where necessary, in administrative detention upon their return to Europe, until such time as due judicial prosecution takes place; |

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|  | 61. | Is seriously convinced that any policymaking in the field of terrorism and radicalisation needs to pool the expertise and assets of the internal and external dimensions of EU policy; believes, in this regard, that it is on the basis of such a holistic approach that an adequate response may be designed to fight terrorism and terrorist recruitment in the EU and its neighbourhood; calls, therefore, on both the Commission and the EEAS, under the leadership and guidance of both the VP/HR and the First Vice-President of the Commission and with the support of the Anti-Terrorism Coordinator, to work together in designing a policy approach that effectively combines the tools of social policy (including employment, integration and anti-discrimination), humanitarian aid, development, conflict resolution, crisis management, trade, energy and any other policy area that might have an internal/external dimension; |

VIII.    Strengthening links between internal and external security in the EU

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|  | 62. | Stresses the vital importance of the EU establishing close cooperation with third countries, notably transit countries and destination countries, insofar as this is possible, in respect of EU laws, principles and values and international human rights, in order to be able to identify EU citizens and non-European residents leaving to fight for terrorist organisations or returning thereafter; also stresses the need to strengthen political dialogue and shared action plans to combat radicalisation and terrorism, in the context of bilateral relations and with regional organisations such as the African Union and the League of Arab States; |

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|  | 63. | Notes VP/HR Mogherini?s willingness to support projects for countering radicalisation in third countries, including Jordan, Lebanon and Iraq and the Sahel/Maghreb region, as stated in the report on the implementation of measures following the European Council meeting of 12 February 2015; stresses that it must now be ensured that these projects receive the necessary funding as soon as possible; |

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|  | 64. | Calls on the EU to increase its cooperation with regional partners in order to curb arms trafficking, targeting in particular the countries where terrorism originates, and to follow closely the export of armaments that could be exploited by terrorists; also calls for foreign policy tools and engagement with third countries to be strengthened with a view to countering the financing of terrorist organisations; draws attention to the conclusion of the G20 Summit of 16 November 2015, which calls on the Financial Action Task Force (FATF) to act more swiftly and efficiently when it comes to cutting off funding for terrorist organisations; |

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|  | 65. | Encourages the EU to conduct targeted and upgraded security and counter-terrorism dialogues with Algeria, Egypt, Iraq, Israel, Jordan, Morocco, Lebanon, Saudi Arabia, Tunisia and the Gulf Cooperation Council, including on past or present state involvement in support of terrorist activities; also believes that cooperation with Turkey should be enhanced in line with the General Affairs Council conclusions of December 2014; |

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|  | 66. | Calls on the Council to keep the EU Regional Strategy for Syria and Iraq and the Counter-Terrorism/Foreign Fighters Strategy, adopted on 16 March 2015, under constant review and development in the light of the developing security situation in the EU?s southern neighbourhood, alongside preventive and other initiatives such as the Commission?s RAN; calls further on the Member States to promote common respect and understanding as crucial elements within the framework of the fight against terrorism, both within the EU and in its Member States, as well as in third countries; |

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|  | 67. | Is convinced that for such enhanced cooperation to be established, the Commission, and the EEAS in particular, need to make greater efforts in terms of increasing and improving expertise in the areas of fighting terrorism, non-conventional armed conflict and radicalisation, and also to reinforce and diversify language skills, for instance for Arabic, Urdu, Russian and Mandarin, given that such skills are currently seriously lacking in the European information and intelligence services; considers it essential that the EU?s call to combat terrorism, radicalisation and violence can be heard beyond its own borders, through ***strategic*** communication that is both incisive and effective; |

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|  | 68. | Supports greater international cooperation and information-sharing on the part of national intelligence services in order to identify EU citizens who are at risk of becoming radicalised and being recruited and travelling to join jihadist or other extremist groups; stresses that countries in the MENA region and the Western Balkans must be supported in their efforts to stem the flow of foreign fighters and to prevent jihadist organisations taking advantage of the political instability within their borders; |

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|  | 69. | Acknowledges that radicalisation and recruitment of individuals by terrorist networks is a global phenomenon; believes that the response to this phenomenon ought to be international and not just local or European; considers it necessary, therefore, to strengthen cooperation with third countries to identify recruitment networks and increase security at the borders of the countries concerned; reiterates also that cooperation with key partners that are facing similar challenges has to be stepped up through diplomatic, political dialogue and intelligence cooperation; |

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|  | 70. | Reiterates that the global reach of terrorism requires an effective and united international response in order to successfully prevent the trafficking of weapons to countries that threaten international peace and security; |

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|  | 71. | Welcomes the Commission's allocation in April 2015 of a budget of EUR 10 million to finance a programme of assistance to partner countries to counter radicalisation in the Sahel/Maghreb and stem the flow of foreign fighters from North Africa, the Middle East and the Western Balkans (a first tranche of EUR 5 million to fund technical assistance to enhance the capacities of criminal justice officials to investigate, prosecute and adjudicate cases of foreign fighters or would-be foreign fighters; a second tranche of EUR 5 million to finance the countering of radicalisation programmes in the Sahel/Maghreb); stresses the importance of strictly monitoring the proper use of these funds to ensure that they do not finance projects linked to proselytism, indoctrination and other extremist purposes; |

IX.    Promoting the exchange of good practices on deradicalisation

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|  | 72. | Considers that a comprehensive policy to preventing the radicalisation and recruitment of EU citizens by terrorist organisations can only be successfully put in place if accompanied by proactive deradicalisation and inclusion policies; calls for the EU, therefore, to facilitate the sharing by Member States and with third countries which have already acquired experience and achieved positive results in this area of good practice on the setting-up of deradicalisation structures to prevent EU citizens and non-EU nationals legally residing in the EU from leaving the EU or to control their return to it; recalls the need to offer support to the families of such individuals as well; |

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|  | 73. | Suggests that Member States examine the idea of including mentors or counselling assistants in the process of deradicalising EU citizens who have returned from conflict areas disillusioned by what they experienced there, so as to support them in their reintegration into society through appropriate programmes; underlines the need for better exchange of best practices among Member States in that respect; stresses that mentors should be willing to contribute to specific programmes through appropriate training; |

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|  | 74. | Calls for an EU-level structured communication campaign to be launched, making use of the cases of former European ?foreign fighters? who have successfully undergone deradicalisation and whose traumatic experiences help expose the deeply perverse and fallacious religious dimension of joining terrorist organisations such as ISIS; encourages Member States, therefore, to develop platforms enabling face-to-face meetings and dialogue with former fighters; emphasises furthermore that contact with victims of terrorism also seems to be an effective means of stripping radical rhetoric of its religious or ideological significance; suggests that this campaign be used as a tool to assist in the deradicalisation process in prisons, schools and all establishments focusing on prevention and rehabilitation; further calls on the Commission to support, particularly through funding, and coordinate such national communication campaigns; |

X.    Dismantling terrorist networks

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|  | 75. | Underlines that money laundering, tax evasion and other fiscal crimes are in some cases major sources of terrorism funding which threaten our internal security, and that tracking and combating crimes affecting the EU?s financial interests must therefore be a priority; |

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|  | 76. | Stresses that terrorist organisations such as IS/Daesh and Jabhat al-Nusra have accrued substantial financial resources in Iraq and Syria from smuggling oil, selling stolen goods, kidnapping and extortion, seizing bank accounts and smuggling antiquities; calls, therefore, for the countries and the intermediaries contributing to this black market to be identified and their activities brought to a halt as a matter of urgency; |

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|  | 77. | Supports measures aimed at weakening terrorist organisations from the inside and lessening their current influence on EU citizens and non-EU nationals legally residing in the EU; urges the Commission and the competent agencies to look into ways of dismantling terrorist networks and identifying how they are funded; to this end, calls for better cooperation between the Financial Intelligence Units of the Member States and for the speedy transposition and implementation of the Anti-Money Laundering Package; encourages the Commission to propose a regulation on identifying and blocking terrorism funding channels and countering the ways in which they are funded; calls on the Commission, therefore, to re-evaluate the creation of a common European terrorist finance tracking system; encourages Member States to implement the highest standards of transparency concerning access to information on beneficiary owners of all corporate structures in the EU and in opaque jurisdictions which may be vehicles for financing terrorist organisations; |

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|  | 78. | Welcomes the recent adoption of the European Agenda on Security, which proposes important steps towards enhancing the fight against terrorism and radicalisation, such as the creation of the European Counter Terrorist Centre within Europol; calls on the Member States to make full use of existing measures, and calls on the Commission to flag sufficient financial and human resources to effectively deliver on its proposed actions; |

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|  | 79. | Reiterates its call on the Commission to urgently review the EU firearms legislation by revising Council Directive 91/477/EEC in order to facilitate the role of national police and investigation authorities in detecting and fighting against arms trafficking on the black market and the dark net, and calls on the Commission to put forward common firearms deactivation standards so that deactivated firearms are rendered irreversibly inoperable; |

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|  | 80. | Calls for a harmonised approach to the definition as a criminal offence of hate speech, online and offline, whereby radicals incite others to disrespect and violate fundamental rights; suggests that this specific offence be added in the relevant Council framework decisions; |

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|  | 81. | Calls on the Member States to participate in efforts to trace external flows of funding and to ensure and display transparency in their relations with certain Gulf countries, with the aim of stepping up cooperation in order to shed light on the financing of terrorism and fundamentalism, in Africa and the Middle East but also by some organisations in Europe; encourages Member States to collaborate in the elimination of the oil black market that provides essential income for terrorist organisations; believes that Member States should not hesitate to use restrictive measures against individuals and organisations where there is credible evidence of financing of or other complicity with terrorism; |

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|  | 82. | Would strongly reject any attempts to remove aspects of the report that focus on fighting acts of terrorism and extremism in their own right; takes the view that it is unhelpful and counter-productive to break the link between fighting radicalisation and fighting its manifestations; calls on the Council to create a blacklist of European jihadists and jihadist terrorist suspects; |

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|  | 83. | Instructs its President to forward this resolution to the Council, the Commission, the governments and parliaments of the EU Member States and the candidate countries, the United Nations, the Council of Europe, the African Union, and the member states of the Union for the Mediterranean, of the League of Arab States and of the Organisation for Security and Cooperation in Europe. |

(1)  Texts adopted, P7\_TA(2013)0384.

(2)  Texts adopted, P8\_TA(2014)0102.

(3)  Texts adopted, P8\_TA(2015)0032.

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[***Summary of Russian press for Friday 13 April 2018***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5S64-BR71-DYRV-34GT-00000-00&context=1516831)

BBC Monitoring Former Soviet Union - Political

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April 13, 2018 Friday

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**Length:** 3579 words

**Body**

By BBC Monitoring

Syria

Newspapers continue to give extensive coverage to the latest developments in Syria

Komsomolskaya Pravda: Viktor Baranets report "Will our S-400 be able to stop US Tomahawk missiles?" says that "Donald Trump tries to frighten Russia with 'nice and new and smart' missiles". Author looks at whether the Russian group of troops [in Syria] will be able to defend itself and its allies from US missile strikes. Military expert Alexei Leonkov looks in detail at the missile systems that Russia and the US have deployed in the region; p 4 (850 words). [*https://www.msk.kp.ru/daily/26818/3854917/*](https://www.msk.kp.ru/daily/26818/3854917/)

Izvestia: Dmitry Bolotov op-ed "Manoeuvres on the edge" says that the US and Russia's military buildup in the Mediterranean Sea "looks like a preparation for a serious conflict". "The situation continues to escalate. The military themselves are actually the last ones who would be interested in an escalation in tension. One careless slip and there may be fatalities and losses", author says; p 3 (1,500 words). [*https://bit.ly/2GU42US*](https://bit.ly/2GU42US)

Nezavisimaya Gazeta: Igor Subbotin article "Putin-Trump meeting on verge of disruption" says that both Russian and US experts are unanimous that the US attempts to conduct strikes on Syria will disrupt a planned meeting of the Russian and US presidents as the outcomes of the talks would be disastrous for Trump; pp 1, 6 (814 words). [*http://www.ng.ru/world/2018-04-12/1\_7211\_summit.html*](http://www.ng.ru/world/2018-04-12/1_7211_summit.html)

Novaya Gazeta: Valery Shiryayev article "Donald's gifts" says that by postponing a strike on Syria, the US leadership has given Russia time to take measures in order to minimise possible damage. As for the response to a possible strike, Russia may hit on US allies in Syria, article notes; p 3 (714 words). [*https://bit.ly/2v9Fw0D*](https://bit.ly/2v9Fw0D)

Novaya Gazeta: Yuri Safronov article "Translation from French" says that France is "considering" a strike on Syria in response to a chemical attack in Douma and adds that a symbolic strike is quite possible; p 5 (568 words). [*https://bit.ly/2HlSCN2*](https://bit.ly/2HlSCN2)

Novaya Gazeta: Pavel Felgengauer article "Trump as time bomb" focuses on unfolding confrontation over Syria and says that Trump is definitely trying to force Putin to a deal: he has promised to help Russia's economy and probably wants Russia to give up Al-Assad and Donbass in exchange; p 4 (1,346 words). [*https://bit.ly/2HA76Xy*](https://bit.ly/2HA76Xy)

Rossiyskaya Gazeta: Yevgeny Shestakov article "Trump fires tweets at Pentagon" focuses on US President Trump's controversial tweets about attacks on Syria; p 8 (750 words). [*https://bit.ly/2HuNi7O*](https://bit.ly/2HuNi7O)

Moskovsky Komsomolets: Mikhail Rostovsky article "Judgement Day for no reason" says that current explosive confronation over Syria between Moscow and Washington does not make sense and urges the sides to calm down and find a solution using diplomatic means; pp 1, 3 (953 words). [*https://bit.ly/2qujgtu*](https://bit.ly/2qujgtu)

Moskovsky Komsomolets: Nikolai Vardul article "Peace and war" urges both sides in current confrontation to use diplomacy rather than tough rhetoric and belligerent statements; p 3 (1,125 words).

Moskovsky Komsomolets: Ekaterina Gabel article "Mass media: US may strike on Syria on the weekend" says that the US may strike at Syrian air fields in the vicinity of Damascus on 14-15 April; p 3 (504 words). [*https://bit.ly/2v9X64r*](https://bit.ly/2v9X64r)

Moskovsky Komsomolets: Andrei Yashlavsky article "Sex scandal as driver of war" says that Donald Trump is using Syria and possible strikes on it in order to distract attention from an unfolding scandal involving him, just like US President Bill Clinton used strikes on Yugoslavia to distract attention from a scandal with Monica Lewinsky; p 3 (658 words). [*https://bit.ly/2EHaDA5*](https://bit.ly/2EHaDA5)

Moskovsky Komsomolets: Sergei Valchenko article "Trump and missiles: Which is smarter?" says that Russia and Syria can thank US President Trump for his warning about a strike on Syria as they have had time to prepare for it; p 3 (647 words). [*https://bit.ly/2INKG4i*](https://bit.ly/2INKG4i)

Nezavisimaya Gazeta: Vladimir Mukhin article "Russia protects al-Assad with 'human shield'" says that a Russian delegation headed by deputy Dmitry Sablin has arrived in Syria "as kind of a peacekeeping shield" which demonstrates Moscow's determination not only to repel any strikes on Syria, but protect the Syrian leader from elimination; pp 1-2 (815 words). [*http://www.ng.ru/world/2018-04-12/1\_7211\_asad.html*](http://www.ng.ru/world/2018-04-12/1_7211_asad.html)

Nezavisimaya Gazeta: Ravil Mustafin article "Syria may be returned to Arab family" looks ahead at a League of Arab States summit and says that Syria may be accepted back in the League; p 6 (830 words). [*http://www.ng.ru/world/2018-04-13/6\_7211\_siria.html*](http://www.ng.ru/world/2018-04-13/6_7211_siria.html)

Rossiyskaya Gazeta: Yuri Gavrilov article "Intelligence and missiles" features experts' comments on tension over Syria and the possibility of a US strike on Bashar al-Assad's facilities; p 8 (850 words). [*https://bit.ly/2IR0gMq*](https://bit.ly/2IR0gMq)

Moskovsky Komsomolets: Dmitry Dokuchayev article "Rouble: Rising from tail-spin" says that US President Trump's threats of a strike on Syria have sent oil prices up, which has helped the rouble start growing and wonders how long the trend will persist; p 2 (667 words). [*https://bit.ly/2JF53ls*](https://bit.ly/2JF53ls)

Skripal case

RBC: Georgy Makarenko report "OPCW sides with London" says that the Organisation for the Prohibition of Chemical Weapons (OPCW) has confirmed conclusions made by the UK about a substance with which former spy Sergei Skripal and his daughter Yulia were poisoned. "London said that a Novichok nerve agent had been used. According to experts, the OPCW report has not answered all the questions in the case," article says. "Experts say that a report summing up the findings of the OPCW will be interpreted by each party in its favour, that is why its publication will not help overcome the deadlock," article adds; p 5 (1,200 words). [*https://www.rbc.ru/newspaper/2018/04/13/5acf2ccc9a794721fa1bfbcd*](https://www.rbc.ru/newspaper/2018/04/13/5acf2ccc9a794721fa1bfbcd)

Moskovsky Komsomolets: Andrei Yashlavsky et al. report "Skripal poisoned by pure agent" says that the international chemical weapons watchdog has backed the UK's findings on the identity of a chemical used to poison the former Russian spy Sergei Skripal and his daughter Yulia in Salisbury. The 'high purity' of the agent established by the watchdog has prompted London to reiterate that only Russia has means, motive and opportunity to use the nerve agent against the former spy and his daughter; pp 1, 4 (1,030 words). [*https://bit.ly/2GU9qvt*](https://bit.ly/2GU9qvt)   [*https://bit.ly/2GU9qvt*](https://bit.ly/2GU9qvt)

Vedomosti: Alexei Nikolsky article "Poisoning without poisoners" says that the findings of the Organization for the Prohibition of Chemical Weapons (OPCW) have confirmed that the Skripals were poisoned in Salisbury with a nerve agent, but have not specified where it had been made. The findings will affect neither London nor Moscow's stances: each side will reiterate what it has already said, an expert says; p 3 (450 words). [*https://bit.ly/2GY1GZq*](https://bit.ly/2GY1GZq)

Vedomosti: Editorial by Vladimir Ruvinsky "The very Novichok" says that the findings of the OPCW have not helped determine whether Russia is behind the poisoning of the Skripals; p 6 (500 words). [*https://bit.ly/2HlNWXu*](https://bit.ly/2HlNWXu)

Rossiyskaya Gazeta: Ekaterina Zabrodina article "Poison only for limited number" says that the OPCW findings on the Skripals poisoning have left all the main questions about the incident unanswered; p 8 (300 words). [*https://bit.ly/2GXaNW6*](https://bit.ly/2GXaNW6)

Novaya Gazeta: Alexander Panov article "Sanctions named after Skripals" mulls the possibility of the US's toughening sanctions over the poisoning of the Skripals; pp 6-7 (1,074 words). [*https://bit.ly/2qooIyb*](https://bit.ly/2qooIyb)

Aftermath of US sanctions

Komsomolskaya Pravda: Sofya Ruchko et. al report "How we can punish US" looks at steps that Russia may take in retaliation for the new US sanctions, including a ban on export and import of certain products, visa restrictions and the use of the dollar in international transactions; p 6 (1,000 words). [*https://www.msk.kp.ru/daily/26818/3854861/*](https://www.msk.kp.ru/daily/26818/3854861/)

Komsomolskaya Pravda: Yevgeny Belyakov report "Russia keeps 100bn dollars in US state bonds. So what will happen to it now?" says that "Russia has decreased a share of the US state bonds in its international reserves since 2014 when the first sanctions were imposed. However, we still keep a quarter of our money in them"; p 7 (1,000 words).

Vedomosti: Op-ed by Kirill Tremasov "New reality of sanctions" says that the fact that the Russian authorities have not offered official reaction to the new US sanctions, gives the impression that the sanctions as well as their consequences came as a total surprise for them. The expert looks at risks arising from the sanctions and urges the authorities to come up with an anti-crisis plan; p 7 (2,000 words). [*https://bit.ly/2GVoKni*](https://bit.ly/2GVoKni)

Sechin at former minister's trial

RBC: Margarita Alyokhina et. al report "Trial with surprise" says that "Rosneft head Igor Sechin has made an unexpected appearance in court to testify at the appeal hearing of former Economic Development Minister Alexei Ulyukayev and helped state prosecution uphold the verdict passed on Ulyukayev". "According to analysts, Sechin did this having taken into account criticism over previous instances of failing to show up in court," article adds; pp 2-3 (1,700 words). [*https://www.rbc.ru/newspaper/2018/04/13/5acf75289a794775705fa038*](https://www.rbc.ru/newspaper/2018/04/13/5acf75289a794775705fa038)

Izvestia: Anna Ivushkina et al. article "Confirmed sentence for Ulyukayev" looks at the trial of the former Russian minister. "This once again confirms the commitment of the authorities to fighting against corruption and the absence of people immune to prosecution", experts say; p 2 (1,000 words). [*https://bit.ly/2IQGnFA*](https://bit.ly/2IQGnFA)

Rossiyskaya Gazeta: Ivan Yegorov article "Key witness tells court about bribe" says that the Moscow city court has upheld the sentence for former minister Ulyukayev and gives account of the hearing; p 7 (950 words). [*https://bit.ly/2GUXKZn*](https://bit.ly/2GUXKZn)

Moskovsky Komsomolets: Daria Fedotova article "Ulyukayev gets to see key witness" says that Igor Sechin, head of Russia's state-controlled oil giant Rosneft, has made an appearance in a Moscow court to testify as a witness at the appeal hearing of former Economic Development Minister Alexei Ulyukayev; pp 1, 4 (683 words). [*https://bit.ly/2qrCQqp*](https://bit.ly/2qrCQqp)

Kommersant: Vsevolod Inyutin article "Moscow city court believes Igor Sechin" says that former Russian Economic Development Minister Alexei Ulukayev's appeal against his conviction for extortion has been rejected; pp 1, 4 (900 words). [*https://www.kommersant.ru/doc/3600943*](https://www.kommersant.ru/doc/3600943)

Vedomosti: Anastasia Kornya and Alina Didkovskaya article "Key executive witness" focuses on testimony of Igor Sechin, who made an appearance as a witness at the appeal hearing of Alexei Ulyukayev. During the original trial, Sechin failed to appear in court as a witness despite being summoned four times; pp 1-2 (1,200 words). [*https://bit.ly/2vbLluo*](https://bit.ly/2vbLluo)

Novaya Gazeta: Vera Chelishcheva article "Matter of honour" says that "when Sechin showed up at the hearing, it was obvious that the court would uphold the sentence for Ulyukayev"; p 2 (661 words). [*https://bit.ly/2JFqgM6*](https://bit.ly/2JFqgM6)

Internet

RBC: Natalya Demchenko report "Block in super-urgent mode" says that the Telegram messenger may be blocked over its failure to hand over encryption keys to the Russian Federal Security Service (FSB) not in 3-6 months, as lawyers believed, but in the next few days. "The Federal Agency for Oversight in the Field of Communications, Information Technologies and Mass Media (Roskomnadzor) has filed a motion that Telegram should be blocked immediately and a court may hear the case on 13 April," article says; p 12 (1,000 words). [*https://www.rbc.ru/newspaper/2018/04/13/5acf0dfc9a7947fce11bfbcd*](https://www.rbc.ru/newspaper/2018/04/13/5acf0dfc9a7947fce11bfbcd)

Vedomosti: Ekaterina Bryzgalova et al. report "And block immediately" says that the Russian media watchdog Roskomnadzor has asked a court to have its ruling enforced immediately if it agrees with a request to have the Telegram messenger blocked; p 13 (750 words). [*https://bit.ly/2HuMaRC*](https://bit.ly/2HuMaRC)

Moskovsky Komsomolets: Marina Ozerova article "You can't break down walls by beating your head against them" says that the State Duma has passed in the third and final reading legislation making it possible to block websites for "undermining" reputation of an individual or a company following a court ruling. In addition, a bill obligating social networks to ***delete*** within 24 hours information that a body of power recognises to be inaccurate, has been adopted in the first reading; p 2 (820 words). [*https://bit.ly/2HjeMPX*](https://bit.ly/2HjeMPX)

***Opposition***

Nezavisimaya Gazeta: Daria Garmonenko article "Yavlinsky strengthens vertical chain of command in Yabloko" says that the Yabloko party is going to cut the powers of the party's Moscow branch and links the changes to the influence of the party founder Yavlinsky's adviser Maxim Kats; pp 1, 3 (633 words). [*http://www.ng.ru/politics/2018-04-13/1\_7211\_yavlinsky.html*](http://www.ng.ru/politics/2018-04-13/1_7211_yavlinsky.html)

Nezavisimaya Gazeta: Alexei Gorbachev article "Navalny negotiates with Parnas on Yashin" says that Alexei Navalny has discussed Ilya Yashin's prospects in the Moscow mayoral election with Parnas. If Yashin ***wins*** primaries, he may be nominated by Parnas; p 3 (666 words). [*http://www.ng.ru/politics/2018-04-13/3\_7211\_navalny.html*](http://www.ng.ru/politics/2018-04-13/3_7211_navalny.html)

Novaya Gazeta: Ilya Azar interview "'I will be model ***opposition*** candidate"' with ***opposition*** politician Ilya Yashin who is going to run for Moscow mayor; pp 8-9 (2,601 words).

Novaya Gazeta: Irina Gordiyenko article "'Open the door, you have flooded us!'" reports on searches in the houses of participants in protests against landfills in Moscow Region; p 2 (685 words). [*https://bit.ly/2GY6deg*](https://bit.ly/2GY6deg)

Oil and gas

Nezavisimaya Gazeta: Anastasia Bashkatova article "Barrel would not have set three-year record without military conflicts" says that oil prices have reached their maximum in three years due to instability in the Middle East; pp 1, 4 (1,031 words). [*http://www.ng.ru/economics/2018-04-13/1\_7211\_oil.html*](http://www.ng.ru/economics/2018-04-13/1_7211_oil.html)

Moskovsky Komsomolets: Nikolai Makeyev article "Pipe poison" says that Europe has interfered in a gas war between Moscow and Kiev and asked Gazprom head Alexei Miller to maintain gas transit via Ukraine after 2019; p 5 (430 words). [*https://bit.ly/2Hjgvox*](https://bit.ly/2Hjgvox)

Military

Nezavisimaya Gazeta: Vladimir Skosyrev article "Moscow to help Delhi to fight underwater" says that Russia is facing tough competition for the Indian arms market and looks at Moscow's proposal for the joint building of a submarine; p 6 (480 words). [*http://www.ng.ru/world/2018-04-13/6\_7211\_india.html*](http://www.ng.ru/world/2018-04-13/6_7211_india.html)

Space

Kommersant: Andrei Kolesnikov report "Vladimir Putin initiates landings" gives an ironic account of President Putin's visit to a newly overhauled facility celebrating Russia's achievements in space at the VDNKh exhibition centre in Moscow; p 5 (1,500 words). [*https://www.kommersant.ru/doc/3600617*](https://www.kommersant.ru/doc/3600617)

Nezavisimaya Gazeta: Anatoly Komrakov article "Budget to finance both international space station and lunar station" says that President Putin has stated that Russia is committed to flights to the Moon and Mars as well as to international cooperation in space and looks at the cost of these ambitious projects for the budget; p 4 (816 words). [*http://www.ng.ru/economics/2018-04-12/4\_7211\_budget.html*](http://www.ng.ru/economics/2018-04-12/4_7211_budget.html)

Domestic political

Nezavisimaya Gazeta: Ekaterina Trifonova article "Putin to be told about details of his victory" says that the presidential human rights council has drafted a report about the 18 March presidential election. The report focuses on revealed violation and proposes a number of amendments to the legislature; p 3 (569 words). [*http://www.ng.ru/politics/2018-04-13/3\_7211\_putin.html*](http://www.ng.ru/politics/2018-04-13/3_7211_putin.html)

Vedomosti: Editorial by Pavel Aptekar "Tycoons of 21st century" recalls that presidential spokesman Dmitry Peskov has stated that the time of tycoons in Russia is long since over and there are no tycoons now. VTsIOM polls, however, show that 94 per cent of Russians say that tycoons do exist in present-day Russia; p 6 (500 words). [*https://bit.ly/2IO56Ku*](https://bit.ly/2IO56Ku)

Vedomosti: Elena Mukhametshina article "Waiting for protests" says that experts forecast growth of social protests in the next two years over existing problems and new ones; p 3 (600 words). [*https://bit.ly/2quhnfL*](https://bit.ly/2quhnfL)

Kommersant: Elena Chernenko and Vladimir Solovyev article "Minister of permanent affairs" says that Russian Foreign Minister Sergei Lavrov is most likely to keep his post after a new government is formed; p 2 (750 words). [*https://www.kommersant.ru/doc/3600929*](https://www.kommersant.ru/doc/3600929)

Kommersant: Sofia Samokhina and Maxim Ivanov article "Aman Tuleyev offered to get re-elected like everyone else" says that the United Russia party has opposed a proposal to use a non-transparent model of primaries to determine candidates for the Kemerovo Region legislative assembly in autumn 2018, which was probably aimed at ensuring former governor Tuleyev's re-election; p 2 (600 words). [*https://www.kommersant.ru/doc/3600964*](https://www.kommersant.ru/doc/3600964)

Kommersant: Kirill Antonov and Sofia Samokhina article "Tatarstan insists on its language" says that Tatarstan's authorities have criticised a law on studying the republics' languages; p 2 (900 words). [*https://www.kommersant.ru/doc/3600958*](https://www.kommersant.ru/doc/3600958)

Domestic economic

Vedomosti: Tatiana Lomskaya and Elizaveta Bazanova article "Budget to wait till May" says that the Economic Development Ministry has not come up with its macro-economic forecast for 2019-21: officials are waiting for new May decrees of the president; p 4 (850 words). [*https://bit.ly/2HjwaUR*](https://bit.ly/2HjwaUR)

Nezavisimaya Gazeta: Mikhail Sergeyev article "Pre-election growth of incomes becomes history" says that instability of the rouble exchange rate has increased inflation expectations and, given low chances of economic growth, people's real incomes are likely to start falling again; p 4 (694 words). [*http://www.ng.ru/economics/2018-04-13/4\_7211\_inflation.html*](http://www.ng.ru/economics/2018-04-13/4_7211_inflation.html)

Moskovsky Komsomolets: Elena Yegorova article "Tycoons long for state support" says that during his visit to St Petersburg, Prime Minister Medvedev has admitted that the situation in the country's economy is not so optimistic as he pictured during his report to the State Duma; p 2 (554 words). [*https://bit.ly/2GTOdl8*](https://bit.ly/2GTOdl8)

Kommersant: Svetlana Samuseva and Vitaly Gaydayev article "Deposits may contribute to rouble weakening" says that amid the current rouble weakening, low deposit interest rates may provoke the outflow of money from banks; pp 1, 8 (750 words). [*https://www.kommersant.ru/doc/3600895*](https://www.kommersant.ru/doc/3600895)

Kommersant: Oleg Sapozhkov et al. report "Capital differences" says that the Economic Development Ministry and the Finance Ministry are arguing about mechanisms of boosting investment: special investment contracts and infrastructure mortgage; pp 1-2 (1,200 words). [*https://www.kommersant.ru/doc/3600859*](https://www.kommersant.ru/doc/3600859)

Russia-US

Kommersant: Sergei Strokan article "Mike Pompeo ensures support of containment" says that at the Senate confirmation hearing, Donald Trump's nominee for secretary of state Mike Pompeo has pledged a tougher line on Moscow and referred to Russia as the main threat for the US; p 5 (700 words). [*https://www.kommersant.ru/doc/3600777*](https://www.kommersant.ru/doc/3600777)

Russia-West

Komsomolskaya Pravda: Oleg Frolov report "Finnish concern threatens Russia's energy security" says that "Western corporations have begun to control a number of Russia's ***strategic*** companies and prepare to deliver a deadly blow". As an example, the article refers to the Finnish company Fortum that has bought 47.12 per cent of shares of the German company Uniper. "As a result, a super-monster appears on the Russian heating and energy market that controls vital sectors of the economy in several Russian regions," article says; p 5 (850 words).

US

Izvestia: Eduard Lozansky op-ed "Glaring in the desert" says that US President Donald Trump "is being cornered, which can lead, and has already sometimes led, to some inappropriate reaction". "Apart from political pressure, there is also an all-out attack on Trump by the press, as well as by many former lovers", author says. "One gets the impression that for Trump's numerous enemies, the most important thing is achieving his impeachment, whereas the interests of the country recede into the background," Lozansky says; p 3 (1,000 words). [*https://bit.ly/2GWOvns*](https://bit.ly/2GWOvns)

Russia-Poland

Nezavisimaya Gazeta: Valery Masterov article "Placing stakes on Smolensk was mistake" says that a new report about the causes of the crash of the Polish president's plane in Russia's Smolensk has triggered negative reaction in Poland; p 3 (892 words). [*http://www.ng.ru/kartblansh/2018-04-13/3\_7211\_kartblansh.html*](http://www.ng.ru/kartblansh/2018-04-13/3_7211_kartblansh.html)

CIS

Nezavisimaya Gazeta: Viktoria Panfilova article "Migrants from Turkmenistan may come to Russia" looks ahead at Russian-Turkmen talks set for 18 April to discuss security, economic cooperation and labour migration. The number of migrants from Turkmenistan may increase due to the growing economic crisis and unemployment; pp 1, 5 (754 words). [*http://www.ng.ru/cis/2018-04-13/1\_7211\_turkmenia.html*](http://www.ng.ru/cis/2018-04-13/1_7211_turkmenia.html)

Nezavisimaya Gazeta: Editorial "Russia may acquire another front nearby" says that recent developments in the Commonwealth of Independent States (CIS) show that the interests of its members are becoming increasingly different, which puts the Eurasian Economic Union and Moscow's integration plans at risk; p 2 (497 words). [*http://www.ng.ru/editorial/2018-04-13/2\_7211\_red.html*](http://www.ng.ru/editorial/2018-04-13/2_7211_red.html)

Ukraine

Nezavisimaya Gazeta: Tatiana Ivzhenko article "Ukraine breaks off remaining ties with CIS" says that Ukrainian President Petro Poroshenko has stated that Ukraine must terminate its membership of the statutory bodies of the CIS and unilaterally cancel certain provisions of the Ukraine-Russia friendship agreement and links the statement to his presidential campaign; pp 1-2 (1,142 words). [*http://www.ng.ru/cis/2018-04-12/1\_7211\_ukraina.html*](http://www.ng.ru/cis/2018-04-12/1_7211_ukraina.html)

Sources: as listed

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[***FEDERAL REGISTER: Assessment and Collection of Regulatory Fees for Fiscal Year 2017 Pages 26019 - 26041 [FR DOC # 2017-11578]***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5P52-B0C1-JDG9-Y3CB-00000-00&context=1516831)

Impact News Service

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**Body**

Washington: Office of the Federal Register has issued the following notice:

FEDERAL COMMUNICATIONS COMMISSION 47 CFR Part 1 [MD Docket Nos. 17-134; FCC 17-62] Assessment and Collection of Regulatory Fees for Fiscal Year 2017 AGENCY: Federal Communications Commission. ACTION: Notice of proposed rulemaking. ----------------------------------------------------------------------- SUMMARY: In this document, the Federal Communications Commission (Commission) will revise its Schedule of Regulatory Fees in order to recover an amount of $356,710,992 that Congress has required the Commission to collect for fiscal year 2017, as amended, provides for the annual assessment and collection of regulatory fees under and respectively, for annual ``Mandatory Adjustments'' and ``Permitted Amendments'' to the Schedule of Regulatory Fees. DATES: Submit comments on or before June 22, 2017, and reply comments on or before July 7, 2017. ADDRESSES: You may submit comments, identified by MD Docket No. 17-134, by any of the following methods:  Federal eRulemaking Portal:

[*http://www.regulations.gov*](http://www.regulations.gov) Follow the instructions for submitting comments.      Federal Communications Commission's Web site:   [*http://www.fcc.gov/cgb/ecfs*](http://www.fcc.gov/cgb/ecfs). Follow the instructions for submitting comments.      People With Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: [*FCC504@fcc.gov*](mailto:FCC504@fcc.gov) or phone: 202-418- 0530 or TTY: 202-418-0432.      Email: [*ecfs@fcc.gov*](mailto:ecfs@fcc.gov) Include MD Docket No. 15-121 in the subject line of the message.      Mail: Commercial overnight mail (other than U.S Postal Service Express Mail, and Priority Mail, must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S Postal Service first- class, Express, and Priority mail should be addressed to 445 12th Street SW., Washington, DC 20554.     For detailed instructions for submitting comments and additional information on the rulemaking process, see the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Roland Helvajian, Office of Managing Director at (202) 418-0444.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), FCC 17-62, MD Docket No. 17-134 adopted on May 22, 2017 and released on May 23, 2017. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Room CY-A257, Portals II, Washington, DC 20554, and may also be purchased from the Commission's copy contractor, BCPI, Inc., Portals II, 445 12th Street SW., Room CY-B402, Washington, DC 20554. Customers may contact BCPI, Inc. via their Web site, [*http://www.bcpi.com*](http://www.bcpi.com), or call 1-800-378-3160. This document is available in alternative formats (computer diskette, large print, audio record, and braille). Persons with disabilities who need documents in these formats may contact the FCC by email: [*FCC504@fcc.gov*](mailto:FCC504@fcc.gov) or phone: 202-418-0530 or TTY: 202-418-0432.

I. Procedural Matters

A. Ex Parte Rules Permit-But-Disclose Proceeding

    1. This Notice of Proposed Rulemaking (FY 2017 NPRM) shall be treated as a ``permit-but-disclose'' proceeding in accordance with the Commission's ex parte rules. Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must list all persons attending or otherwise participating in the meeting at which the ex parte presentation was made, and summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in

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lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with section 1.1206(b). In proceedings governed by section 1.49(f) or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g , .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

B. Comment Filing Procedures

    2. Comments and Replies. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).      Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: [*http://fjallfoss.fcc.gov/ecfs2*](http://fjallfoss.fcc.gov/ecfs2)/ or the Federal eRulemaking Portal:   [*http://www.regulations.gov*](http://www.regulations.gov)      Paper Filers: Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.     Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.     [ssquf] All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m to 7:00 p.m All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.     [ssquf] Commercial overnight mail (other than U.S Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.     [ssquf] U.S Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.     People With Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to [*fcc504@fcc.gov*](mailto:FCC504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202- 418-0432 (tty).     3. Availability of Documents. Comments, reply comments, and ex parte submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., CY-A257, Washington, DC 20554. These documents will also be available free online, via ECFS. Documents will be available electronically in ASCII, Word, and/or Adobe Acrobat.     4. Accessibility Information. To request information in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to [*fcc504@fcc.gov*](mailto:FCC504@fcc.gov) or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY). This document can also be downloaded in Word and Portable Document Format (``PDF'') at:   [*http://www.fcc.gov*](http://www.fcc.gov)

C. Initial Regulatory Flexibility Analysis

    5. An initial regulatory flexibility analysis (IRFA) is contained in this summary. Comments to the IRFA must be identified as responses to the IRFA and filed by the deadlines for comments on the Notice. The Commission will send a copy of the Notice, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

D. Initial Paperwork Reduction Act of 1995 Analysis

    6. This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C 3506(c)(4).

II. Introduction

    7. In this Notice of Proposed Rulemaking, we seek comment on the Commission's proposed regulatory fees for fiscal year (FY) 2017. We propose to collect $356,710,992 in regulatory fees for FY 2017, as detailed in the proposed fee schedules attached in Table 4.

III. Background

    8. The Commission is required by Congress to assess regulatory fees each year in an amount that can reasonably be expected to equal the amount of its appropriation.\1\ Regulatory fees, mandated by Congress, are collected ``to recover the costs of . . . enforcement activities, policy and rulemaking activities, user information services, and international activities.'' \2\ Regulatory fees are to ``be derived by determining the full-time equivalent number of employees performing'' these activities, ``adjusted to take into account factors that are reasonably related to the benefits provided to the payer of the fee by the Commission's activities . . . .'' \3\ Regulatory fees recover direct costs, such as salary and expenses; indirect costs, such as overhead functions; and support costs, such as rent, utilities, or equipment.\4\ Regulatory fees also cover the costs incurred in regulating entities that are statutorily exempt from paying regulatory fees,\5\ entities whose regulatory fees are waived,\6\ and entities providing services for which we do not assess regulatory fees. ---------------------------------------------------------------------------

    \1\ 47 U.S.C 159(b)(1)(B). The Commission collected $4.25 million above the required regulatory fee target goal in FY 2016, which the Commission deposited into the U.S Treasury. The cumulative overcollection is $102.62 million as of September 30, 2016.     \2\ 47 U.S.C 159(a).     \3\ 47 U.S.C 159(b)(1)(A).     \4\ Assessment and Collection of Regulatory Fees for Fiscal Year 2004, Report and Order, 19 FCC Rcd 11662, 11666, para. 11 (2004) (FY 2004 Report and Order).     \5\ For example, governmental and nonprofit entities are exempt from regulatory fees under section 9(h). 47 U.S.C 159(h); 47 CFR 1.1162     \6\ 47 CFR 1.1166 ---------------------------------------------------------------------------

    9. Congress sets the amount the Commission must collect each year in the Commission's fiscal year appropriations. Section 9(a)(2) of the Communications Act of 1934, as amended (Communications Act or Act) requires the Commission to collect fees sufficient to offset the amount appropriated.\7\ To calculate regulatory fees, the Commission allocates the total collection target across all regulatory fee categories. The allocation of fees to fee categories is based on the Commission's calculation of Full Time Employees (or

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FTEs) in each regulatory fee category.\8\ FTEs are classified as ``direct'' if the employee is in one of the four ``core'' bureaus; otherwise, that employee is considered an ``indirect'' FTE.\9\ The total FTEs for each fee category includes the direct FTEs associated with that category, plus a proportional allocation of indirect FTEs.\10\ The Commission then allocates the total amount to be collected among the various regulatory fee categories within each of the core bureaus. Each regulatee within a fee category pays its proportionate share based on an objective measure, e.g , revenues or number of subscribers.\11\ ---------------------------------------------------------------------------

    \7\ 47 U.S.C 159(a)(2).     \8\ One FTE is a unit of measure equal to the work performed annually by a full time person (working a 40 hour workweek for a full year) assigned to the particular job, and subject to agency personnel staffing limitations established by the U.S Office of Management and Budget.     \9\ The core bureaus are the Wireline Competition Bureau, Wireless Telecommunications Bureau, Media Bureau, and part of the International Bureau. The indirect FTEs are the employees from the following bureaus and offices: Enforcement Bureau, Consumer & Governmental Affairs Bureau, Public Safety and Homeland Security Bureau, part of the International Bureau, Chairman and Commissioners' offices, Office of the Managing Director, Office of General Counsel, Office of the Inspector General, Office of Communications Business Opportunities, Office of Engineering and Technology, Office of Legislative Affairs, Office of ***Strategic*** Planning and Policy Analysis, Office of Workplace Diversity, Office of Media Relations, and Office of Administrative Law Judges.     \10\ The Commission observed in the FY 2013 Report and Order that ``the high percentage of the indirect FTEs is indicative of the fact that many Commission activities and costs are not limited to a particular fee category and instead benefit the Commission as a whole.'' See Assessment and Collection of Regulatory Fees for Fiscal Year 2013, Report and Order, 28 FCC Rcd 12351, 12357, para. 17 (2013) (FY 2013 Report and Order).     \11\ See Procedures for Assessment and Collection of Regulatory Fees, Notice of Proposed Rulemaking, 27 FCC Rcd 8458, 8461 through 62, paras. 8 through 11 (2012) (FY 2012 NPRM). ---------------------------------------------------------------------------

    10. The Commission annually reviews the regulatory fee schedule, proposes changes to the schedule to reflect changes in the amount of its appropriation, and proposes increases or decreases to the schedule of regulatory fees.\12\ The Commission will make changes to the regulatory fee schedule ``if the Commission determines that the schedule requires amendment to comply with the requirements'' \13\ of section 9(b)(1)(A) of the Act.\14\ The Commission may also add, ***delete***, or reclassify services in the fee schedule to reflect additions, ***deletions***, or changes in the nature of its services ``as a consequence of Commission rulemaking proceedings or changes in law.'' \15\ ---------------------------------------------------------------------------

    \12\ 47 U.S.C 159(b)(1)(B).     \13\ 47 U.S.C 159(b)(2).     \14\ 47 U.S.C 159(b)(1)(A).     \15\ 47 U.S.C 159(b)(3). ---------------------------------------------------------------------------

    11. As part of its annual review, the Commission regularly seeks to improve its regulatory fee analysis. For example, in the FY 2013 Report and Order, the Commission adopted updated FTE allocations to more accurately reflect the number of FTEs working on regulation and oversight of the regulatees in the various fee categories; \16\ reallocated some FTEs from the International Bureau as indirect; \17\ combined the UHF and VHF television stations into one regulatory fee category; \18\ and added Internet Protocol Television (IPTV) to the cable television regulatory fee category.\19\ Subsequently, in the FY 2014 Report and Order, the Commission adopted a new regulatory fee subcategory for toll free numbers within the Interstate Telecommunications Service Provider (ITSP) \20\ category; \21\ increased the de minimis threshold to $500 for annual regulatory fee payors; \22\ and eliminated several categories from the regulatory fee schedule.\23\ In the FY 2015 NPRM, the Commission adjusted regulatory fees for radio and television broadcasters, based on the type and class of service and on the population served; \24\ adopted an increase in the regulatory fee for Direct Broadcast Satellite (DBS) providers in the subcategory within the cable television and IPTV regulatory fee category; \25\ and adopted an across the board fee increase for the Commission's moving expenses.\26\ ---------------------------------------------------------------------------

    \16\ FY 2013 Report and Order, 28 FCC Rcd at 12354-58, paras. 10-20. The Commission now updates the FTE allocations annually. This was recommended in a report issued by the Government Accountability Office (GAO) in 2012. See GAO ``Federal Communications Commission Regulatory Fee Process Needs to be Updated,'' GAO-12-686 (August 2012) (GAO Report) at 36 (available at [*http://www.gao.gov/products/GAO-12-686*](http://www.gao.gov/products/GAO-12-686)).     \17\ FY 2013 Report and Order, 28 FCC Rcd at 12355 through 58, paras. 13 through 20.     \18\ Id., 28 FCC Rcd at 12361 through 62, paras. 29 through 31.     \19\ Id., 28 FCC Rcd at 12362-63, paras. 32-33.     \20\ The ITSP category includes interexchange carriers (IXCs), incumbent local exchange carriers, toll resellers, and other IXC service providers.     \21\ Assessment and Collection of Regulatory Fees for Fiscal Year 2014, Report and Order and Further Notice of Proposed Rulemaking, 29 FCC Rcd 10767, 10777 through 79, paras. 25 through 28 (2014) (FY 2014 Report and Order).     \22\ FY 2014 Report and Order, 29 FCC Rcd at 10774 through 76, paras. 18 through 21.     \23\ Id., 29 FCC Rcd at 10776-77, paras. 22 through 24.     \24\ Assessment and Collection of Regulatory Fees for Fiscal Year 2016, Report and Order, 31 FCC Rcd 10339, 10350-51, paras. 31 through 33 (2016) (FY 2016 Report and Order).     \25\ FY 2016 Report and Order, 31 FCC Rcd at 10347-350, paras. 25-30.     \26\ Id., 31 FCC Rcd at 10341, para. 7. ---------------------------------------------------------------------------

IV. Discussion

    12. The Commission proposes to collect $356,710,992 in regulatory fees for FY 2017,\27\ pursuant to section 9 of the Communications Act.\28\ These regulatory fees are mandated by Congress and are collected ``to recover the costs of . . . enforcement activities, policy and rulemaking activities, user information services, and international activities.'' \29\ We seek comment on the proposed regulatory fee schedule in Table 4. ---------------------------------------------------------------------------

    \27\ See Consolidated Appropriations Act, 2017, Division E-- Financial Services and General Government Appropriations Act, 2017, Title V--Independent Agencies, Public Law 115-31 (May 5, 2017), available at [*https://www.congress.gov/bill/115th-congress/house-bill/244/text*](https://www.congress.gov/bill/115th-congress/house-bill/244/text). This provides the Commission with $356,710,992 for salaries and expenses, to be raised through section 9 regulatory fees, of which $16,866,992 is directed to be spent on completing the Commission's move and/or restacking.     \28\ 47 U.S.C 159.     \29\ 47 U.S.C 159(a). ---------------------------------------------------------------------------

A. Allocating FTEs for Regulatory Fee Purposes

    13. Under section 9 of the Act, regulatory fees are to ``be derived by determining the full-time equivalent number of employees performing'' these activities, ``adjusted to take into account factors that are reasonably related to the benefits provided to the payer of the fee by the Commission's activities . . . .'' \30\ As a general matter, we reasonably expect that the work of the FTEs in the core bureaus should remain focused on the industry segment regulated by each of those bureaus. The work of the FTEs in the indirect bureaus and offices benefits the Commission and the telecommunications industry and is not specifically focused on the licensees of a particular core bureau. Given the significant implications of reassignment of FTEs in our fee calculation, we make changes to FTE classifications only after performing considerable analysis and finding the clearest case for reassignment.\31\ For example, the Commission in the FY 2016 Report and Order declined to combine the regulatory fee categories for CMRS and ITSP categories, finding that doing so would not account for the substantial differences between the services in terms of regulatory oversight by the two bureaus.\32\ ---------------------------------------------------------------------------

    \30\ 47 U.S.C 159(b)(1)(A).     \31\ FY 2013 Report and Order, 28 FCC Rcd at 12357, para. 19. The Commission observed that the International Bureau was a ``singular case'' because the work of those FTEs ``primarily benefits licensees regulated by other bureaus.'' Id., 28 FCC Rcd at 12355, para. 14.     \32\ FY 2016 Report and Order, 31 FCC Rcd at 10346-47, para. 22.

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    14. The Commission has 1,431 FTEs funded by regulatory fees, of which 424 are currently direct FTEs.\33\ Of these, 167 would be allocated to Wireline Competition Bureau regulatees, 141 would be allocated to Media Bureau regulatees, 92 would be allocated to Wireless Telecommunications Bureau regulatees, and 24 would be allocated to International Bureau regulatees.\34\ As explained below, we propose to reallocate 38 FTEs associated with Universal Service Fund work as indirect and to reallocate four FTEs that work on wireless numbering issues to the Wireless Telecommunications Bureau. As a result of this proposed reallocation, we project that we would collect approximately 32.38 percent of regulatory fees (or $115.5 million) from Wireline Competition Bureau regulatees, 36.53 percent of regulatory fees (or $130.3 million) from Media Bureau regulatees, 24.87 percent of regulatory fees (or $88.7 million) from Wireless Telecommunications Bureau regulatees, and 6.22 percent of regulatory fees (or $22.2 million) from International Bureau regulatees. ---------------------------------------------------------------------------

    \33\ All numbers in this paragraph are for the current fiscal year (starting October 1, 2016) and exclude auction-funded FTEs.     \34\ This includes space stations, earth stations, and submarine cable, terrestrial, and satellite international bearer circuits (IBCs). ---------------------------------------------------------------------------

1. Reallocating FTEs Associated With the Universal Service Fund     15. We believe that continuing changes to the USF regulatory landscape requires us to reexamine the appropriateness of treating Universal Service Fund FTEs as direct FTEs. To start, we estimate that there are approximately 51 FTEs in the Wireline Competition Bureau, including the bureau front office, devoted to the Universal Service Fund, with 13 of those FTEs devoted to the high-cost program. We also estimate that there are approximately 3 FTEs in the Wireless Telecommunications Bureau, including the bureau front office, devoted to implementing the Mobility Fund, a universal service high-cost support mechanism devoted exclusively to mobile services.\35\ We note that other FTEs throughout the Commission working on universal service issues are assigned as indirect FTEs. This includes the many FTEs working on universal service issues in the Enforcement Bureau, the Office of the Managing Director, the Office of the Inspector General, and the Office of the General Counsel. ---------------------------------------------------------------------------

    \35\ See Connect America Fund, et al., Report and Order and Further Notice of Proposed Rulemaking, 26 FCC Rcd 17663 (2011). ---------------------------------------------------------------------------

    16. We propose to ``adjust[ ]'' the allocation of these direct FTEs ``to take into account factors that are reasonably related to the benefits provided to the payer of the fee by the Commission's activities . . . '' \36\ Specifically, we propose to reallocate the 38 FTEs associated with the non-high-cost programs of the Universal Service Fund as indirect. First, we note that contributions to the Universal Service Fund are not only required from Wireline Competition Bureau regulatees but every provider using any technology that has end- user interstate telecommunications revenue is required to contribute to the Universal Service Fund.\37\ Second, we note that three of the distribution programs--E-Rate, Lifeline, and Rural Healthcare--tie funding eligibility to the beneficiary, whether it be a school, a library, a low-income individual or family, or a rural healthcare provider. None of these beneficiaries are Commission regulatees. Third, we note that wireless carriers now serve a substantial, if not majority, of Lifeline subscribers, and satellite operators, Wi-Fi network installers, and fiber builders may all receive funding through the E-Rate and Rural Healthcare programs. Fourth, we note that treating these FTEs as indirect would be more consistent with how FTEs working on universal service issues are treated elsewhere in the Commission. We seek comment on this proposal. We specifically seek comment on whether the statute requires us to impose regulatory fees on the regulatees of a single bureau even though the benefits provided by those FTEs accrue to regulatees of other bureaus as well as non-regulatees. ---------------------------------------------------------------------------

    \36\ 47 U.S.C 159(b)(1)(A).     \37\ 47 CFR 54.706(a). ---------------------------------------------------------------------------

    17. We also seek comment on alternatives. Although the high-cost program has historically been tied to Wireline Competition Bureau regulatees, the Commission's recent actions such as the adoption of the Mobility Fund Phase II and the Connect America Fund Phase II reverse auctions open eligibility to many other providers. Do these recent changes justify reallocating the 13 Wireline Competition Bureau FTEs and three Wireless Telecommunications Bureau FTEs as indirect? Or should any such reallocation await the full implementation of these reverse auctions? Alternatively, should some portion of the 38 FTEs that work on non-high-cost programs of the Universal Service Fund not be reallocated as indirect? If so, what portion?     18. Commenters should provide legal and policy reasoning in support or ***opposition*** to the proposal and to the alternatives. We note that the Commission has said that it ``would be inconsistent with section 9 to delay reallocating . . . FTEs, where the reallocation is clearly warranted, while we engage in painstaking examinations of less clear and more factually complex situations in other bureaus.'' \38\ We seek comment on whether reallocation is clearly warranted here, and we ask commenters to address the impact any change in the allocation of FTEs will have on payors in other fee categories as well as the Commission's goal of ensuring that regulatory fees are administrable and sustainable.\39\ ---------------------------------------------------------------------------

    \38\ FY 2013 Report and Order, 28 FCC Rcd at 12357-58, paras. 19 through 20.     \39\ Id., 28 FCC Rcd at 12354, para 9. ---------------------------------------------------------------------------

2. Reallocating FTEs Associated With Numbering     19. We estimate that 7-8 FTEs in the Wireline Competition Bureau work on numbering issues. We propose to ``adjust[ ]'' the allocation of these direct FTEs ``to take into account factors that are reasonably related to the benefits provided to the payer of the fee by the Commission's activities . . . .'' \40\ Specifically, we estimate approximately half of the benefit of the work of these FTEs accrue to Wireless Telecommunications Bureau regulatees, who control 44.02 percent of assigned numbers under the North American Numbering Plan \41\ and 73.01 percent of voice subscriptions.\42\ We therefore propose to reallocate four of the Wireline Competition Bureau FTEs that work on numbering issues to the Wireless Telecommunications Bureau as direct FTEs for regulatory fee purposes. We seek comment on this proposal. We specifically seek comment on whether the statute requires us to impose regulatory fees on the regulatees of a single bureau even though the benefits provided by those FTEs accrue to regulatees of another bureau. ---------------------------------------------------------------------------

    \40\ 47 U.S.C 159(b)(1)(A).     \41\ Industry Analysis and Technology Division, Wireline Competition Bureau, FCC, Numbering Resource Utilization in the United States NRUF Data as of June 30, 2010 at 12 Table 1 (2013).     \42\ Industry Analysis and Technology Division, Wireline Competition Bureau, FCC, Voice Telephone Services: Status as of December 31, 2015 at 2 Figure 1 (2016). ---------------------------------------------------------------------------

    20. Commenters should provide legal and policy reasoning in support or ***opposition*** to the proposal, as well as whether the Commission should consider any alternatives. We note that the Commission has said that it ``would

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be inconsistent with section 9 to delay reallocating . . . FTEs, where the reallocation is clearly warranted, while we engage in painstaking examinations of less clear and more factually complex situations in other bureaus.'' \43\ We seek comment on whether reallocation is clearly warranted here, and we ask commenters to address the impact any change in the allocation of FTEs will have on payors in these two fee categories as well as the Commission's goal of ensuring that regulatory fees are administrable and sustainable.\44\ ---------------------------------------------------------------------------

    \43\ FY 2013 Report and Order, 28 FCC Rcd at 12357-58, paras. 19 through 20.     \44\ Id., 28 FCC Rcd at 12354, para 9. ---------------------------------------------------------------------------

B. Direct Broadcast Satellite (DBS) Regulatory Fees

    21. The proposed fee schedule includes an updated regulatory fee for DBS, a subcategory in the cable television and IPTV category.\45\ In 2015, the Commission adopted an initial regulatory fee for DBS, as a subcategory in the cable television and IPTV category, of 12 cents per year per subscriber, or one cent per month.\46\ At that time, the Commission committed to updating the regulatory fee rate for FY 2016, as necessary for ensuring an appropriate level of regulatory parity with cable television and IPTV and considering the Media Bureau resources dedicated to this subcategory.\47\ Such examination is consistent with a report issued by the Government Accountability Office (GAO) in 2012, which observed it is important for the Commission to ``regularly update analyses to ensure that fees are set based on relevant information.'' \48\ ---------------------------------------------------------------------------

    \45\ DBS also pays a regulatory fee per operational station in geostationary orbit.     \46\ Assessment and Collection of Regulatory Fees for Fiscal Year 2015, Report and Order and Further Notice of Proposed Rulemaking, 30 FCC Rcd 10268, 10276-77, paras. 19 through 20 (2015) (FY 2015 Report and Order).     \47\ FY 2015 Report and Order, 30 FCC Rcd at 10277, para. 20.     \48\ GAO Report at 12, available at [*http://www.gao.gov/products/GAO-12-686*](http://www.gao.gov/products/GAO-12-686). ---------------------------------------------------------------------------

    22. DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic dish antenna at the subscriber's location. The two DBS providers, AT&T and DISH Network, are multichannel video programming distributors (MVPDs).\49\ When the Commission adopted this regulatory fee subcategory, it recognized numerous recent regulatory developments increased Media Bureau FTE activity involving regulation and oversight of MVPDs, including DBS providers.\50\ During the FY 2016 regulatory fee proceeding, commenters representing the cable television industry observed that the Media Bureau FTEs increasingly devote time to issues involving the entire MVPD industry, and that DBS, cable television, and IPTV all receive oversight and regulation as a result of the work of the Media Bureau FTEs on MVPD issues.\51\ Recognizing this, in the FY 2016 Report and Order, the Commission increased the regulatory fee for DBS providers to 24 cents, plus an across-the-board increase of three cents for the Commission's moving expenses, for a total of 27 cents per subscriber, per year.\52\ The increase was adopted in response to the increase in DBS oversight and regulation due to Media Bureau rulemakings regarding MVPD issues.\53\ Nevertheless, the FY 2016 fee of 27 cents per subscriber adopted last year, increased from 12 cents, was still significantly below parity with the cable television/IPTV rate of $1.00 per year.\54\ ---------------------------------------------------------------------------

    \49\ MVPD is defined in section 602(13) of the Act, 47 U.S.C 522(13).     \50\ FY 2015 NPRM, 30 FCC Rcd at 5367 through 68, para. 31. See, e.g , Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010, Notice of Proposed Rulemaking, 31 FCC Rcd 2463 (2016); Amendment to the Commission's Rules Concerning Market Modification, Implementation of Section 102 of the STELA Reauthorization Act of 2014, Report and Order, 30 FCC Rcd 10406 (2015); Implementation of Section 103 of the STELA Reauthorization Act of 2014, Notice of Proposed Rulemaking, 30 FCC Rcd 10327 (2015); Implementation of the Commercial Advertisement, Loudness Mitigation (CALM) Act, Report and Order, 26 FCC Rcd 17222 (2011) (CALM Act Report and Order).     \51\ American Cable Association (ACA) Comments at 3-11 (filed in MD Docket No. 16-166); National Cable & Telecommunications Association (NCTA) Reply Comments at 3-7 (filed in MD Docket No. 16- 166).     \52\ FY 2016 Report and Order, 31 FCC Rcd at 10348 through 49, para. 26.     \53\ Id., 31 FCC Rcd at 10348 through 49, para. 26. Commenters representing the cable industry continue to observe that ``[w]hile cable, IPTV, and DBS providers are not regulated identically, they offer similar multichannel video services, participate in the same proceedings at the same level in terms of the number of filings and meetings, and benefit in a similar fashion from Media Bureau regulation of MVPDs.'' See Letter from Barbara Esbin, Cinnamon Mueller, attorney for ACA, to Marlene H. Dortch, Secretary, Federal Communications Commission (Dec. 16, 2016) (ACA ex parte) at 1.     \54\ The agency is not required to calculate its costs with ``scientific precision.'' Central & Southern Motor Freight Tariff Ass'n v. United States, 777 F.2d 722, 736 (D.C Cir. 1985). Reasonable approximations will suffice. Id.; National Cable Television Ass'n v. FCC, 554 F.2d 1094, 1105 (D.C Cir. 1976). ---------------------------------------------------------------------------

    23. Based on our updated analysis of the cable television/IPTV category, we find Media Bureau resources devoted to MVPD proceedings, including DBS,\55\ supports revising the DBS regulatory fee rate again. Specifically, we propose a regulatory fee rate of 36 cents per subscriber per year, plus two cents due to the increase in the Commission's budget for moving expenses, for a total of 38 cents per subscriber per year for FY 2017, as set forth in the proposed fee schedule in Table 4. This proposed incremental increase of approximately one cent per subscriber per month would result in bringing the DBS industry regulatory fees closer to those for cable television/IPTV. We seek comment on this proposal. ---------------------------------------------------------------------------

    \55\ See, e.g , Expanding Consumers' Video Navigation Choices, Commercial Availability of Navigation Devices, Notice of Proposed Rulemaking and Memorandum Opinion and Order, 31 FCC Rcd 1544 (2016); Promoting the Availability of Diverse and Independent Sources of Video Programming, Notice of Inquiry, 31 FCC Rcd 1610 (2016); Expansion of Online Public File Obligations to Cable and Satellite TV Operators and Broadcast and Satellite Radio Licensees, Report and Order, 31 FCC Rcd 526 (2016); Amendment of the Commission's Rules Concerning Market Modification; Implementation of Section 102 of the STELA Reauthorization Act of 2014, Report and Order, 30 FCC Rcd 10406 (2015). ---------------------------------------------------------------------------

C. Broadcaster Regulatory Fees

    24. In the FY 2016 NPRM, the Commission proposed to include a higher population row in the table for AM and FM broadcasters,\56\ to standardize the incremental increase in fees,\57\ and to better assess fees based on the type and class of service.\58\ The Commission also proposed to adjust the television broadcasters table so that Top 10 market stations paid approximately twice what stations in markets 26-50 paid.\59\ In response to the FY 2016 NPRM, several commenters contended that the proposed regulatory fees were too burdensome for small independent stations.\60\ After reviewing the record, including the comments filed by the industry identifying the economic hardship faced by small independent radio stations, the Commission adopted a revised version of the proposed table and reduced the regulatory fees in the two lowest population tiers for AM and FM broadcasters from the rates

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proposed in the FY 2016 Report and Order.\61\ ---------------------------------------------------------------------------

    \56\ FY 2016 NPRM, 31 FCC Rcd at 5762 through 63, para. 12. The Commission also sought comment on this issue in the Further Notice of Proposed Rulemaking attached to the FY 2015 Report and Order. See FY 2015 Report and Order, 30 FCC Rcd at 10280, para. 28.     \57\ Id. Specifically, the Commission sought comment on standardizing the incremental increase in fees as radio broadcasters increase the population they serve, such as by requiring that fee adjustments between tiers monotonically increase as the population served increases. Id.     \58\ Id.     \59\ FY 2016 NPRM, 31 FCC Rcd at 5763 through 64, para. 13. The Commission also sought comment on this issue in the Further Notice of Proposed Rulemaking attached to the FY 2015 Report and Order. See FY 2015 Report and Order, 30 FCC Rcd at 10280 through 81, para. 29.     \60\ FY 2016 Report and Order, 31 FCC Rcd at 10351, para. 32.     \61\ Id., 31 FCC Rcd at 10351, para. 33. ---------------------------------------------------------------------------

    25. We seek comment on further adjusting the regulatory fees for FY 2017. The following chart proposes regulatory fees for AM and FM broadcasters, with revised ratios so that the difference between each tier is proportional. The second chart, for illustrative purposes, has the regulatory fees with the ratios used in the proposal for FY 2016. The second chart does not include the reduction for the two lowest tiers adopted in FY 2016. We seek comment on this proposal. Commenters should also discuss whether the regulatory fees should be reduced further for the AM and FM broadcasters in the two lowest tiers.

                                                 Table 1--Proposed FY 2017 Radio Station Regulatory Fees --------------------------------------------------------------------------------------------------------------------------------------------------------                                 Proposed FY 2017 radio station regulatory fees This uses the proposed ratios for FY 2017 ---------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                                                                            FM Classes B,                     Population served                     AM Class A ($)  AM Class B ($)  AM Class C ($)  AM Class D ($)   FM Classes A,  C, C0, C1 & C2                                                                                                                             B1 & C3 ($)         ($) -------------------------------------------------------------------------------------------------------------------------------------------------------- <=25,000................................................          $1,050            $750            $650            $715          $1,150          $1,300 25,001-75,000...........................................           1,575           1,125             975           1,075           1,725           1,950 75,001-150,000..........................................           2,375           1,700           1,475           1,600           2,600           2,925 150,001-500,000.........................................           3,550           2,525           2,200           2,425           3,875           4,400 500,001-1,200,000.......................................           5,325           3,800           3,300           3,625           5,825           6,575 1,200,001-3,000,000.....................................           7,975           5,700           4,950           5,425           8,750           9,875 3,000,001-6,000,000.....................................          11,950           8,550           7,400           8,150          13,100          14,800 >6,000,000..............................................          17,950          12,825          11,100          12,225          19,650          22,225 --------------------------------------------------------------------------------------------------------------------------------------------------------

                                         Table 2--FY 2017 Radio Station Regulatory Fees Based on FY 2016 Ratios --------------------------------------------------------------------------------------------------------------------------------------------------------                   FY 2017 Radio station regulatory fees, based on proposed FY 2016 fees This chart uses the proposed ratios in FY 2016 ---------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                                                                            FM Classes B,                     Population served                     AM Class A ($)  AM Class B ($)  AM Class C ($)  AM Class D ($)   FM Classes A,  C, C0, C1 & C2                                                                                                                             B1 & C3 ($)         ($) -------------------------------------------------------------------------------------------------------------------------------------------------------- <=25,000................................................          $1,125            $825            $710            $780          $1,250          $1,425 25,001-75,000...........................................           1,700           1,250           1,075           1,175           1,875           2,150 75,001-150,000..........................................           2,250           1,650           1,425           1,550           2,500           2,850 150,001-500,000.........................................           3,375           2,475           2,125           2,350           3,750           4,275 500,001-1,200,000.......................................           5,625           4,125           3,550           3,900           6,250           7,125 1,200,001-3,000,000.....................................           8,450           6,200           5,325           5,850           9,375          10,700 3,000,001-6,000,000.....................................          11,250           8,250           7,100           7,800          12,500          14,250 >6,000,000..............................................          14,075          10,325           8,875           9,750          15,625          17,825 --------------------------------------------------------------------------------------------------------------------------------------------------------

D. Broadcast Television Satellites

    26. Broadcast television satellite stations pay a lower regulatory fee than standalone, full-service broadcast television stations, and are designated as such pursuant to note 5 to section 73.3555 of the Commission's rules.\62\ In 1995, the Commission made a permissive amendment to the regulatory fees schedule to permit television satellite stations that had received authorization to retransmit programming of the primary station to pay a fee separate from the fee for fully operational television stations. This amount is based upon the fee passed by the House of Representatives for television satellite stations for FY 1994.\63\ Other full-service television licensees remain subject to the regulatory fee payment required for the class of station and market. Of note, since 1995, we have consistently defined, and thereby limited, a television satellite station as one commonly owned, authorized under note 5 of section 73.3555 of the Commission's rules, and also shown as such in the Television and Cable Factbook. Periodically, the Television and Cable Factbook includes information concerning satellite status that is inconsistent with our records. ---------------------------------------------------------------------------

    \62\ E.g , for FY 2016, satellite television was assessed $1,750, whereas digital broadcast UHF and VHF TV was assessed $5,000 to $60,675, depending on the market size.     \63\ Assessment and Collection of Regulatory Fees for Fiscal Year 1995, Report and Order, 10 FCC Rcd 13512, 13534-35, para. 60 (1995). See also Implementation of Section 9 of the Communications Act, Assessment and Collection of Regulatory Fees for the 1994 Fiscal Year, Report and Order, 9 FCC Rcd 5333, para. 82 (1994) (``Section 9(g)'s fee schedule establishes specific fees for commercial television stations. These fees are to be assessed against a licensee solely on the basis of the market in which the station operates. The text of the schedule makes no distinction between commercial stations that are fully operational and those that are satellite stations.''). ---------------------------------------------------------------------------

    27. There is a standalone full-service station usually within the same market that serves as the ``parent'' to the satellite station that could not be commonly owned or controlled with the satellite, but for such a waiver. Section 76.55(e)(2) of the Commission's rules specifies that a commercial broadcast television station's market is its Designated Market Area (DMA), which reflects viewing patterns, as determined by Nielsen Media Research and published in its Nielsen Station Index Directory and Nielsen Station Index US Television Household Estimates or any successor publications.\64\ We are

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unaware of the existence of any reliable published source that can identify which television stations are serving small markets at the fringe of larger DMA's.\65\ In a particular situation, the licensee of a broadcast television satellite station that is not carried by cable, satellite, or alternate methods, may have signal contours that cover the fringes of a DMA (generally, rural communities), whereas other full-service TV stations have greater over-the-air coverage of the DMA market. As a result, advertisers may devote more commercial spending to other full-service TV stations rather than to the more limited broadcast television satellite stations in the same DMA market. Such broadcast television satellite stations may originate their own programming, multicast their broadcasts, and with cable or satellite carriage, provide programming to the entire DMA market. For purposes of paying regulatory fees, the Commission identifies those stations that it deems to be broadcast satellite television stations based on Consolidated Data Base System (CDBS) and other Media Bureau data. However, some stations claim to operate as ``satellites,'' and pay a lower regulatory fee ($1,750 in FY 2016), although they have not been officially granted satellite status by the Commission. Because satellite status may be derived only as a result of Commission action, only stations granted such status by the Commission may pay the satellite television regulatory fee; other stations that claim such status must pay the fee for a full-service station. Attached in Appendix E is a list of the bona fide licensed broadcast satellite television stations, according to the Media Bureau records. This list is generated from the Commission's CDBS and other information provided to the Media Bureau. We invite comment on the accuracy of this list. ---------------------------------------------------------------------------

    \64\ 47 CFR 76.55(e)(2); Assessment and Collection of Regulatory Fees for Fiscal Year 2000, Report and Order, 15 FCC Rcd 14478, 14492, para. 34 (2000) (FY 2000 Report and Order) (``Fees for television stations are based on market size as determined by Nielsen. This is the only consistent source the Commission has for determining which market a station serves.''). See also Amendment to the Commission's Rules Concerning Market Modification, 30 FCC Rcd 10406, para. 6, n. 19 (2015) (``The Nielsen Company delineates television markets by assigning each U.S county (except for certain counties in Alaska) to one market based on measured viewing patterns both off-air and via MVPD distribution.''); Designated Market Areas: Report to Congress, 31 FCC Rcd 5463, 5465 through 66, para. 6 (2015).     \65\ FY 2000 Report and Order, 15 FCC Rcd 14478, 14492, para. 34 (Commission rejected commenter's ``argu[ment] that small television stations located near large designated market areas (DMA) are assessed disproportionately high fees because the A.C Nielsen ratings include them in the DMA but they do not serve households in the DMA. Fees for television stations are based on market size as determined by Nielsen. This is the only consistent source the Commission has for determining which market a station serves.''). ---------------------------------------------------------------------------

    28. Recognizing that the Commission permitted a lesser fee for television satellite stations, we seek comment on whether we should increase the regulatory fees for broadcast satellite television stations to ensure that all television broadcasters are paying an appropriate regulatory fee based on Media Bureau FTE oversight and regulation. The circumstances that existed in 1994 when the Commission explained that it would permit consideration of a reduced fee in very limited circumstances have changed.\66\ As it relates to television satellite stations, should the satellite regulatory fee be increased to a higher percentage of standalone full-service broadcast television stations for ``remaining markets''? In particular, we seek comment on whether the fee for broadcast television satellite stations should be increased to 50 or 75 percent of the regulatory fee for remaining markets for FY 2017 applicable if the station were not a broadcast satellite station, but a full-service standalone broadcast station. Commenters supporting an increase in the broadcast satellite television fee should explain why the fee should be closer to the regular standalone full-service broadcast television fee. ---------------------------------------------------------------------------

    \66\ See Implementation of section 9 of the Communications Act and Assessment and Collection of Regulatory Fees of the 1994 Fiscal Year, Memorandum Opinion and Order, 10 FCC Rcd 12759, 12763, para. 21 (1995) (Applicants considered for relief ``were generally UHF stations . . . lack[ing] network affiliations . . . located outside of the principal city's metropolitan area and do not provide a Grade B signal to a substantial portion of the market's metropolitan areas. Often these stations are not carried by cable systems serving the principal metropolitan areas.''); Assessment and Collection of Regulatory Fees for Fiscal Year 1996, Report and Order, 11 FCC Rcd 18774, 18786, para. 32 (1966) (``We . . .rely on Nielsen's DMA market rankings . . . Nielsen data is generally accepted throughout the industry and will be updated and published annually . . . We will consider the equities concerning the fees of licensees that change markets on a case-by-case basis, upon request, and, where a licensee demonstrates that it does not serve its assigned market, we will consider reducing the assigned fees to a more equitable level, based upon the area actually served by the licensee.''). ---------------------------------------------------------------------------

E. International Bearer Circuits

    29. Historically, regulatory fees for international bearer circuits (IBCs) have been paid by facilities-based common carriers based on the number of active international bearer circuits they have in a transmission facility used to provide service to specified types of entities--specifically, by facilities-based common carriers that have active international bearer circuits in any transmission facility for the provision of service to an end user or resale carrier, which includes active circuits to themselves or to their affiliates.\67\ In 2009, the Commission revised this methodology by allocating submarine IBC costs among service providers in an equitable and competitively neutral manner, without distinguishing between common carriers and non- common carriers, and assessing a flat per cable landing license fee for all submarine cable systems.\68\ It nonetheless declined to simplify terrestrial and satellite IBCs at that time because of the ``complexity of the legal, policy and equity issues involved.'' \69\ In the FY 2016 NPRM, the Commission revisited the disparate treatment of terrestrial and satellite IBCs vis-[agrave]-vis submarine IBCs,\70\ but decided in the FY 2016 Report and Order, that the record was insufficient to change the fee methodology at that time.\71\ ---------------------------------------------------------------------------

    \67\ Assessment and Collection of Regulatory Fees for Fiscal Year 2008, Second Report and Order, 24 FCC Rcd 4208, 4211, para. 4 (2009) (Subcable Order).     \68\ Subcable Order, 24 FCC Rcd at 4214-16, paras. 13-17.     \69\ Assessment and Collection of Regulatory Fees for Fiscal Year 2009, Report and Order, 24 FCC Rcd 10301, 10306 through 07, paras. 16 through 17 (2009).     \70\ FY 2016 NPRM, 31 FCC Rcd at 5764 through 65, paras. 15 through 16.     \71\ FY 2016 Report and Order, 31 FCC Rcd at 10343, para. 11. ---------------------------------------------------------------------------

    30. The international services marketplace has continued to evolve and we seek comment on how to update and improve our regulatory fee assessment for terrestrial and satellite IBCs to reflect these changes.\72\ We seek comment on how to make our fee assessment more efficient, equitable, and less burdensome. In particular, we seek comment on adopting a flat, per-provider fee similar to how we treat submarine cable regulatory fees, with a tiered regulatory fee methodology for terrestrial IBCs based on capacity. Similar to the regulatory fee treatment of submarine cable IBCs, under this

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proposal, terrestrial and satellite IBCs would be treated the same regardless of whether they are offered on a common-carrier or non- common-carrier basis. We seek comment on this proposal and how to divide the terrestrial IBCs into categories based on capacity. ---------------------------------------------------------------------------

    \72\ The Commission has a pending proceeding that seeks comment on the federal need for the international services reporting requirements set forth in section 43.62 of the Commission's rules. Section 43.62 Reporting Requirements for U.S Providers of International Services; 2016 Biennial Review of Telecommunications Regulations, IB Docket Nos. 16 through 131 and 17 through 55, Notice of Proposed Rulemaking, 32 FCC Rcd 2606 (2017). Relevant to this proceeding, the Commission seeks comment on whether there are ways to further streamline the Circuit Capacity Reports, which require providers of international telecommunications services to file annual reports identifying the submarine cable, satellite, and terrestrial capacity between the United States and foreign points. As noted below, we rely on the reporting requirements for terrestrial, satellite, and submarine cable capacity data to administer the annual regulatory fees established in section 9 of the Act. See infra at Appendix C; see 47 CFR 43.62(a)(1). ---------------------------------------------------------------------------

    31. Level 3 states that non-common carrier terrestrial IBCs should not be exempt from regulatory fees, as it finds the practice to be administratively burdensome, not equitable or competitively neutral, and a disincentive to compliance with the Commission's regulatory fee rules.\73\ Level 3, for example, states that it ``spends dozens of person hours each year polling multiple systems to identify international terrestrial facilities in service, generating reports of the circuits that have been sold over those facilities, and identifying whether any of the circuits were sold on a non-common carrier basis.'' \74\ Level 3 asserts that the disparate treatment of common carrier and non-common carrier circuits is neither equitable nor competitively neutral as ``[p]roviders that offer international terrestrial service on a common carrier basis are at a significant disadvantage vis a vis providers that characterize their service as non-common carrier.'' \75\ Level 3 states that ``[c]arriers currently have a strong incentive to characterize circuits as non-common carrier circuits in order to reduce their regulatory fee burden.'' \76\ According to Level 3, a flat fee will improve compliance with the Commission's regulatory fee requirements \77\ and ``a flat-fee system will remove incentives for providers to not deploy terrestrial IBCs, or to sell international capacity over submarine cable systems instead of terrestrial IBCs.'' \78\ We seek comment on these arguments and whether we should harmonize the regulatory treatment of common carrier and non-common carrier terrestrial circuits. ---------------------------------------------------------------------------

    \73\ Level 3 Comments, MD Docket No. 16-166, at 5.     \74\ Id. at 5.     \75\ Id. at 6 (stating that ``the fact that non-common carrier circuits are `unregulated' is not relevant to the Commission's authority to collect regulatory fees on those circuits. All terrestrial IBCs are `telecommunications' subject to the Commissions' jurisdiction, and benefit from the Commissions' `international activities,' including cross-border coordination with Canada and Mexico'').     \76\ Id. at 5.     \77\ Id. at 5.     \78\ Id. at 4. ---------------------------------------------------------------------------

    32. We also seek comment on whether we should make changes to the IBC fees for satellite circuits. The number of satellite IBCs are relatively small as compared to terrestrial IBCs.\79\ We also note that in addition to being assessed regulatory fees on their common carrier and non-common carrier circuits, earth station, geostationary orbit space station, and non-geostationary orbit space station licensees pay separate regulatory fees for their facilities that are licensed and operational.\80\ We seek comment on whether there is a basis to eliminate the IBC regulatory fee for satellite providers of international communications. If we retain the IBC regulatory fees for satellite circuits, should we adopt the methodology discussed herein for assessing the number of active circuits (either only assessing fees on systems active as of December 31 of the prior year, or assessing fees on IBCs that were active at any point during the preceding calendar year)? If we adopt the proposal for a flat-fee methodology, should we apply it to satellite circuits as well as terrestrial circuits? Are there any other steps we should take to harmonize our regulatory fee treatment of terrestrial and satellite IBCs? ---------------------------------------------------------------------------

    \79\ For example, for data as of December 31, 2014, there were a total of 21,911,703 circuit units (64 kbps) with terrestrial circuits accounting for 99.63 percent (21,830,546) while satellite accounted for only 0.37 percent (81,157). FCC, International Bureau, 2014 U.S International Circuit Capacity Report at 3 (IB 2016), [*https://apps.fcc.gov/edocs\_public/attachmatch/DOC-337257A2.pdf*](https://apps.fcc.gov/edocs_public/attachmatch/DOC-337257A2.pdf)     \80\ See infra para. 39; FY 2016 Report and Order, 31 FCC Rcd at 10356, para. 42. ---------------------------------------------------------------------------

    33. We also seek comment on whether we should continue to assess regulatory fees based on IBCs that were active as of December 31 of the prior year.\81\ Commenters should discuss whether instead we should assess regulatory fees based on IBCs that were active at any point during the preceding calendar year.\82\ ---------------------------------------------------------------------------

    \81\ 47 CFR 43.62(a)(1); see infra at para. 30.     \82\ We recognize that this could require modification of section 43.62(a)(1) of our rules and any successor rules. 47 CFR 43.62(a)(1). ---------------------------------------------------------------------------

    34. Finally, we tentatively conclude that adding non-common carrier international bearer circuits to the regulatory fee schedule would be a permitted amendment as defined in section 9(b)(3) of the Act,\83\ and pursuant to section 9(b)(4)(B) must be submitted to Congress at least 90 days before it would become effective.\84\ ---------------------------------------------------------------------------

    \83\ 47 U.S.C 159(b)(3).     \84\ 47 U.S.C 159(b)(4)(B). ---------------------------------------------------------------------------

F. Revising the De Minimis Threshold and Eliminating Regulatory Fee Categories

    35. Under the Commission's current de minimis rule for regulatory fee payments, a regulatee is exempt from paying regulatory fees if the sum total of all of its regulatory fee liabilities for annual regulatory fees is $500 or less for the fiscal year.\85\ The Commission increased the de minimis threshold from $10 to $500 in the FY 2014 Report and Order.\86\ The higher threshold reflected the estimated costs of collecting an unpaid regulatory fee, i.e , at least $350 in direct costs, and the benefits to these entities of a higher de minimis threshold. The Commission's estimate of approximately $350 excluded overhead or other costs involved in regulatory fee collection.\87\ In addition, the Commission observed that setting the de minimis threshold at $500 was unlikely to reduce fee collections to an amount below the full amount of the Commission's annual appropriation.\88\ ---------------------------------------------------------------------------

    \85\ FY 2014 Report and Order, 29 FCC Rcd at 10774-76, paras. 18 through 21.     \86\ Id.     \87\ Id., 29 FCC Rcd at 10775, para. 20 & n. 62.     \88\ Id. ---------------------------------------------------------------------------

    36. In the FY 2014 regulatory fee proceeding, commenters argued the threshold should be increased to $750 or $1,000.\89\ For example, ACA suggested that the Commission adopt a threshold of 1000 or fewer subscribers for cable operators and the National Association of Broadcasters (NAB) argued that the Commission should adopt a de minimis threshold of $750 or $1,000 in order to provide relief for smaller entities.\90\ These commenters explained that a higher de minimis threshold may contribute to the difference between a small operator staying in business or closing operations.\91\ NAB also observed that a higher de minimis threshold would allow stations in smaller markets to devote more resources to improved programming and signal quality.\92\ The Commission adopted a new threshold of $500 for annual regulatory fee and committed to further monitor the de minimis threshold and consider whether to increase the threshold or revise on some other basis.\93\ ---------------------------------------------------------------------------

    \89\ Id.     \90\ Id.     \91\ Id., 29 FCC Rcd at 10774 through 75, para. 19.     \92\ Id.     \93\ Id., 29 FCC Rcd at 10775, para. 20. ---------------------------------------------------------------------------

    37. Consistent with this commitment, we seek comment on increasing the de minimis threshold to $1,000 to improve the cost effectiveness of the Commission's collection of regulatory fees and to provide regulatory fee relief to smaller entities, particularly those that have little Commission regulation or oversight.\94\ As we explained in the

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FY 2014 Report and Order, smaller entities with limited funds are less likely to be able to budget for regulatory fees on a timely basis and therefore may incur late fees and consequently use more Commission resources for fee collection.\95\ The administrative burden on small regulatees, and the Commission's operational costs associated with processing and collecting these smaller fees, likely outweigh the benefits of such payments. For example, payors between $500 and $1,000 account for less than one percent of all regulatory fee payments. In addition, the cost of researching, creating, and sending a bill to a non-payer, and completing all follow-up discussion and correspondence, totals more than $350. Added to this cost is the overhead and the costs of administering the regulatory fee program.\96\ We seek comment on whether it makes sense to incur upwards of $350 in administrative costs to collect not even that much in regulatory fees that can offset the costs fees paid by other regulatees (as is the case for regulatees that owe $501 to $700). We seek comment on whether a $1,000 threshold is high enough to ensure that the regulatory fees collected from any regulatee substantially exceed the costs of collection. We invite comment whether the cost of collections and burden on small entities outweigh the associated regulatory fee payments. ---------------------------------------------------------------------------

    \94\ Id. (observing that many small entities ``are subject to little Commission oversight and regulation which serves to further exacerbate this inequity [of the administrative burden].'').     \95\ Id.     \96\ Id. ---------------------------------------------------------------------------

    38. We also seek comment on whether we should include multi-year wireless licenses in the de minimis threshold. If we adopt a de minimis threshold for multi-year wireless licensees, should the threshold be fee-based, or should it be determined by the number of licenses, frequencies, or paths the licensee holds? We recognize that some entities hold many multi-year licenses and the licenses can be renewed at different times of the year. Commenters should discuss whether including multi-year licenses in the de minimis threshold would be too administratively burdensome. We also seek comment on whether we should adopt a de minimis threshold based on number of cable television subscribers, as suggested by ACA.\97\ ---------------------------------------------------------------------------

    \97\ ACA observes that ``exempting cable/IPTV providers serving fewer than 1,000 subscribers from the Cable/IPTV fee category would be consistent with other exemptions the Commission has created for these operators, and would serve similar purposes.'' ACA ex parte at 4. ACA suggests a progressive fee structure, with the level of rates gradually increasing based on the number of subscribers. Id. at 5 through 6. ---------------------------------------------------------------------------

    39. In addition, we seek comment on eliminating regulatory fee categories, such as CMRS Messaging (Paging).\98\ This category accounts for a very small amount of regulatory fees; we seek comment on the benefits of discontinuing such collections. Commenters should discuss other changes to the regulatory fee framework that would facilitate the goal of ensuring that regulatory fees are administrable and sustainable. For example, are there categories of regulatory fee payors that now have very little Commission oversight or regulation, apart from the application fee process? We seek comment on whether there are regulatory fees adopted for some categories in the past where now there is a clear case to conclude that the fee is no longer ``reasonably related to the benefits provided to the payer of the fee by the Commission's activities . . . .'' \99\ ---------------------------------------------------------------------------

    \98\ The Commission has sought comment on this issue previously. See Assessment and Collection of Regulatory Fees for Fiscal Year 2014, Notice of Proposed Rulemaking, 29 FCC Rcd 6417, 6429, para. 32 (2014) (FY 2014 NPRM).     \99\ 47 U.S.C 159(b)(1)(A). We note, however, that the Communications Act provides for ``waiver, reduction, and deferment'' of a regulatory fee in any specific instance for good cause shown, where such action would promote the public interest. As a result, commenters should not focus suggestions on the merits of individual regulatory fee payors but rather improvements to the system that are consistent with Congressional directive contained in section 9 of the Communications Act. ---------------------------------------------------------------------------

    40. We tentatively conclude that eliminating categories from our regulatory fee schedule would be a permitted amendment as defined in section 9(b)(3) of the Act,\100\ and pursuant to section 9(b)(4)(B) must be submitted to Congress at least 90 days before it would become effective.\101\ ---------------------------------------------------------------------------

    \100\ 47 U.S.C 159(b)(3).     \101\ 47 U.S.C 159(b)(4)(B). ---------------------------------------------------------------------------

G. Other Reforms

    41. We also seek comment on ways to further improve our regulatory fee process to make it less burdensome for all entities. In particular, we seek comment on ways we can communicate better with smaller regulatees, such as mass emails (instead of through the U.S Postal Service), and if we should therefore require a current email address for all regulatory fee payors.

V. Procedural Matters

A. Payment of Regulatory Fees

1. Checks Will Not Be Accepted for Payment of Annual Regulatory Fees     42. Pursuant to an Office of Management and Budget (OMB) directive,\102\ the Commission is moving towards a paperless environment, extending to disbursement and collection of select federal government payments and receipts.\103\ In 2015, the Commission stopped accepting checks (including cashier's checks and money orders) and the accompanying hardcopy forms (e.g , Forms 159, 159-B, 159-E, 159-W) for the payment of regulatory fees.\104\ All regulatory fee payments must be made by online Automated Clearing House (ACH) payment, online credit card, or wire transfer. Any other form of payment (e.g , checks, cashier's checks, or money orders) will be rejected. For payments by wire, a Form 159-E should still be transmitted via fax so that the Commission can associate the wire payment with the correct regulatory fee information. ---------------------------------------------------------------------------

    \102\ Office of Management and Budget (OMB) Memorandum M-10-06, Open Government Directive, Dec. 8, 2009; see also [*http://www.whitehouse.gov/the-press-office/2011/06/13/executive-order-13576-delivering-efficient-effective-and-accountable-gov*](http://www.whitehouse.gov/the-press-office/2011/06/13/executive-order-13576-delivering-efficient-effective-and-accountable-gov).     \103\ See U.S Department of the Treasury, Open Government Plan 2.1, September 2012.     \104\ FY 2015 Report and Order, 30 FCC Rcd at 10282 through 83, para. 35. See 47 CFR 1.1158 ---------------------------------------------------------------------------

2. Credit Card Transaction Levels     43. Since June 1, 2015, in accordance with U.S Treasury Announcement No. A-2014-04 (July 2014), the amount that can be charged on a credit card for transactions with federal agencies has is $24,999.99 \105\ Transactions greater than $24,999.99 will be rejected. This limit applies to single payments or bundled payments of more than one bill. Multiple transactions to a single agency in one day may be aggregated and treated as a single transaction subject to the $24,999.99 limit. Customers who wish to pay an amount greater than $24,999.99 should consider available electronic alternatives such as Visa or MasterCard debit cards, ACH debits from a bank account, and wire transfers. Each of these payment options is available after filing regulatory fee information in Fee Filer. Further details will be provided regarding payment methods and procedures at the time of FY 2017 regulatory fee collection in Fact Sheets, available at [*https://www.fcc.gov/regfees*](https://www.fcc.gov/regfees). ---------------------------------------------------------------------------

    \105\ Customers who owe an amount on a bill, debt, or other obligation due to the federal government are prohibited from splitting the total amount due into multiple payments. Splitting an amount owed into several payment transactions violates the credit card network and Fiscal Service rules. An amount owed that exceeds the Fiscal Service maximum dollar amount, $24,999.99, may not be split into two or more payment transactions in the same day by using one or multiple cards. Also, an amount owed that exceeds the Fiscal Service maximum dollar amount may not be split into two or more transactions over multiple days by using one or more cards. ---------------------------------------------------------------------------

3. De Minimis Regulatory Fees     44. Under the Commission's present de minimis rule for regulatory fee

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payments, a regulatee is exempt from paying regulatory fees if the sum total of all of its annual regulatory fee liabilities is $500 or less for the fiscal year. The de minimis threshold applies only to filers of annual regulatory fees (not regulatory fees paid through multi-year filings), and it is not a permanent exemption. Each regulatee will need to reevaluate the total annual fee liability each fiscal year to determine whether they meet the de minimis exemption. This de minimis threshold could change as a result of this Notice of Proposed Rulemaking. 4. Standard Fee Calculations and Payment Dates     45. The Commission will accept fee payments made in advance of the window for the payment of regulatory fees. The responsibility for payment of fees by service category is as follows:      Media Services: Regulatory fees must be paid for initial construction permits that were granted on or before October 1, 2016 for AM/FM radio stations, VHF/UHF full service television stations, and satellite television stations. Regulatory fees must be paid for all broadcast facility licenses granted on or before October 1, 2016.      Wireline (Common Carrier) Services: Regulatory fees must be paid for authorizations that were granted on or before October 1, 2016. In instances where a permit or license is transferred or assigned after October 1, 2016, responsibility for payment rests with the holder of the permit or license as of the fee due date. Audio bridging service providers are included in this category.\106\ For Responsible Organizations (RespOrgs) that manage Toll Free Numbers (TFN), regulatory fees should be paid on all working, assigned, and reserved toll free numbers as well as toll free numbers in any other status as defined in section 52.103 of the Commission's rules.\107\ The unit count should be based on toll free numbers managed by RespOrgs on or about December 31, 2016. ---------------------------------------------------------------------------

    \106\ Audio bridging services are toll teleconferencing services.     \107\ 47 CFR 52.103 ---------------------------------------------------------------------------

     Wireless Services: CMRS cellular, mobile, and messaging services (fees based on number of subscribers or telephone number count): Regulatory fees must be paid for authorizations that were granted on or before October 1, 2016. The number of subscribers, units, or telephone numbers on December 31, 2016 will be used as the basis from which to calculate the fee payment. In instances where a permit or license is transferred or assigned after October 1, 2016, responsibility for payment rests with the holder of the permit or license as of the fee due date.      Wireless Services, Multi-year fees: The first eight regulatory fee categories in our Schedule of Regulatory Fees pay ``small multi-year wireless regulatory fees.'' Entities pay these regulatory fees in advance for the entire amount period covered by the five-year or ten-year terms of their initial licenses, and pay regulatory fees again only when the license is renewed or a new license is obtained. We include these fee categories in our rulemaking to publicize our estimates of the number of ``small multi-year wireless'' licenses that will be renewed or newly obtained in FY 2017.      Multichannel Video Programming Distributor Services (cable television operators, CARS licensees, DBS, and IPTV): Regulatory fees must be paid for the number of basic cable television subscribers as of December 31, 2016.\108\ Regulatory fees also must be paid for CARS licenses that were granted on or before October 1, 2016. In instances where a permit or license is transferred or assigned after October 1, 2016, responsibility for payment rests with the holder of the permit or license as of the fee due date. For providers of Direct Broadcast Satellite (DBS) service and IPTV-based MVPDs, regulatory fees should be paid based on a subscriber count on or about December 31, 2016. In instances where a permit or license is transferred or assigned after October 1, 2016, responsibility for payment rests with the holder of the permit or license as of the fee due date. ---------------------------------------------------------------------------

    \108\ Cable television system operators should compute their number of basic subscribers as follows: Number of single family dwellings + number of individual households in multiple dwelling unit (apartments, condominiums, mobile home parks, etc.) paying at the basic subscriber rate + bulk rate customers + courtesy and free service. Note: Bulk-Rate Customers = Total annual bulk-rate charge divided by basic annual subscription rate for individual households. Operators may base their count on ``a typical day in the last full week'' of December 2016, rather than on a count as of December 31, 2016. ---------------------------------------------------------------------------

     International Services: Regulatory fees must be paid for (1) earth stations and (2) geostationary orbit space stations and non- geostationary orbit satellite systems that were licensed and operational on or before October 1, 2016. In instances where a permit or license is transferred or assigned after October 1, 2016, responsibility for payment rests with the holder of the permit or license as of the fee due date.      International Services: (Submarine Cable Systems): Regulatory fees for submarine cable systems are to be paid on a per cable landing license basis based on circuit capacity as of December 31, 2016. In instances where a license is transferred or assigned after October 1, 2016, responsibility for payment rests with the holder of the license as of the fee due date. For regulatory fee purposes, the allocation in FY 2017 will remain at 87.6 percent for submarine cable and 12.4 percent for satellite/terrestrial facilities.      International Services: (Terrestrial and Satellite Services): Regulatory fees for Terrestrial and Satellite IBCs are to be paid by facilities-based common carriers that have active (used or leased) international bearer circuits as of December 31, 2016 in any terrestrial or satellite transmission facility for the provision of service to an end user or resale carrier. When calculating the number of such active circuits, the facilities-based common carriers must include circuits used by themselves or their affiliates. In addition, non-common carrier satellite operators must pay a fee for each circuit they and their affiliates hold and each circuit sold or leased to any customer, other than an international common carrier authorized by the Commission to provide U.S international common carrier services. For these purposes, ``active circuits'' include backup and redundant circuits as of December 31, 2016. Whether circuits are used specifically for voice or data is not relevant for purposes of determining that they are active circuits.\109\ In instances where a permit or license is transferred or assigned after October 1, 2016, responsibility for payment rests with the holder of the permit or license as of the fee due date. For regulatory fee purposes, the allocation in FY 2017 will remain at 87.6 percent for submarine cable and 12.4 percent for satellite/terrestrial facilities.\110\ ---------------------------------------------------------------------------

    \109\ We encourage terrestrial and satellite service providers to seek guidance from the International Bureau's Telecommunications and Analysis Division to verify their particular IBC reporting processes to ensure that their calculation methods comply with our rules.     \110\ We remind facilities-based common carriers to review their reporting processes to ensure that they accurately calculate and report IBCs. ---------------------------------------------------------------------------

B. Commercial Mobile Radio Service (CMRS) and Mobile Services Assessments

    46. The Commission will compile data from the Numbering Resource Utilization Forecast (NRUF) report that is based on ``assigned'' telephone number (subscriber) counts that have been adjusted for porting to net Type 0 ports (``in'' and ``out'').\111\ This

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information of telephone numbers (subscriber count) will be posted on the Commission's electronic filing and payment system (Fee Filer) along with the carrier's Operating Company Numbers (OCNs). ---------------------------------------------------------------------------

    \111\ See Assessment and Collection of Regulatory Fees for Fiscal Year 2005, Report and Order and Order on Reconsideration, 20 FCC Rcd 12259, 12264, paras. 38 through 44 (2005). ---------------------------------------------------------------------------

    47. A carrier wishing to revise its telephone number (subscriber) count can do so by accessing Fee Filer and follow the prompts to revise their telephone number counts. Any revisions to the telephone number counts should be accompanied by an explanation or supporting documentation.\112\ The Commission will then review the revised count and supporting documentation and either approve or disapprove the submission in Fee Filer. If the submission is disapproved, the Commission will contact the provider to afford the provider an opportunity to discuss its revised subscriber count and/or provide additional supporting documentation. If we receive no response from the provider, or we do not reverse our initial disapproval of the provider's revised count submission, the fee payment must be based on the number of subscribers listed initially in Fee Filer. Once the timeframe for revision has passed, the telephone number counts are final and are the basis upon which CMRS regulatory fees are to be paid. Providers can view their final telephone counts online in Fee Filer. A final CMRS assessment letter will not be mailed out. ---------------------------------------------------------------------------

    \112\ In the supporting documentation, the provider will need to state a reason for the change, such as a purchase or sale of a subsidiary, the date of the transaction, and any other pertinent information that will help to justify a reason for the change. ---------------------------------------------------------------------------

    48. Because some carriers do not file the NRUF report, they may not see their telephone number counts in Fee Filer. In these instances, the carriers should compute their fee payment using the standard methodology that is currently in place for CMRS Wireless services (i.e , compute their telephone number counts as of December 31, 2016), and submit their fee payment accordingly. Whether a carrier reviews its telephone number counts in Fee Filer or not, the Commission reserves the right to audit the number of telephone numbers for which regulatory fees are paid. In the event that the Commission determines that the number of telephone numbers that are paid is inaccurate, the Commission will bill the carrier for the difference between what was paid and what should have been paid.

VI. Additional Tables

                                         Table 3--Calculation of FY 2017 Revenue Requirements and Pro-Rata Fees  [Regulatory fees in the first seven fee categories are collected by the Commission in advance to cover the term of the license and are submitted at the                                                              time the application is filed.] --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                               FY 2016      Pro-Rated FY     Computed FY                Fee Category                  FY 2017 Payment     Years        Revenue      2017 Revenue        2017         Rounded  FY    Expected  FY                                                   units                      estimate       requirement   Regulatory fee  2017  reg. fee   2017  revenue -------------------------------------------------------------------------------------------------------------------------------------------------------- PLMRS (Exclusive Use).....................              1,300         10         625,000         326,950              25              25         325,000 PLMRS (Shared use)........................             16,000         10       3,110,000       1,609,600              10              10       1,600,000 Microwave.................................             11,800         10       3,125,000       2,967,700              25              25       2,950,000 Marine (Ship).............................              8,100         10       1,035,000       1,222,290              15              15       1,215,000 Aviation (Aircraft).......................              4,200         10         470,000         422,520              10              10         420,000 Marine (Coast)............................                150         10         192,500          60,360              40              40          60,000 Aviation (Ground).........................              1,100         10         220,000         221,329              20              20         220,000 AM Class A \4\............................                 65          1         313,500         307,333           4,728           4,725         307,125 AM Class B \4\............................              1,523          1       3,875,875       3,830,345           2,515           2,525       3,845,575 AM Class C \4\............................                870          1       1,400,175       1,356,591           1,559           1,550       1,348,500 AM Class D \4\............................              1,492          1       4,587,900       4,502,856           3,018           3,025       4,513,300 FM Classes A, B1 & C3 \4\.................              3,150          1       9,678,200       9,427,478           2,993           3,000       9,450,000 FM Classes B, C, C0, C1 & C2 \4\..........              3,114          1      11,849,725      11,590,931           3,722           3,725      11,599,650 AM Construction Permits \1\...............                 10          1           9,300           6,500             650             650           6,500 FM Construction Permits\1\................                113          1         192,425         129,950           1,150           1,150         129,950 Satellite TV..............................                126          1         224,000         218,654           1,735           1,725         217,350 Digital TV Markets 1-10...................                139          1       8,433,825       8,355,082          60,109          60,100       8,353,900 Digital TV Markets 11-25..................                131          1       6,348,825       5,933,665          45,295          45,300       5,934,300 Digital TV Markets 26-50..................                181          1       5,525,025       5,471,684          30,230          30,225       5,470,725 Digital TV Markets 51-100.................                285          1       4,301,600       4,314,986          15,140          15,150       4,317,750 Digital TV Remaining Markets..............                367          1       1,825,000       1,818,320           4,955           4,950       1,816,650 Digital TV Construction Permits \1\.......                  3          1          15,000          14,864           4,955           4,950          14,850 LPTV/Translators/Boosters/Class A TV......              4,051          1       1,785,420       1,752,382             433             435       1,762,185 CARS Stations.............................                230          1         220,875         216,340             941             940         216,200 Cable TV Systems, including IPTV..........         62,000,000          1      64,200,000      59,253,400           .9557             .96      59,520,000 Direct Broadcast Satellite (DBS)..........         32,500,000          1       9,180,000      12,424,100             .38             .38      12,350,000 Interstate Telecommunication Service           37,300,000,000          1     142,722,000     112,571,400        0.003018         0.00302     112,646,000  Providers................................ Toll Free Numbers.........................         32,700,000          1       4,745,000       3,947,544          0.1207            0.12       3,924,000

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  CMRS Mobile Services (Cellular/Public             385,000,000          1      73,200,000      81,336,108           0.211            0.21      80,850,000  Mobile).................................. CMRS Messag. Services.....................          2,100,000          1         184,000         168,000          0.0800           0.080         168,000 BRS \2\...................................                870          1         645,250         561,398             805             805         700,350 LMDS......................................                395          1         286,375         456,976             805             805         317,975 Per 64 kbps Int'l Bearer Circuits                  26,500,000          1         638,000         791,219           .0299             .03         795,000  Terrestrial (Common) & Satellite (Common  & Non-Common)............................ Submarine Cable Providers (see chart in                 41.19          1       5,486,242       5,589,583         135,709         135,700       5,589,212  Appendix C) \3\.......................... Earth Stations............................              3,400          1       1,173,000       1,228,896             361             360       1,224,000 Space Stations (Geostationary)............                 95          1      13,155,125      13,725,182         144,476         144,475      13,725,125 Space Stations (Non-Geostationary)........                  6          1         911,700         951,190         158,532         158,525         951,150                                            -------------------------------------------------------------------------------------------------------------     \*\*\*\*\*\* Total Estimated Revenue to be    .................  .........     384,890,362     359,083,693  ..............  ..............     358,855,322      Collected............................                                            -------------------------------------------------------------------------------------------------------------         \*\*\*\*\*\* Total Revenue Requirement..  .................  .........     384,012,497     356,710,992  ..............  ..............     356,710,992                                            -------------------------------------------------------------------------------------------------------------             Difference....................  .................  .........         877,865       2,372,701  ..............  ..............       2,144,330 -------------------------------------------------------------------------------------------------------------------------------------------------------- Notes on Table 3 \1\ The AM and FM Construction Permit revenues and the Digital (VHF/UHF) Construction Permit revenues were adjusted, respectively, to set the regulatory   fee to an amount no higher than the lowest licensed fee for that class of service. Reductions in the Digital (VHF/UHF) Construction Permit revenues,   and in the AM and FM Construction Permit revenues, were offset by increases in the revenue totals for Digital television stations by market size, and   in the AM and FM radio stations by class size and population served, respectively. \2\ MDS/MMDS category was renamed Broadband Radio Service (BRS). See Amendment of Parts 1, 21, 73, 74 and 101 of the Commission's Rules to Facilitate   the Provision of Fixed and Mobile Broadband Access, Educational and Other Advanced Services in the 2150-2162 and 2500-2690 MHz Bands, Report & Order   and Further Notice of Proposed Rulemaking, 19 FCC Rcd 14165, 14169, para. 6 (2004). \3\ The chart at the end of Table 4 lists the submarine cable bearer circuit regulatory fees (common and non-common carrier basis) that resulted from   the adoption of the Assessment and Collection of Regulatory Fees for Fiscal Year 2008, Report and Order and Further Notice of Proposed Rulemaking, 24   FCC Rcd 6388 (2008) and Assessment and Collection of Regulatory Fees for Fiscal Year 2008, Second Report and Order, 24 FCC Rcd 4208 (2009). \4\ The fee amounts listed in the column entitled ``Rounded New FY 2017 Regulatory Fee'' constitute a weighted average broadcast regulatory fee by class   of service. The actual FY 2017 regulatory fees for AM/FM radio station are listed on a grid located at the end of Table 4.

                    Table 4--Proposed Regulatory Fees  Regulatory fees in the first eight fee categories are collected by the Commission in advance to cover the term of the license and are submitted                   at the time the application is filed. ------------------------------------------------------------------------                                                              Annual                      Fee category                        regulatory fee                                                            (U.S $'s) ------------------------------------------------------------------------ PLMRS (per license) (Exclusive Use) (47 CFR part 90).                 25 Microwave (per license) (47 CFR part 101)............                 25 Marine (Ship) (per station) (47 CFR part 80).........                 15 Marine (Coast) (per license) (47 CFR part 80)........                 40 Rural Radio (47 CFR part 22) (previously listed under                 10  the Land Mobile category)........................... PLMRS (Shared Use) (per license) (47 CFR part 90)....                 10 Aviation (Aircraft) (per station) (47 CFR part 87)...                 10 Aviation (Ground) (per license) (47 CFR part 87).....                 20 CMRS Mobile/Cellular Services (per unit) (47 CFR                     .21  parts 20, 22, 24, 27, 80 and 90).................... CMRS Messaging Services (per unit) (47 CFR parts 20,                 .08  22, 24 and 90)...................................... Broadband Radio Service (formerly MMDS/MDS) (per                     805  license) (47 CFR part 27)........................... Local Multipoint Distribution Service (per call sign)                805  (47 CFR, part 101).................................. AM Radio Construction Permits........................                650 FM Radio Construction Permits........................              1,150 Digital TV (47 CFR part 73) VHF and UHF Commercial...  .................     Markets 1-10.....................................             60,100

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      Markets 11-25....................................             45,300     Markets 26-50....................................             30,225     Markets 51-100...................................             15,150     Remaining Markets................................              4,950     Construction Permits.............................              4,950 Satellite Television Stations (All Markets)..........              1,725 Low Power TV, Class A TV, TV/FM Translators &                        435  Boosters (47 CFR part 74)........................... CARS (47 CFR part 78)................................                940 Cable Television Systems (per subscriber) (47 CFR                    .96  part 76), Including IPTV............................ Direct Broadcast Service (DBS) (per subscriber) (as                  .38  defined by section 602(13) of the Act).............. Interstate Telecommunication Service Providers (per               .00302  revenue dollar)..................................... Toll Free (per toll free subscriber) (47 CFR section                 .12  52.101 (f) of the rules)............................ Earth Stations (47 CFR part 25)......................                360 Space Stations (per operational station in                       144,475  geostationary orbit) (47 CFR part 25) also includes  DBS Service (per operational station) (47 CFR part  100)................................................ Space Stations (per operational system in non-                   158,525  geostationary orbit) (47 CFR part 25)............... International Bearer Circuits--Terrestrial/Satellites                .03  (per 64KB circuit).................................. Submarine Cable Landing Licenses Fee (per cable          See Table Below  system)............................................. ------------------------------------------------------------------------

                                                          FY 2017 Radio Station Regulatory Fees --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                                                                            FM Classes B,                     Population served                       AM Class A      AM Class B      AM Class C      AM Class D     FM Classes A,   C, C0,  C1 &                                                                 ($)             ($)             ($)             ($)        B1 & C3  ($)       C2  ($) -------------------------------------------------------------------------------------------------------------------------------------------------------- <=25,000................................................           1,050             750             650             715           1,150           1,300 25,001-75,000...........................................           1,575           1,125             975           1,075           1,725           1,950 75,001-150,000..........................................           2,375           1,700           1,475           1,600           2,600           2,925 150,001-500,000.........................................           3,550           2,525           2,200           2,425           3,875           4,400 500,001-1,200,000.......................................           5,325           3,800           3,300           3,625           5,825           6,575 1,200,001-3,000,00......................................           7,975           5,700           4,950           5,425           8,750           9,875 3,000,001-6,000,00......................................          11,950           8,550           7,400           8,150          13,100          14,800 >6,000,000..............................................          17,950          12,825          11,100          12,225          19,650          22,225 --------------------------------------------------------------------------------------------------------------------------------------------------------

             International Bearer Circuits--Submarine Cable ------------------------------------------------------------------------   Submarine cable systems (capacity as of December 31,      Fee amount                           2016)                                 ($) ------------------------------------------------------------------------ <2.5 Gbps...............................................           8,475 2.5 Gbps or greater, but less than 5 Gbps...............          16,975 5 Gbps or greater, but less than 10 Gbps................          33,925 10 Gbps or greater, but less than 20 Gbps...............          67,850 20 Gbps or greater......................................         135,700 ------------------------------------------------------------------------

 Sources of Payment Unit Estimates for FY 2017     In order to calculate individual service fees for FY 2017, we adjusted FY 2016 payment units for each service to more accurately reflect expected FY 2017 payment liabilities. We obtained our updated estimates through a variety of means. For example, we used Commission licensee data bases, actual prior year payment records and industry and trade association projections when available. The databases we consulted include our Universal Licensing System (ULS), International Bureau Filing System (IBFS), Consolidated Database System (CDBS) and Cable Operations and Licensing System (COALS), as well as reports generated within the Commission such as the Wireless Telecommunications Bureau's Numbering Resource Utilization Forecast.     We sought verification for these estimates from multiple sources and, in all cases, we compared FY 2017 estimates with actual FY 2016 payment units to ensure that our revised estimates were reasonable. Where appropriate, we adjusted and/or rounded our final estimates to take into consideration the fact that certain variables that impact on the number of payment units cannot yet be estimated with sufficient accuracy. These include an unknown number of waivers and/or exemptions that may occur in FY 2017 and the fact that, in many services, the number of actual licensees or station operators fluctuates from time to time due to economic, technical, or other reasons. When we note, for example, that our estimated FY 2017 payment units are based on FY 2016 actual payment units, it does not necessarily mean that our FY 2017 projection is exactly the same number as in FY 2016. We have either rounded the FY 2017 number or adjusted it slightly to account for these variables.

------------------------------------------------------------------------          Fee category              Sources of payment unit estimates ------------------------------------------------------------------------ Land Mobile (All), Microwave,  Based on Wireless Telecommunications  Marine (Ship & Coast),         Bureau (WTB) projections of new  Aviation (Aircraft &           applications and renewals taking into  Ground), Domestic Public       consideration existing Commission  Fixed.                         licensee data bases. Aviation (Aircraft)                                 and Marine (Ship) estimates have been                                 adjusted to take into consideration the                                 licensing of portions of these services                                 on a voluntary basis.

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  CMRS Cellular/Mobile Services  Based on WTB projection reports, and FY                                 16 payment data. CMRS Messaging Services......  Based on WTB reports, and FY 16 payment                                 data. AM/FM Radio Stations.........  Based on CDBS data, adjusted for                                 exemptions, and actual FY 2016 payment                                 units. Digital TV Stations (Combined  Based on CDBS data, adjusted for  VHF/UHF units).                exemptions, and actual FY 2016 payment                                 units. AM/FM/TV Construction Permits  Based on CDBS data, adjusted for                                 exemptions, and actual FY 2016 payment                                 units. LPTV, Translators and          Based on CDBS data, adjusted for  Boosters, Class A Television.  exemptions, and actual FY 2016 payment                                 units. BRS (formerly MDS/MMDS) LMDS.  Based on WTB reports and actual FY 2016                                 payment units. Based on WTB reports and                                 actual FY 2016 payment units. Cable Television Relay         Based on data from Media Bureau's COALS  Service (CARS) Stations.       database and actual FY 2016 payment                                 units. Cable Television System        Based on publicly available data sources  Subscribers, Including IPTV    for estimated subscriber counts and  Subscribers.                   actual FY 2016 payment units. Interstate Telecommunication   Based on FCC Form 499-Q data for the four  Service Providers.             quarters of calendar year 2016, the                                 Wireline Competition Bureau projected                                 the amount of calendar year 2016 revenue                                 that will be reported on 2017 FCC Form                                 499-A worksheets due in April, 2017. Earth Stations...............  Based on International Bureau (``IB'')                                 licensing data and actual FY 2016                                 payment units. Space Stations (GSOs & NGSOs)  Based on IB data reports and actual FY                                 2016 payment units. International Bearer Circuits  Based on IB reports and submissions by                                 licensees, adjusted as necessary. Submarine Cable Licenses.....  Based on IB license information. ------------------------------------------------------------------------

 TABLE 6--Factors, Measurements, and Calculations That Determine Station            Signal Contours and Associated Population Coverages ------------------------------------------------------------------------   -------------------------------------------------------------------------                                AM Stations ------------------------------------------------------------------------ For stations with nondirectional daytime antennas, the theoretical  radiation was used at all azimuths. For stations with directional  daytime antennas, specific information on each day tower, including  field ratio, phase, spacing, and orientation was retrieved, as well as  the theoretical pattern root-mean-square of the radiation in all  directions in the horizontal plane (RMS) figure (milliVolt per meter  (mV/m) @1 km) for the antenna system. The standard, or augmented  standard if pertinent, horizontal plane radiation pattern was  calculated using techniques and methods specified in sections 73.150  and 73.152 of the Commission's rules. Radiation values were calculated  for each of 360 radials around the transmitter site. Next, estimated  soil conductivity data was retrieved from a database representing the  information in FCC Figure R3. Using the calculated horizontal radiation  values, and the retrieved soil conductivity data, the distance to the  principal community (5 mV/m) contour was predicted for each of the 360  radials. The resulting distance to principal community contours were  used to form a ***geographical*** polygon. Population counting was  accomplished by determining which 2010 block centroids were contained  in the polygon. (A block centroid is the center point of a small area  containing population as computed by the U.S Census Bureau.) The sum  of the population figures for all enclosed blocks represents the total  population for the predicted principal community coverage area. ------------------------------------------------------------------------                                FM Stations ------------------------------------------------------------------------ The greater of the horizontal or vertical effective radiated power (ERP)  (kW) and respective height above average terrain (HAAT) (m) combination  was used. Where the antenna height above mean sea level (HAMSL) was  available, it was used in lieu of the average HAAT figure to calculate  specific HAAT figures for each of 360 radials under study. Any  available directional pattern information was applied as well, to  produce a radial-specific ERP figure. The HAAT and ERP figures were  used in conjunction with the Field Strength (50-50) propagation curves  specified in 47 CFR 73.313 of the Commission's rules to predict the  distance to the principal community (70 dBu (decibel above 1 microVolt  per meter) or 3.17 mV/m) contour for each of the 360 radials. The  resulting distance to principal community contours were used to form a  ***geographical*** polygon. Population counting was accomplished by  determining which 2010 block centroids were contained in the polygon.  The sum of the population figures for all enclosed blocks represents  the total population for the predicted principal community coverage  area.

**Load-Date:** August 1, 2017

**End of Document**



[***FEDERAL REGISTER: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Pages 56336 - 56527 [FR DOC # 2017-25068]***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5R2J-NC51-F0YC-N4F5-00000-00&context=1516831)

Impact News Service

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**Body**

Washington: Office of the Federal Register has issued the following notice:

Department of Health and Human Services ----------------------------------------------------------------------- Centers for Medicare & Medicaid Services ----------------------------------------------------------------------- 42 CFR Parts 405, 417, 422, et al. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program; Proposed Rule Federal Register / Vol. 82 , No. 227 / Tuesday, November 28, 2017 / Proposed Rules [[Page 56336]] ----------------------------------------------------------------------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services 42 CFR Parts 405, 417, 422, 423, and 498 [CMS-4182-P] RIN 0938-AT08 Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for- Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule. ----------------------------------------------------------------------- SUMMARY: This proposed rule would revise the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act; improve program quality, accessibility, and affordability; improve the CMS customer experience; address program integrity policies related to payments based on prescriber, provider and supplier status in Medicare Advantage, Medicare cost plan, Medicare Part D and the PACE programs; provide a proposed update to the official Medicare Part D electronic prescribing standards; and clarify program requirements and certain technical changes regarding treatment of Medicare Part A and Part B appeal rights related to premiums adjustments. DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m on January 16, 2018. ADDRESSES: In commenting, please refer to file code CMS-4182-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed): 1. Electronically. You may submit electronic comments on this regulation to [*http://www.regulations.gov*](http://www.regulations.gov) Follow the ``Submit a comment'' instructions. 2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4182-P, P.O Box 8013, Baltimore, MD 21244-8013. Please allow sufficient time for mailed comments to be received before the close of the comment period. 3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4182-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850. 4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC--Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp- in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.) b. For delivery in Baltimore, MD--Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850. If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period. For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section. FOR FURTHER INFORMATION CONTACT: Theresa Wachter, (410) 786-1157, Part C Issues. Marie Manteuffel, (410) 786-3447, Part D Issues. Kristy Nishimoto, (206) 615-2367, Beneficiary Enrollment and Appeals Issues. Raghav Aggarwal, (410) 786-0097, Part C and D Payment Issues. Vernisha Robinson-Savoy, (267) 970-2395, Part C and D Compliance Issues. Frank Whelan, (410) 786-1302, Preclusion List Issues. Shelly Winston, (410) 786-3694, Part D E-Prescribing Program. SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received:   [*http://www.regulations.gov*](http://www.regulations.gov) Follow the search instructions on that Web site to view public comments. Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m to 4 p.m To schedule an appointment to view public comments, phone 1-800-743-3951. Table of Contents I. Executive Summary A. Purpose B. Summary of the Major Provisions 1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions 2. Updating the Part D E-Prescribing Standards (Sec. 423.160) 3. Revisions to Timing and Method of Disclosure Requirements 4. Preclusion List a. Part D b. Part C C. Summary of Costs and Benefits II. Provisions of the Proposed Regulations A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability 1. 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Conclusion Acronyms ACA Affordable Care Act ACS American Community Survey AEP Annual Election Period ANDA Abbreviated New Drug Application ANOC Annual Notice of Change AMA American Medical Association AO Accrediting Organization ASPE Office of the Assistant Secretary for Planning and Evaluation AWP Any Willing Pharmacy CAI Categorical Adjustment Index CARA Comprehensive Addiction and Recovery Act CCIP Chronic Care Improvement Program CMS Centers for Medicare & Medicaid Services CPT Current Procedural Terminology DAB Departmental Appeals Board DE Dual Eligible DIR Direct or Indirect Remuneration DME Durable Medical Equipment DSMO Designated Standards Maintenance Organization D-SNP Dual-Eligible Special Needs Plan EDM Enhanced Disease Management EHR Electronic Health Record EOC Evidence of Coverage EP Eligible Professionals FFS Fee-for-Service ePA Electronic Prior Authorization eRx Electronic Prescription (e-prescribing) FDA Food and Drug Administration FIDE Fully Integrated Dual Eligible FMV Fair Market Value FPL Federal Poverty Level HPMS Health Plan Management System ICD-10 ICD-10-CM IRE Independent Review Entity LIS Low Income Subsidy LPPO Local Preferred Provider Organization LTC Long Term Care MA Medicare Advantage MADP Medicare Advantage Disenrollment Period MA-PD Medicare Advantage Prescription Drug MAO Medicare Advantage Organizations MIPPA Medicare Improvements for Patients and Providers Act MLR Medical Loss Ratio MOOP Maximum Out-of-Pocket NCPDP National Council of Prescription Drug Programs NCQA National Committee for Quality Assurance NDC National Drug Code NSO National Standard Organization OIG Office of Inspector General OEP Open Enrollment Period OMHA Office of Medicare Hearings and Appeals OOPC Out-of-Pocket Cost PA Prior Authorization PBM Pharmacy Benefit Manager PBP Plan Benefit Package PDP Prescription Drug Plan PHSA Public Health Service Act [[Page 56339]] PIP Physician Incentive Plan PQA Pharmacy Quality Alliance PSO Provider Sponsored Organization PSP Provider Specific Plan QBP Quality Bonus Payment QI Quality Improvement QIA Quality Improvement Activities QIP Quality Improvement Project REMS Risk Evaluation and Mitigation Strategies RFI Request for Information RHC Rural Health Center RI Rewards and Incentives RPPO Regional Preferred Provider Organization RRB Railroad Retirement Board SE Standard Error SEP Special Enrollment/Election Period SES Socio-Economic Status SNP Special Needs Plan SSA Social Security Administration TMP Timeliness Monitoring Project I. Executive Summary A. Purpose The primary purpose of this proposed rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act. The proposed changes are necessary to--(1) Support Innovative Approaches to Improving Quality, Accessibility, and Affordability; (2) Improve the CMS Customer Experience; and (3) Implement Other Changes. In addition, this rule proposes technical changes related to treatment of Part A and Part B premium adjustments and updates the Script standard used for Part D electronic prescribing. While the Part D program has high satisfaction among users, we continually evaluate program policies and regulations to remain responsive to current trends and newer technologies. Specifically, this regulation meets the Administration's priorities to reduce burden and provide the regulatory framework to develop MA and Part D products that better meet the individual beneficiary's healthcare needs. Additionally, this regulation includes a number of provisions that will help address the opioid epidemic and mitigate the impact of increasing drug prices in the Part D program. B. Summary of the Major Provisions 1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions This proposed regulatory provision would implement statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, which amended the Social Security Act and includes new authority for Medicare Part D drug management programs, effective on or after January 1, 2019. Through this provision, CMS proposes a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or ``at-risk beneficiaries.'' CMS proposes that, under such programs, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are ``frequently abused drugs'' to a selected prescriber(s) and/or network pharmacy(ies). CMS also proposes to limit the use of the special enrollment period (SEP) for dually- or other low income subsidy (LIS)-eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such a drug management program. Finally, this provision proposes to codify the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) by integrating this current policy with our proposals for implementing the drug management program provisions. The current policy involves Part D prescription drug benefit plans engaging in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Through the adoption of this policy, from 2011 through 2016, there was a 61 percent decrease (over 17,800 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers.\1\ Thus, this proposal expands upon an existing, innovative, successful approach to reduce opioid overutilization in the Part D program by improving quality of care through coordination while maintaining access to necessary pain medications. --------------------------------------------------------------------------- \1\ CY 2018 Final Parts C&D Call Letter, April 3, 2017. --------------------------------------------------------------------------- 2. Updating the Part D E-Prescribing Standards (Sec. 423.160) This provision proposes an update to the electronic standards to be used by Medicare Part D prescription drug plans. This includes the proposed adoption of the NDPDP SCRIPT Standard Version 2017071, and retirement of the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals. These changes would become effective January 1, 2019. The NCPDP SCRIPT standards are used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans. Although e-prescribing is optional for physicians and pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit e- prescriptions and related communications electronically must utilize the adopted standards. The proposed updated NCPDP SCRIPT standards have been requested by the industry and could provide a number of efficiencies which the industry and CMS supports. In order to facilitate this change, we propose to update Sec. 423.160, and also make a number of conforming technical changes to other sections of part 423. In addition, we are proposing to correct a typographical error that occurred in the regulatory text listing the applicability dates of the standards by changing the reference in Sec. 423.160(b)(1)(iv) to reference (b)(2)(iii) instead of (b)(2)(ii) to correctly cite to the present use of the currently adopted NCPDP SCRIPT Standard Version 10. 3. Revisions to Timing and Method of Disclosure Requirements We are proposing to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC). Additionally, we are proposing to change the timeframe for delivery of the EOC in particular to the first day of the Annual Election Period (AEP) rather than fifteen days prior to that date. Allowing plans to provide the EOC electronically would alleviate plan burden related to printing and mailing, and simultaneously would reduce the number of paper documents that beneficiaries receive from plans. This would allow beneficiaries to focus on materials, like the Annual Notice of Change (ANOC), that drive decision making. Changing the date by which plans must provide the EOC to members would allow plans more time to finalize the formatting and ensure the accuracy of the information, as well as further distance it from the ANOC, which must still be delivered 15 days prior to the AEP. We see this proposed change as an overall reduction of impact that our regulations have on plans and beneficiaries. In aggregate, we estimate a savings (to plans for not producing [[Page 56340]] and mailing hard-copy EOCs) of approximately $51 million. 4. Preclusion List a. Part D This proposed rule would rescind the current provisions in Sec. 423.120(c)(6) that require physicians and eligible professionals (as defined in section 1848(k)(3)(B) of the Act) to enroll in or validly opt-out of Medicare in order for a Part D drug prescribed by the physician or eligible professional to be covered. As a replacement, we propose that a Part D plan sponsor must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the ``preclusion list,'' which would be defined in Sec. 423.100 and would consist of certain prescribers who are currently revoked from the Medicare program under Sec. 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. We recognize, however, the need to minimize interruptions to Part D beneficiaries' access to needed medications. Therefore, we also propose to prohibit plan sponsors from rejecting claims or denying beneficiary requests for reimbursement for a drug on the basis of the prescriber's inclusion on the preclusion list, unless the sponsor has first covered a 90-day provisional supply of the drug and provide individualized written notice to the beneficiary that the drug is being covered on a provisional basis. b. Part C This proposed rule would rescind the current provisions in Sec. 422.222 stating that providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act must be enrolled in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. As a replacement, we propose that an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the ``preclusion list.'' The preclusion list, which would be defined in Sec. 422.2, would consist of certain individuals and entities that are currently revoked from the Medicare program under Sec. 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. C. Summary of Costs and Benefits ------------------------------------------------------------------------ Provision Savings ------------------------------------------------------------------------ Implementation of the Besides the benefits of preventing opioid Comprehensive Addiction and dependency in beneficiaries we estimate Recovery Act of 2016. a net savings in 2019 of $13 million to the Trust Fund because of reduced scripts, modestly increasing to a savings of $14 million in 2023. The cost to industry is estimated at about $2.8 million per year. Revisions to Timing and We estimate 67% of the current 47.8 Method of Disclosure million beneficiaries will prefer use of Requirements. the internet vs. hard copies. This wi

ll result in savings of $55 million in 2019 and growing due to inflation to $67 million in 2023. ------------------------------------------------------------------------ II. Provisions of the Proposed Regulations A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability 1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions a. Medicare Part D Drug Management Programs The Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, amended the Social Security Act and includes new authority for the establishment of drug management programs in Medicare Part D, effective on or after January 1, 2019. In accordance with section 704(g)(3) of CARA and revised section 1860D- 4(c) of the Act, CMS must establish through notice and comment rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at-risk for prescription drug abuse, or ``at-risk beneficiaries.'' Under such a Part D drug management program, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are ``frequently abused drugs'' to a selected prescriber(s) and/or network pharmacy(ies). While such programs, commonly referred to as ``lock-in programs,'' have been a feature of many state Medicaid programs for some time, prior to the enactment of CARA, there was no statutory authority to allow Part D plan sponsors to require beneficiaries to obtain controlled substances from a certain pharmacy or prescriber in the Medicare Part D program. In summary, this proposed rule would implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) (``current policy''). As explained in more detail later in this section, this integration would mean that Part D sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of opioids beginning 2019 through a point-of-sale (POS) claim edit and/or by requiring the beneficiary to obtain opioids from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary would have to meet clinical guidelines that factor in that the beneficiary is taking a high-risk dose of opioids over a sustained time period and that the beneficiary is obtaining them from multiple prescribers and multiple pharmacies. This proposed rule would also implement a limitation on the use of the special enrollment period (SEP) for low income subsidy (LIS)-eligible beneficiaries who are identified as potential at-risk beneficiaries. b. Stakeholder Input Informing This Notice of Proposed Rulemaking Section 704(g)(2) of CARA required us to convene stakeholders to provide input on specific topics so that we could take such input into account in promulgating regulations governing Part D drug management programs. Stakeholders include Medicare beneficiaries with Part A or Part B, advocacy groups representing Medicare beneficiaries, physicians, pharmacists, and other clinicians (particularly other lawful prescribers of controlled [[Page 56341]] substances), retail pharmacies, Part D plan sponsors and their delegated entities (such as pharmacy benefit managers), and biopharmaceutical manufacturers. We hosted a Listening Session on the CARA drug management program provisions via a public conference call on November 14, 2016 that was announced in the October 26, 2016 Federal Register (81 FR 74388). We sought stakeholder input on specific topics enumerated in sections 704(a)(1) and 704(g)(2)(B) of the CARA and other related topics of concern to the stakeholders. In developing this proposed rule, we considered the stakeholders' comments provided during the Listening Session, as well as written comments submitted afterward, including those submitted in response to the Request for Information associated with the publication of the Plan Year 2018 Medicare Parts C&D Final Call Letter. We refer to this input in this preamble using the terms ``stakeholders,'' ``commenters'' and ``comments.'' c. Integration of CARA and the Current Part D Opioid DUR Policy and OMS As noted in section II.A.1 of this proposed rule previously, we are proposing to implement the CARA Part D drug management program provisions by integrating them with our current policy that is not currently codified, but would be under this proposal. In using the term ``current policy'', we refer to the aspect of our current Part D opioid overutilization policy that is based on retrospective DUR.\2\ Specifically, we are proposing a regulatory framework for Part D plan sponsors to voluntarily adopt drug management programs through which they address potential overutilization of frequently abused drugs identified retrospectively through the application of clinical guidelines/criteria that identify potential at-risk beneficiaries and conduct case management which incorporates clinical contact and prescriber verification that a beneficiary is an at-risk beneficiary. If deemed necessary, a sponsor could limit at-risk beneficiaries' access to coverage for such drugs through pharmacy lock-in, prescriber lock-in, and/or a beneficiary-specific point-of-sale (POS) claim edit. Finally, sponsors would report to CMS the status and results of their case management to OMS and any beneficiary coverage limitations they have implemented to MARx, CMS' system for payment and enrollment transactions. While plan sponsors would have the option to implement a drug management program, our proposal codifies a framework that would place requirements upon such programs. We foresee that all plan sponsors will implement such drug management programs based on our experience that all plan sponsors' are complying with the current policy as laid out in guidance, the fact that our proposal largely incorporates the CARA drug management provisions into existing CMS and sponsor operations, and especially, in light of the national opioid epidemic and the declaration that the opioid crisis is a nationwide Public Health Emergency. --------------------------------------------------------------------------- \2\ Please refer to the CMS Web site, ``Improving Drug Utilization Review Controls in Part D'' at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) which contains CMS communications regarding the current policy. --------------------------------------------------------------------------- Because we propose to integrate the CARA Part D drug management program provisions with the current policy and codify them both, we describe the current policy in section II.A.1.c (1) of this proposed rule, noting where our proposal incorporates changes to the current policy in order to comply with CARA and achieve operational consistency. Where we do not note a change, our intent is to codify the current policy, and we seek specific comment as to whether we have overlooked any feature of the current policy that should be codified. CMS communications regarding the current policy can be found at the CMS Web site, ``Improving Drug Utilization Review Controls in Part D'' at   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) Then we set forth our proposal for codification of the regulatory framework for drug management programs in section II.A.1.c (2) of this proposed rule, which includes provisions specific to lock-in, which is not a feature of the current policy. (1) Current Part D Opioid DUR Policy and OMS CMS is actively engaged in addressing the opioid epidemic and committed to implementing effective tools in Medicare Part D. We will work across all stakeholder, beneficiary and advocacy groups, health plans, and other federal partners to help address this devastating epidemic. CMS has worked with plan sponsors and other stakeholders to implement Medicare Part D opioid overutilization policies with multiple initiatives to address opioid overutilization in Medicare Part D through a medication safety approach. These initiatives include better formulary and utilization management; real-time safety alerts at the pharmacy aimed at coordinated care; retrospective identification of high risk opioid overutilizers who may need case management; and regular actionable patient safety reports based on quality metrics to sponsors. The goal of the current policy and OMS is to reduce opioid overutilization in Part D. In conjunction with related Part D opioid overutilization policies that address prospective opioid use, the current policy has played a key role in reducing high risk opioid overutilization in the Part D program by 61 percent (representing over 17,800 beneficiaries) from 2011 (pre-policy pilot) through 2016, even as the number of beneficiaries enrolled in Part D increased overall during this period from 31.5 million to 43.6 million enrollees, or a 38 percent increase.\3\ --------------------------------------------------------------------------- \3\ Final CY 2018 Parts C&D Call Letter, April 3, 2017. --------------------------------------------------------------------------- The purpose of the current policy is to provide Part D plan sponsors with specific guidance about compliance with Sec. 423.153(b)(2) as to opioid overutilization, which requires a Part D plan sponsor to have a reasonable and appropriate drug utilization management program that maintains policies and systems to assist in preventing overutilization of prescribed medications. We adopted the current policy on January 1, 2013, and it has evolved over time in scope in several ways with stakeholder feedback and support, including through the addition of the OMS in July 2013, primarily via the annual Parts C&D Call Letter process. The current policy has two aspects. First, in the CY 2013 final Call Letter and subsequent supplemental guidance, we provided guidance about our expectations for Part D plan sponsors to retrospectively identify beneficiaries who are at high risk for potential opioid overutilization and provide appropriate case management aimed at coordinated care.\4\ More specifically, we currently expect Part D plan sponsors' Pharmacy and Therapeutics (P&T) committees to establish criteria consistent with CMS guidance to retrospectively identify potential opioid overutilizers at high risk for an adverse event enrolled in their plans who may warrant case management because they are receiving opioid prescriptions from multiple prescribers and pharmacies. Enrollees [[Page 56342]] with cancer or in hospice are excluded from the current policy, because the benefit of their high opioid use may outweigh the risk associated with such use. This exclusion was supported by stakeholder feedback on the current policy. --------------------------------------------------------------------------- \4\ An excerpt from the Final 2013 Call Letter, the supplemental guidance, and additional information about the policy and OMS are available on the CMS Web page, ``Improving Drug Utilization Controls in Part D'' at   [*https://www.cms.gov/Medicare/Prescription-Drug/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug/PrescriptionDrugCovContra/RxUtilization.html) --------------------------------------------------------------------------- Once such enrollees are identified through retrospective prescription drug claims review, we expect the Part D plan sponsors to diligently assess each case, and if warranted, have their clinical staff conduct case management with the beneficiary's opioid prescribers until the case is resolved. According to the supplemental guidance,\5\ case management entails: --------------------------------------------------------------------------- \5\ September 6, 2012 HPMS memo, ``Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D.'' ---------------------------------------------------------------------------  The personnel communicating with prescribers have appropriate credentials.      Written inquiries to the prescribers of the opioid medications about the appropriateness, medical necessity and safety of the apparent high dosage for their patient.      Attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period from the issuance of the written inquiry notification, if necessary.      The clinician-to-clinician communication includes information about the existence of multiple prescribers and the beneficiary's total opioid utilization, and the plan's clinician elicits the information necessary to identify any complicating factors in the beneficiary's treatment that are relevant to the case management effort.      After discussion or communication about the appropriate level of opioid use, the consensus reached by the prescribers is implemented by the sponsor, with a beneficiary-specific opioid POS claim edit, as deemed appropriate by the prescribers, to prevent further Part D coverage of an unsafe level of drug.      In cases of non-responsive prescribers, the sponsor may also implement a beneficiary-specific opioid POS claim edit to prevent further coverage of an unsafe level of drug and to encourage the prescribers to participate in case management.     Thus, we expect case management to confirm that the beneficiary's opioid use is medically necessary or resolve an overutilization issue.     As part of the current policy, and because the Food and Drug Administration (FDA)-approved labeling for opioids generally does not include maximum daily doses, CMS developed specific criteria to identify beneficiaries at high risk through retrospective review of their opioid use in order to assist Part D sponsors in identifying such beneficiaries. These criteria incorporate a morphine milligram equivalent (MME) \6\ approach, which is a method to uniformly calculate the total daily dosage of opioids across all of a patient's opioid prescription drug claims. Beginning with plan year 2018, we adjusted these criteria to align with the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline) \7\ issued in March 2016 in terms of using 90 MME as a threshold to identify beneficiaries who appear to be at high risk due to their opioid use. In its guideline, after considering information from relevant studies and experts, the CDC identifies 50 MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME. Our criteria, which we will discuss more fully later in the preamble, also incorporate a multiple prescriber and pharmacy count to focus on beneficiaries who appear to be not only overutilizing opioids but who also are at increased risk due to potential coordination of care issues, such that the providers who are prescribing or dispensing opioids to these beneficiaries may not know that other providers are also doing so. ---------------------------------------------------------------------------

    \6\ Please note that CMS will use the term ``MME'' going forward instead of morphine equivalent dose (MED), which CMS has used to date. CMS used the term MED in a manner that was equivalent to MME. We will update CMS documents that currently refer to MED as soon as practicable.     \7\ Please see [*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*](https://www.cdc.gov/drugoverdose/prescribing/guideline.html) ---------------------------------------------------------------------------

    The second aspect of the current policy came into place in July 2013, when CMS launched the OMS as a tool to monitor Part D plan sponsors' effectiveness in complying with Sec.  423.153(b)(2) to address opioid overutilization. Through the OMS, CMS sends sponsors quarterly reports about their Part D enrollees who meet the criteria for being at high risk of opioid overutilization. Then, we expect sponsors to address each case through the case management process previously described and respond to CMS through the OMS using standardized responses. In addition, we expect sponsors to provide information to their regional CMS representatives and the MARx system about beneficiary-specific opioid POS claim edits that they intend to or have implemented.\8\ ---------------------------------------------------------------------------

    \8\ Please refer to the CMS Web site, ``Improving Drug Utilization Review Controls in Part D'' at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) which contains CMS communications regarding the current policy. ---------------------------------------------------------------------------

    Because case management is very resource intensive for sponsors and PBMs, we have limited the scope of the current policy in terms of the number of beneficiaries identified by OMS, and when expanding that number, we have made changes incrementally through annual Parts C&D Call Letter process. (2) Proposed Requirements for Part D Drug Management Programs (Sec. Sec.  423.100 and 423.153)     We first propose several definitions for terms we propose to use in establishing requirements for Part D drug management programs. (i) Definitions (Sec.  423.100) (A) Definition of ``Potential At-Risk Beneficiary'' and ``At-Risk Beneficiary'' (Sec.  423.100)     Section 1860D-4(c)(5)(C) of the Act contains a definition for ``at- risk beneficiary'' that we propose to codify at Sec.  423.100 In addition, although the section 1860D-4(c)(5) of the Act does not explicitly define a ``potential at-risk beneficiary,'' it contemplates a beneficiary who is potentially at-risk. Accordingly, we propose to define these two terms at Sec.  423.100 as follows: Potential at-risk beneficiary means a Part D eligible individual--(1) Who is identified using clinical guidelines (as defined in Sec.  423.100); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. At-risk beneficiary means a Part D eligible individual--(1) who is--(i) Identified using clinical guidelines (as defined in Sec.  423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program in accordance with the requirements of Sec.  423.153(f); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most

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recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. The distinction between a ``potential at-risk beneficiary'' and an ``at- risk beneficiary'' is important for a few reasons that we will explain later in this preamble. Also, we added the phrase, ``and the new plan has adopted the identification'' to both definitions for cases where a beneficiary has been identified as a potential at-risk or at-risk beneficiary by the immediately prior plan to indicate that the beneficiary's status in the subsequent plan is not automatic. (B) Definition of ``Frequently Abused Drug'', ``Clinical Guidelines'', ``Program Size'', and ``Exempted Beneficiary'' (Sec.  423.100)     Because we use these terms in the proposed definitions of ``potential at-risk beneficiary'' and ``at-risk beneficiary,'' we propose to define ``frequently abused drug,'' ``clinical guidelines'', ``program size'', and ``exempted beneficiary'' at Sec.  423.100 as follows:  Frequently Abused Drug     Section 1860D-4(c)(5)(G) of the Act defines ``frequently abused drug'' as a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted. Consistent with the statutory definition, we propose to define ``Frequently abused drug'' at Sec.  423.100 to mean a controlled substance under the federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account the following factors: (1) The drug's schedule designation by the Drug Enforcement Administration; (2) Government or professional guidelines that address that a drug is frequently abused or misused; and (3) An analysis of Medicare or other drug utilization or scientific data. This definition is intended to provide enough specificity for stakeholders to know how the Secretary will determine a frequently abused drug, while preserving flexibility to update which drugs CMS considers to be frequently abused drugs based on relevant factors, such as actions by the Drug Enforcement Administration and/or trends observed in Medicare or scientific data.     We plan to publish and update a list of frequently abused drugs for purposes of Part D drug management programs. We propose that future designations of frequently abused drugs by the Secretary primarily be included in the annual Parts C&D Call Letter or in similar guidance, which would be subject to public comment, if necessary to address midyear entries to the drug market or evolving government or professional guidelines. This approach would be consistent with our approach under the current policy and necessary for Part D drug management programs to be responsive to changing public health issues over time.     While this is the approach we propose for future designations of frequently abused drugs, we are including a discussion of the designation for plan year 2019 in this preamble. For plan year 2019, consistent with current policy, we propose that opioids are frequently abused drugs. Our proposal to designate opioids as frequently abused drugs illustrates how the proposed definition could work in practice:     First, the Secretary determines opioids are frequently abused or diverted, because they are controlled substances, and drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are so considered precisely because they have abuse potential. The Drug Enforcement Administration (DEA) divides controlled substances into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. Most prescription opioids are Schedule II, where the DEA places substances with a high potential for abuse with use potentially leading to severe psychological or physical dependence.\9\ A few opioids are Schedule III or IV, where the DEA places substances that have a potential for abuse. ---------------------------------------------------------------------------

    \9\ The abuse rate is a determinate factor in the DEA's scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes-- Schedule II, Schedule III, etc., so does the abuse potential-- Schedule V drugs represents the least potential for abuse. See DEA Web site about Drug Scheduling: [*https://www.dea.gov/druginfo/ds.shtml*](https://www.dea.gov/druginfo/ds.shtml) ---------------------------------------------------------------------------

    Second, on October 26, 2017, the President directed that executive agencies use all appropriate emergency authorities and other relevant authorities to address drug addiction and opioid abuse, and the Acting Secretary of Health and Human Services declared a nationwide Public Health Emergency to address the opioid crisis.\10\ In addition, the CDC has declared opioid overuse a national epidemic, both of which are relevant factors.\11\ More than 33,000 people died from opioid overuse in 2015, which is the highest number per year on record. From 2000 to 2015, more than half a million people died from drug overdoses, and 91 Americans die every day from an opioid overdose. Nearly half of all opioid overdose deaths involve a prescription opioid. Given that opioids, including prescription opioids, are the main driver of drug overdose deaths in the U.S , it is reasonable for the Secretary to conclude that opioids are frequently abused and misused. ---------------------------------------------------------------------------

    \10\ See White House Web site [*https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies*](https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies), and the HHS Web site   [*https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html*](https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html)     \11\ See CDC Web site   [*https://www.cdc.gov/drugoverdose/index.html*](https://www.cdc.gov/drugoverdose/index.html) for all statistics in this paragraph. ---------------------------------------------------------------------------

    Third, government or professional guidelines support determining that opioids are frequently abused or misused. Consistent with current policy, we propose to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables. The CDC MME Conversion Factor file \12\ does not include all formulations of buprenorphine for MAT so that access is not limited, and injectables are not included due to low claim volume. Therefore, CMS cannot determine the MME. CMS will consider revisions to the CDC MME Conversion Factor file when updating the list of opioids designated as frequently abused drugs in future guidance. ---------------------------------------------------------------------------

    \12\ See [*https://www.cdc.gov/drugoverdose/resources/data.html*](https://www.cdc.gov/drugoverdose/resources/data.html) ---------------------------------------------------------------------------

    Fourth, an analysis of Medicare data supports designating opioids as ``frequently abused drugs,'' at least initially. Over 727,000 Part D beneficiaries had an average MME of at least 90 mg during the 6-month period from July 1, 2015 to December 31, 2015 (``90 mg MME + users''), a number which excludes beneficiaries with cancer or in hospice, whom we propose to exempt from drug management programs, as we discuss later. As noted earlier, the CDC recommends prescribers generally avoid increasing the daily opioid dosage to 90 MME. Given that so many beneficiaries have an average MME above this threshold, it is reasonable that the Secretary consider this data to be a relevant factor in determining that opioids are frequently abused or diverted.     Most stakeholders recommended designating opioids as frequently abused drugs. In this regard, we note

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that our current policy applies only to opioids and that we are integrating the drug management provisions of CARA with our current policy. Therefore, designating opioids as frequently abused drugs, at least in the initial implementation of drug management programs, would have the added benefit of allowing CMS and stakeholders to gain experience with the use of lock-in in the Part D program, before potentially designating other controlled substances as frequently abused drugs.     Some commenters expressed support for including other or all controlled substances, such as benzodiazepines, sedatives, and certain muscle relaxants as frequently abused drugs; however, we are not persuaded. Opioids are unique in that there is generally no maximum dose for them in the FDA labeling. Also, in the proposed Contract Year 2016 Parts C&D Call Letter, we solicited feedback on expanding the current policy to other drugs, and the comments were mixed. A few commenters suggested that we expand the current policy to benzodiazepines and muscle relaxants when used with opioids. In respond to the feedback, we did not expand the current policy beyond the opioid class but indicated that we would investigate. Subsequently, the CDC Guideline was published and it specifically recommends that clinicians avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible due to increased risk for overdose. Therefore, we added a concurrent benzodiazepine-opioid flag to OMS in October 2016 to alert Part D sponsors that concurrent use may be an issue that should be addressed during case management, and we will continue to do so.\13\ ---------------------------------------------------------------------------

    \13\ Please refer to the memo, ``Medicare Part D Overutilization Monitoring System (OMS) Update: Addition of the Concurrent Opioid- Benzodiazepine Use Flag'' dated October 21, 2016. ---------------------------------------------------------------------------

    Other than conveying the concurrent benzodiazepine use information to sponsors, we have not expanded the current policy to address non- opioid medications. However, we have stated that if a sponsor chooses to implement the current policy for non-opioid medications, we would expect the sponsor to employ the same level of diligence and documentation with respect to non-opioid medications that we expect for opioid medications.\14\ We have taken this approach to the current policy so that we could focus on the opioid epidemic and also due to the difficulty in establishing overuse guidelines for non-opioid controlled substances. For this reason our proposal would not identify benzodiazepines as frequently abused drugs. However, we solicit additional comment on our proposed approach to frequently abused drugs. Also, we propose that, if finalized, this rule would supersede our current policy, and sponsors would no longer be allowed to implement the current policy for non-opioid medications. We seek feedback on allowing sponsors to continue to implement the current policy for non- opioid medications with respect to beneficiary-specific claim edits. ---------------------------------------------------------------------------

    \14\ See ``Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D,'' dated September 6, 2012. ---------------------------------------------------------------------------

 Clinical Guidelines and Program Size     Section 1860D-4(c)(5)(C)(i)(I) of the Act requires at-risk beneficiaries to be identified using clinical guidelines that indicate misuse or abuse of frequently abused drugs and that are developed in consultation with stakeholders. We propose to include a definition of ``clinical guidelines'' that cross references standards that we are proposing at Sec.  423.153(f) for how the guidelines would be established and updated. Specifically, we propose to define clinical guidelines for purposes of a Part D drug management program as criteria to identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs, and that are developed in accordance with the proposed standards in Sec.  423.153(f)(16) and published in guidance annually.     We also propose to add Sec.  423.153(f)(16) to state that potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or the Part D sponsor using clinical guidelines that: (1) Are developed with stakeholder consultation; (2) Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs, or any combination of these factors; (3) Are derived from expert opinion and an analysis of Medicare data; and (4) Include a program size estimate. This proposed approach to developing and updating the clinical guidelines is intended to provide enough specificity for stakeholders to know how CMS would determine the guidelines by identifying the standards we would apply in determining them.     This proposed approach indicates that the program size would be determined as part of the process to develop the clinical guidelines--a process into which stakeholders would provide input. Section 1860D- 4(c)(5)(C)(iii) of the Act states that the Secretary shall establish policies, including the guidelines and exemptions, to ensure that the population of enrollees in drug management programs could be effectively managed by plans. We propose to define ``program size'' in Sec.  423.100 to mean the estimated population of potential at-risk beneficiaries in drug management programs (described in Sec.   423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.     This proposed approach to developing and updating the clinical guidelines would also be flexible enough to allow for updates to the guidelines outside of the regulatory process to address trends in Medicare with respect to the misuse and/or diversion of frequently abused drugs. We have determined this approach is appropriate to enable CMS to assist Part D drug management programs in being responsive to public health issues over time. This approach would also be consistent with how the OMS criteria have been established over time through the annual Medicare Parts C&D Call Letter process, which we plan to continue except for 2019.     For plan year 2019, we propose the clinical guidelines in this preamble to be the OMS criteria established for plan year 2018, which meet the proposed standards for the clinical guidelines for the following reasons: First, as described earlier, the OMS criteria incorporate a 90 MME threshold cited in a CDC Guideline, which was developed by experts as the level that prescribers should avoid reaching with their patients. This threshold does not function as a prescribing limit for the Part D program; rather, it identifies potentially risky and dangerous levels of opioid prescribing in terms of misuse or abuse. Second, the OMS criteria also incorporate a multiple prescriber and pharmacy count. A high MED level combined with multiple prescribers and/or pharmacies may also indicate the abuse or misuse of opioids due to the possible lack of care coordination among the providers for the patient. Third, the OMS criteria have been revised over time based on analysis of Medicare data and with stakeholder input via the annual Parts C&D Call Letter process. Indeed, many stakeholders recommended the use of the CDC Guideline as part of the clinical guidelines the Secretary must develop, with some noting that they would need to be used in a way that accounts for use of multiple providers, which the OMS criteria do. Fourth, these criteria are familiar to Part D sponsors--they will already have experience with them by

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2019, and they were established with an estimate of program size.     Several stakeholders in their comments referred to various criteria used in state Medicaid lock-in programs to identify beneficiaries appropriate for lock-in, without suggesting that any particular ones be adopted. Other commenters suggested CMS consider other guidelines, such as the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use and the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline on Opioid Therapy for Chronic Pain. However, these guidelines are similar to or moving toward an MME methodology which we currently use or address a more narrow population than persons who may be abusing or misusing frequently abused drugs, and they do not directly address situations involving multiple opioid providers. The VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain is similar to the scope of the CDC Guideline. The ASAM Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use was developed specifically for the evaluation and treatment of opioid use disorder and for the management of opioid overdose, which would not be applicable here because it serves a different purpose. Therefore, we do not see a reason to adopt these guidelines instead of the 2018 OMS criteria.     The clinical guidelines for use in drug management programs we are proposing for 2019 are: Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies OR 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. We note that we have described alternative clinical guidelines that we considered in the Regulatory Impact Analysis section of this rule. Stakeholders are invited to comment on those alternatives and any others which would involve identifying more or fewer potential at-risk beneficiaries.     We propose that under the proposed clinical guidelines, prescribers associated with the same single Tax Identification Number (TIN) be counted as a single prescriber. This is consistent with the current policy under which we have found that such prescribers are typically in the same group practice that is coordinating the care of the patients served by it. Thus, it is appropriate to count such prescribers as one, so as not to identify beneficiaries who are not at-risk.     In this regard, in applying the OMS criteria, CMS counts prescribers with the same TIN as one prescriber, unless any of the prescribers are associated with multiple TINs. For example, under the criteria we have proposed, a beneficiary who meets the 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 3 independent opioid prescribers (1 group practice + 3 prescribers = 4 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies, would still meet the criteria, which is appropriate. However, a beneficiary who meets that 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 1 independent opioid prescriber (1 group practice + 1 prescriber = 2 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies would not meet the criteria, which is also appropriate at this time given program size concerns.     Section 1860D-4(c)(5)(D) of the Act specifies that for purposes of limiting access to coverage of frequently abused drugs to those obtained from a selected pharmacy, if the pharmacy has multiple locations that share real-time electronic data, all such locations of the pharmacy collectively are treated as one pharmacy. Given this provision, as well as our proposal to treat multiple prescribers from the same group practice as one prescriber under the clinical guidelines, we propose that where a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines.     Because not all Part D plans' data systems may be able to account for group practice prescribers as we described above, or chain pharmacies through data analysis alone, or may not be able to fully account for them, we request information on sponsors' systems capabilities in this regard. Also, if a plan sponsor does not have the systems capability to automatically determine when a prescriber is part of a group or a pharmacy is part of a chain, the plan sponsor would have to make these determinations during case management, as they do with respect to group practices under the current policy. If through such case management, the Part D plan finds that the multiple prescribers who prescribed frequently abused drugs for the beneficiary are members of the same group practice, the Part D plan would treat those prescribers as one prescriber for purposes of identification of the beneficiary as a potential at-risk beneficiary. Similarly, if through such case management, the Part D plan finds that multiple locations of a pharmacy used by the beneficiary share real-time electronic data, the Part D plan would treat those locations as one pharmacy for purposes of identification of the beneficiary as a potential at-risk beneficiary. Both of these scenarios may result in a Part D sponsor no longer conducting case management for a beneficiary because the beneficiary does not meet the clinical guidelines. We also note that group practices and chain pharmacies are important to consider for purposes of the selection of a prescriber(s) and pharmacy(ies) in cases when a Part D plan limits a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s), which we discuss in more detail later in this preamble.     Under the current policy, sponsors must use 90 MME as a ``floor'' for their own criteria to identify beneficiaries who may be overutilizing opioids, but they may vary the prescriber and pharmacy count. This means sponsors may review beneficiaries who do not meet the OMS criteria but meet the sponsors' internal criteria for review, or they may not review beneficiaries who meet the OMS criteria but do not meet the sponsors' internal criteria for review. However, under our proposal to adopt the 2018 OMS criteria as the 2019 clinical guidelines for Part D drug management programs, we also propose to mostly eliminate this feature of the current policy. Under our proposal, Part D plan sponsors would not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs, except that we propose to continue to permit plan sponsors to apply the criteria more frequently than CMS would apply them through OMS in 2018, which can result in sponsors identifying beneficiaries earlier. This is because CMS evaluates enrollees quarterly using a 6-month look back period, whereas sponsors may evaluate enrollees more frequently (for example, monthly).     While several commenters stated that Part D plan sponsors should have flexibility in developing their own criteria for identifying at- risk beneficiaries in their plans, a more conservative and uniform approach is warranted for the initial implementation of Part D drug management programs. While we already have experience with how frequently Part D plan sponsors use beneficiary-specific opioid POS claim edits to prevent opioid overutilization, we wish to learn how sponsors will use

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lock-in as a tool to address this issue before adopting clinical guidelines that might include parameters for permissible variations of the criteria. We plan to monitor compliance of drug management programs as we monitor compliance with the current policy through various CMS data sources, such as OMS, MARx, beneficiary complaints and appeals.     Also, we note that despite sponsors' additional identification of some beneficiaries currently, in practice, we have found that CMS identifies the vast majority of beneficiaries who are reviewed by Part D sponsors through OMS. CMS identifies over 80 percent of the cases reviewed through OMS, and about 20 percent are identified by sponsors based on their internal criteria. We understand that most of the beneficiaries representing the 20 percent were reported to OMS due to the sponsors averaging the MME calculations across all opioid prescriptions, which has subsequently been changed in the 2018 OMS criteria. The 2018 OMS criteria also have a lower MME threshold and account for additional beneficiaries who receive their opioids from many prescribers regardless of the number of pharmacies, which will result in the identification of more beneficiaries through OMS. Thus, our proposal would not substantially change the current practice. Furthermore, in approximately 39 percent of current OMS cases, sponsors respond that the case does not meet the sponsor's internal criteria for review.\15\ We found that the original OMS criteria generated false positives that some sponsors' internal criteria did not because these sponsors used a shorter look back period or were able to group prescribers within the same practice or chain pharmacies. These best practices have also been incorporated into the revised 2018 OMS criteria, which are the basis of the proposed 2019 clinical guidelines. Thus, while our proposal will prevent sponsors from voluntarily reviewing more potential at-risk beneficiaries than CMS identifies through OMS, it will likely require sponsors to review more beneficiaries than they currently do. ---------------------------------------------------------------------------

    \15\ We noted in the final CY Parts C&D Call Letter, for the January 2014 OMS reports, 67 percent of the potential opioid overutilization responses were that the beneficiary did not meet the sponsor's internal criteria. We explained the reasons for this figure and the actions we took to reduce it. ---------------------------------------------------------------------------

    Table 1 shows that in 2015 approximately 33,000 beneficiaries would have met the proposed 2019 clinical guidelines, which is approximately 0.08 percent of the 42 million beneficiaries enrolled in Part D in 2015. We think this population would constitute a manageable program size because this is the estimated OMS population we finalized during the Plan Year 2018 Parts C&D Call Letter process. Moreover, we have no evidence to suggest that this program size will be problematic for sponsors.     In addition, current Medicaid lock-in programs support the notion that this program size would be manageable by Part D plan sponsors. In 2015, an average 0.37 percent of Medicaid recipients were locked-in and the percentage of recipient's locked-in by state programs ranged from 0.01 percent to 1.8 percent.\16\ ---------------------------------------------------------------------------

    \16\ Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug-Fee-For-Service Programs (December 2016), pg. 26. ---------------------------------------------------------------------------

    To derive this estimated population of potential at-risk beneficiaries, we analyzed prescription drug event data (PDE) from 2015,\17\ using the CDC opioid drug list and MME conversion factors, and applying the criteria we proposed earlier as the clinical guidelines. This estimate is over-inclusive because we did not exclude beneficiaries in long-term care (LTC) facilities who would be exempted from drug management programs, as we discuss later in this section. However, based on similar analyses we have conducted, this exclusion would not result in a noteworthy reduction to our estimate. Also, we were unable to count all locations of a pharmacy that has multiple locations that share real-time electronic data as one, which is a topic we discussed earlier and will return to later. Thus, there likely are beneficiaries counted in our estimate who would not be identified as potential at-risk beneficiaries because they are in an LTC facility or only use multiple locations of a retail chain pharmacy that share real- time electronic data. ---------------------------------------------------------------------------

    \17\ Unique count of beneficiaries who met the criteria in any 6 month measurement period (January 2015-June 2015; April 2015- September 2015; or July 2015-December 2015).

      Table 1--Clinical Guidelines or Identifying Potential At-Risk                               Beneficiaries ------------------------------------------------------------------------             Criteria applied                 Impact to Part D program ------------------------------------------------------------------------ [gteqt]90 mg MED and either:             33,053 beneficiaries in 2015                                           (76.3% were LIS).     4+ opioid prescribers AND 4+ opioid  Represents 0.08% of 41,835,016      dispensing pharmacies.               Part D beneficiaries in 2015. OR                                       LTC beneficiaries included in                                           estimate but are exempt.     6+ opioid prescribers (regardless    Prescribers associated with the      of the number of opioid dispensing   same single Tax Identification      pharmacies).                         Numbers (TIN) are counted as a                                           single prescriber. ------------------------------------------------------------------------

    We note that the alternatives for clinical guidelines that we considered, which are described in the Regulatory Impact Analysis (RIA) section of this rule, also include estimated population of potential at-risk beneficiaries for each alternative. Most of the options include a 90 MME threshold with varying prescriber and pharmacy counts and range from identifying 33,053 to 319,133 beneficiaries. Again, stakeholders are invited to comment on these alternatives. We are particularly interested in receiving comments on whether CMS should adjust the clinical guidelines so that more or fewer potential at-risk beneficiaries are identified, and if more are identified, whether the additional number would result in a manageable program size for plan sponsors (or too few beneficiaries to be meaningful).  Exempted Beneficiary     Section 1860D-4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. Consistent with this, we propose that an exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents

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through a contract with a single pharmacy; or (3) Has a cancer diagnosis.     While the first two exceptions are required under CARA, we propose to exercise the authority in section 1860D-4(c)(5)(C)(ii)(III) of the Act to treat a beneficiary who has a cancer diagnosis as an exempted individual for two reasons. First, many commenters recommended that the Secretary exempt beneficiaries who have a cancer diagnosis, because a Part D drug management program should not be able to interfere administratively with their pain control regimen in the form of additional notices from their prescription drug benefit plans and limitations on their access to coverage for frequently abused drugs. We agree with these commenters. Second, exempting beneficiaries with a cancer diagnosis would be consistent with current policy. Under the current policy, which has been developed through stakeholder feedback, beneficiaries with cancer are excluded because the benefit of their opioid use may outweigh the risk associated with their opioid use. Also, as noted previously, some commenters requested that implementation of the drug management program provisions of CARA be as consistent as possible with the current policy for operational ease. We also agree with these commenters.     Some commenters recommended against exempting beneficiaries with cancer diagnoses, stating that there is no standard clinical reason why a beneficiary with cancer should be receiving opioids from multiple prescribers and/or multiple pharmacies, and that such situations warrant further review. While we understand the concern of these commenters, we maintain that beneficiaries who have a cancer diagnosis should be exempted for the reasons stated just above. Moreover, our experience with this exemption under the current policy suggests that the exemption is workable and appropriate. We understand beneficiaries with cancer diagnoses are identifiable by Part D plan sponsors either through recorded diagnoses, their drug regimens or case management, and no major concerns have been expressed about this exemption under our current policy, including from standalone Part D plan sponsors who may not have access to their enrollees' medical records.     A few commenters suggested exempting beneficiaries who are receiving palliative and end-of-life care, since not all patients receiving this type of care are necessarily enrolled in hospice or reside in an LTC facility. Two commenters suggested exempting beneficiaries in assisted living. Other commenters suggested exempting beneficiaries in various other health care facilities, such as group homes and adult day care centers, where medication is supervised. Other commenters suggested exempting beneficiaries with debilitating disorders or receiving medication-assisted treatment for substance abuse disorders.     We have not proposed to exempt these additional categories of beneficiaries but we seek specific comment on whether to do so and our rationale. First, we have not exempted these other beneficiaries under the current policy, and we thus do not think it is necessary to exempt them from drug management programs. Second, unlike with cancer diagnoses, we are not able to determine administratively through CMS data who these beneficiaries are to exempt them from OMS reporting. Consequently, it could be burdensome for Part D sponsors to attempt to exempt these beneficiaries, by definition, from their drug management programs. Third, it is important to remember that the proposed clinical guidelines would only identify potential at-risk beneficiaries in the Part D program who are receiving potentially unsafe doses of opioids from multiple prescribers and/or multiple pharmacies who typically do not know about each other in terms of providing services to the beneficiary. Thus, it is likely that a plan would discover during case management that a potential at-risk beneficiary is receiving palliative and end-of-life care during case management. Absent a compelling reason, we would expect the plan not to seek to implement a limit on such beneficiary's access to coverage of opioids under the current policy nor a drug management program, as it would seem to outweigh the medication risk in such circumstances. Moreover, in cases where a prescriber is cooperating with case management, we would not expect the prescriber to agree to such a limitation, again, absent a compelling reason. With respect to beneficiaries receiving medication-assisted treatment for substance abuse for opioid use disorder, we decline to propose to treat these individuals as exempted individuals. It is these beneficiaries who are among the most likely to benefit from a drug management program. (ii) Requirements of Drug Management Programs (Sec. Sec.  423.153, 423.153(f))     As noted previously, we are proposing to codify a regulatory framework under which Part D plan sponsors may adopt drug management programs to address overutilization of frequently abused drugs. Therefore, we propose to amend Sec.  423.153(a) by adding this sentence at the end: ``A Part D plan sponsor may establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section,'' in accordance with our authority under revised section 1860D-4(c)(5)(A) of the Act.     We also propose to revise Sec.  423.153 by adding a new paragraph (f) about drug management programs for which the introductory sentence would read: ``(f) Drug Management Programs. A drug management program must meet all the following requirements.'' Thus, the requirements that a Part D plan sponsor must meet to operate a drug management program would be codified in various provisions under subsection Sec.   423.153(f). (iii) Written Policies and Procedures (Sec.  423.153(f)(1))     We propose to require Part D sponsors document their programs in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate, which is consistent with the current policy. Also consistent with the current policy, we would require these policies and procedures to address the appropriate credentials of the personnel conducting case management and the necessary and appropriate contents of files for case management. We additionally propose to require sponsors to monitor information about incoming enrollees who would meet the definition of a potential at-risk and an at-risk beneficiary in proposed Sec.  423.100 and respond to requests from other sponsors for information about potential at-risk and at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. We discuss potential at-risk and at- risk beneficiaries who are identified as such in their most recent Part D plan later in this preamble.     To codify these requirements, we propose that section Sec.   423.153(f)(1) read as follows: (1) Written policies and procedures. A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. The policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following: (i) The appropriate credentials of the personnel conducting case management required under

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paragraph (f)(2); (ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2); and (iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary and a potential at-risk beneficiary in Sec.  423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at- risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. Thus, Part D sponsors would have flexibility--as they do today under the current policy--to adopt specific policies and procedures for their drug management programs, as long as they are consistent with the requirements of Sec.  423.153, as finalized. (iv) Case Management/Clinical Contact/Prescriber Verification (Sec.   423.153(f)(2))     As discussed earlier, case management is a key feature of the current policy, under which we currently expect Part D plan sponsors' clinical staff to diligently engage in case management with the relevant opioid prescribers to coordinate care with respect to each beneficiary reported by OMS until the case is resolved (unless the beneficiary does not meet the sponsor's internal criteria). We propose that the second requirement for drug management programs in a new Sec.   423.153(f)(2) reflect the current policy with some adjustment to the current policy to require all beneficiaries reported by OMS to be reviewed by sponsors.     Our proposal for a new Sec.  423.153(f)(2) also meets the requirements of section 1860D-4I(5)(C) of the Act. This section of the Act requires that, with respect to each at-risk beneficiary, the sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions. Further, our proposal meets the requirements of Section 1860D-4(c)(5)(B)(i)(II) of the Act, which requires that a Part D sponsor first verify with the beneficiary's providers that the beneficiary is an at-risk beneficiary, if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs.     Specifically, we propose that a new Sec.  423.153(f)(2) read as follows: Case Management/Clinical Contact/Prescriber Verification. (i) General Rule. The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Proposed Sec.  423.153(f)(2)(i) would further state that, except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following: (A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at-risk beneficiary; (B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary; and (C) In cases where the prescribers have not responded to the inquiry described in (i)(B), make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.     Given the ``Except as provided in paragraph (f)(2)(ii) of this section'', we propose to add paragraph (ii) to Sec.  423.153(f)(2) that would read: (ii) Exception for identification by prior plan. If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan, and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is still clinically adequate and up to date. This proposal is to avoid unnecessary burden on health care providers when additional case management outreach is not necessary. This is consistent with the current policy under which sponsors are expected to enter information into MARx about pending, implemented and terminated beneficiary- specific POS claim edits, which is transferred to the next sponsor, if applicable. Pending and implemented POS claim edits are actions that sponsors enter into MARx after case management. We discuss potential at-risk and at-risk beneficiaries who change plans again later in this preamble.     The information that the plan sends to the prescribers and elicits from them is intended to assist a Part D sponsor to understand why the beneficiary meets the clinical guidelines and if a plan intervention is warranted for the safety of the beneficiary. Also, sponsors use this information to choose standardized responses in OMS and provide information to MARx about plan interventions that were referenced earlier. We will address required reporting to OMS and MARx by sponsors again later.     We note that, currently, OMS standardized responses generally fall into four categories: First, in approximately 18 percent of cases, the enrollee's opioid use is medically necessary. Second, approximately 38 percent of cases are resolved without a beneficiary-specific POS opioid claim edit, for example, when the sponsor takes a ``wait and see'' approach to observe if the prescribers adjust their management of, and the opioid prescriptions they are writing for, their patient due to the written information they received from the sponsor about their patient. Third, a small subset of cases--on average 1.3 percent--need a beneficiary-specific opioid POS claim edit to resolve the beneficiary's opioid overutilization issue. From 2013 through of July 4, 2017, CMS received 4,617 contract-beneficiary-level opioid POS claim edit notifications through MARx for 3,961 unique beneficiaries. Fourth, as previously mentioned, approximately 39 percent of cases do not meet the sponsor's internal criteria for review. We expect adjustment to these percentages under our proposal, particularly since we anticipate that plans will no longer be able to respond that a case does not meet its internal criteria for review. In addition, the revised 2018 OMS criteria which are the basis of the proposed 2019 clinical guidelines should reduce ``false positives'' which may have been reported through OMS but not identified through sponsors' internal criteria due to a shorter look back period and ability to group prescribers within the same practice.     We also note that under the current policy, sponsors are expected to make ``at least three (3) attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period (for example, a 10 business day period) from the issuance of the written inquiry notification.'' If the prescribers are unresponsive to case management, under our current policy, a sponsor may also implement a beneficiary-specific POS claim edit for opioids as a last resort to encourage prescriber engagement with case management.     By contrast, our proposed Sec.  423.153(f)(2) uses the terms ``reasonable attempts'' and ``reasonable period'' rather than a specific number of attempts or a specific timeframe for plan to call prescribers. The reason for this proposed adjustment to our policy is because our current policy also states that ``[s]ponsors are not required to

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automatically contact prescribers telephonically,'' but those that ``employ a wait-and-see approach'' should understand that ``we expect sponsors to address the most egregious cases of opioid overutilization without unreasonable delay, and that we do not believe that all such cases can be addressed through a prescriber letter campaign.'' Our guidance further states that, ``to the extent that some cases can be addressed through written communication to prescribers only, we would acknowledge the benefit of not aggravating prescribers with unnecessary telephonic communications.'' Finally, our guidance states that, ``[s]ponsors must determine for themselves the usefulness of attempting to call or contact all opioid prescribers when there are many, particularly when they are emergency room physicians.'' \18\ ---------------------------------------------------------------------------

    \18\ See ``Supplemental Guidance Relating to Improving Drug Utilization Review Controls in Part D'', September 6, 2012 (pp. 5, 19-20) at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) ---------------------------------------------------------------------------

    Given the competing priorities of sponsors' diligently addressing opioid overutilization in the Part D program through case management, which may necessitate telephone calls to the prescribers, while being cognizant of the need to be judicious in contacting prescribers telephonically in order to not unnecessarily disrupt their practices, we wish to leave flexibility in the regulation text for sponsors to balance these priorities on a case-by-case basis in their drug management programs, particularly since this flexibility exists under the current policy. We note however, that we propose a 3 attempts/10 business days requirement for sponsors to conclude that a prescriber is unresponsive to case management in Sec.  423.153(f)(4) discussed later in this section. (v) Limitations on Access to Coverage for Frequently Abused Drugs (Sec.  423.153(f)(3))     As described earlier, under the current policy, Part D sponsors may implement a beneficiary-specific opioid POS claim edit to prevent continued overutilization of opioids, with prescriber agreement or in the case of an unresponsive prescriber during case management. If a sponsor implements a POS claim edit, the sponsor thereafter does not cover opioids for the beneficiary in excess of the edit, absent a subsequent determination, including a successful appeal.     As noted earlier, revised section 1860D-4(c)(5)(A) of the Act provides additional tools commonly known as ``lock-in'', for Part D plans to limit an at-risk beneficiary's access to coverage for frequently abused drugs. Prescriber lock-in would limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers, and pharmacy lock-in would restrict an at-risk beneficiary's access to coverage for frequently abused drugs to those that are dispensed to the beneficiary by one or more network pharmacies.     If the sponsor uses a lock-in tool(s), the sponsor must generally cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) and/or prescriber(s), as applicable, absent a subsequent determination, including a successful appeal. Pursuant to section 1860D-4(c)(5)(D)(i)(II) of the Act, a sponsor would also have to cover frequently abused drugs from a non- selected pharmacy or prescriber, if such coverage were necessary in order to provide reasonable access. We discuss selection of pharmacies and prescribers and reasonable access later.     We propose to describe all the tools that would be available to sponsors to limit an at-risk beneficiary's access to coverage for frequently abused drugs through a drug management program in Sec.   423.153(f)(3) as follows: Limitation on Access to Coverage for Frequently Abused Drugs. Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following: (i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary; or (ii) In accordance with paragraphs (f)(10) and (f)(11) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are (A) Prescribed for the beneficiary by one or more prescribers; (B) Dispensed to the beneficiary by one or more network pharmacies; or (C) Specified in both paragraphs (3)(ii)(B)(1) and (2) of this paragraph. Paragraph (iii)(A) would state that if the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal. Paragraph (iii)(B) would state that if the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) and/or prescriber(s), or both, as applicable, (1) in accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal, and (2) except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section. (vi) Requirements for Limiting Access to Coverage for Frequently Abused Drugs (Sec.  423.153(f)(4))     We propose that before a Part D plan sponsor could limit the access of at-risk beneficiary to coverage for frequently abused drugs, the sponsor must first take certain actions, consistent with current policy. We propose that a sponsor must first conduct the case management discussed earlier, which includes clinical contact to determine whether prescribed medications are appropriate for the potential at-risk beneficiary's medical conditions and prescriber verification that the beneficiary is an at-risk beneficiary. We also propose that the sponsor must first obtain the agreement of the prescribers of frequently abused drugs with the limitation, unless the prescribers were not responsive to the required case management, in light of the risk to the beneficiary's health. We further propose that the sponsor must first provide notice to the beneficiary in accordance with section 1860D-4(c)(5)(B)(i)(I) of the Act.     We propose to require the additional step of prescriber agreement, which is consistent with the current policy as discussed earlier, because a prescriber may verify that the beneficiary is an at-risk beneficiary but may not view a limitation on the beneficiary's access to coverage for frequently abused drugs as appropriate. Given the additional information the prescribers would have from the Part D sponsor through case management about the beneficiary's utilization of frequently abused drugs, the prescribers' professional opinion may be that an adjustment to their prescribing for, and care of, the beneficiary is all that is needed to safely manage the beneficiary's use of frequently abused drugs going forward. We invite stakeholders to comment on not requiring prescriber agreement to implement pharmacy lock-in. We could foresee a case in which the prescriber is responsive, but does not agree with pharmacy lock-in.     We also propose language that would provide an exception to the case management requirement in Sec.  423.153(f)(2) when an at-risk

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beneficiary was identified as an at-risk beneficiary by the beneficiary's most recent prior prescription drug benefit plan. We discuss such cases more later in this section. Given the foregoing, we propose to add a paragraph (f)(4) to Sec.  423.153 that reads: Requirements for Limiting Access to Coverage for Frequently Abused Drugs. (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following: (A) Conducted the case management required by paragraph (f)(2) of this section and updated it, if necessary; (B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate; and (C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section. We would also state in subsection (ii) that if the sponsor complied with the requirement of paragraph (f)(2)(i)(C) of this section, and the prescribers were not responsive after 3 attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section. Finally, we would state in a subsection (iii) that if the beneficiary meets paragraph (2) of the definition of a potential at- risk beneficiary or an at-risk beneficiary, and the sponsor has obtained the applicable case management information from the sponsor of the beneficiary's most recent plan and updated it as appropriate, the sponsor has met the case management requirement in paragraph (f)(2)(i). (vii) Beneficiary Notices and Limitation of Special Enrollment Period (Sec. Sec.  423.153(f)(5), 423.153(f)(6), 423.38) (A) Initial Notice to Beneficiary and Sponsor Intent To Implement Limitation on Access to Coverage for Frequently Abused Drugs (Sec.   423.153(f)(5))     The notices referred to in proposed Sec.  423.153(f)(4)(i)(C) are the initial and second notice that section 1860D-4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to send to potential at-risk and at- risk beneficiaries regarding their drug management programs. We remind Part D sponsors that under Section 504 of the Rehabilitation Act of 1973, effective communications requirements would apply to both these notices. We first discuss the initial notice.     We propose in Sec.  423.153(f)(5) that if a Part D plan sponsor intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs, the sponsor would be required to provide an initial written notice to the potential at-risk beneficiary. We also propose that the language be approved by the Secretary and be in a readable and understandable form that contains the language required by section 1860D-4(c)(5)(B)(ii) of the Act to which we propose to add detail in the regulation text. Finally, we propose that the sponsor be required to make reasonable efforts to provide the prescriber(s) of frequently abused drugs with a copy of the notice.     We propose that Sec.  423.153(f)(5)(i) read as follows: Initial Notice to Beneficiary. A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary. Paragraph (f)(5)(ii) would require that the notice use language approved by the Secretary and be in a readable and understandable form that provides the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary; (2) A description of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits); (3) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at Sec.  423.580 et seq.; (4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under Sec.   423.153(f)(3)(ii); (5) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including an explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program, the timeframe for the sponsor's decision, and if applicable, any limitation on the availability of the special enrollment period described in Sec.   423.38; (6) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(4); (7) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program; and (8) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     We propose to require at Sec.  423.153(f)(5)(iii) that the Part D plan sponsor make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i).     The content of the initial notice we propose in Sec.  423.153(f)(5) closely follows the content required by section 1860D-4(c)(5)(B)(ii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (f)(5)(ii)(C)(2)--which would require a description of public health resources that are designed to address prescription drug abuse--we propose to require that the notice contain information on how to access such services. We also included a reference in proposed paragraph (ii)(C)(4) to the fact that a beneficiary would have 30 days to provide information to the sponsor, which is a timeframe we discuss later in this preamble. We propose an additional requirement in paragraph (ii)(C)(5) that the sponsor include the limitation the sponsors intends to place on the beneficiary's access to coverage for frequently abused drugs, the timeframe for the sponsor's decision, and, if applicable, any limitation on the availability of the SEP. Finally, we proposed a requirement in paragraph (ii)(C)(8) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.     We note that our proposed implementation of the statutory requirements for the initial notice would permit the notice also to be used when the sponsor intends to implement a beneficiary-specific POS claim edit for frequently abused drugs. This is consistent with our current policy and would streamline beneficiary notices about opioids since we propose frequently abused drugs to consist of opioids for 2019.

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    Although section 1860D-4(c)(5) is silent as to the sequence of the steps of clinical contact, prescriber verification, and the initial notice, we propose to implement these requirements such that they would occur in the following order: First, the plan sponsor would conduct the case management which encompasses clinical contact and prescriber verification required by Sec.  423.153(f)(2) and prescriber agreement required by Sec.  423.153(f)(4), and second would, as applicable, indicate the sponsor's intent to limit the beneficiary's access to frequently abused drugs by providing the initial notice. In our view, a sponsor cannot reasonably intend to limit the beneficiary's access unless it has first undertaken case management to make clinical contact and obtain prescriber verification and agreement. Further, under our proposal, although the proposed regulatory text of (f)(4)(i) states that the sponsor must verify with the prescriber(s) that the beneficiary is an at-risk beneficiary in accordance with the applicable statutory language, the beneficiary would still be a potential at-risk beneficiary from the sponsor's perspective when the sponsor provides the beneficiary the initial notice. This is because the sponsor has yet to solicit information from the beneficiary about his or her use of frequently abused drugs, and such information may have a bearing on whether a sponsor identifies a potential at-risk beneficiary as an at- risk beneficiary.     Moreover, we believe that in general, a sponsor should not send a potential at-risk beneficiary an initial notice until after the sponsor has been in contact with the beneficiary's prescribers of frequently abused drugs, so as to avoid unnecessarily alarming the beneficiary, considering that a sponsor may learn from the prescribers that the beneficiary's use of the drugs is medically necessary, or that the beneficiary is an exempted beneficiary. This proposed approach is also consistent with our current policy and stakeholder comments. Therefore, under this approach, a sponsor would provide an initial notice to a potential at-risk beneficiary if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, and the sponsor would provide a second notice to an at-risk beneficiary when it actually limits the beneficiary's access to coverage for frequently abused drugs. Alternatively, the sponsor would provide an alternate second notice if it decides not to limit the beneficiary's access to coverage for frequently abused drugs. We discuss the second notice and alternate second notice later in this preamble.     We intend to develop language for the initial notice. Therefore, the proposed regulatory text states that the notice must use language approved by the Secretary. (B) Limitation on the Special Enrollment Period for LIS Beneficiaries With an At-Risk Status (Sec.  423.38)     In addition to providing relevant information to a potential at- risk beneficiary, we propose that the initial notice will notify dually- and other low income subsidy (LIS)-eligible beneficiaries, that they will be unable to use the special enrollment period (SEP) for LIS beneficiaries due to their at-risk status. (Hereafter, this SEP is referred to as the ``duals' SEP''). Section 1860D-1(b)(3)(D) of the Act requires the Secretary to establish a Part D SEP for full-benefit dually eligible (FBDE) beneficiaries. This SEP, codified at Sec.   423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries (75 FR 19720) so that all LIS-eligible beneficiaries were treated uniformly. The duals' SEP currently allows such individuals to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans) throughout the year, unlike other Part D enrollees who generally may make enrollment changes only during the annual election period (AEP). Individuals using this SEP can enroll in either a stand-alone Part D prescription drug plan (PDP) or a Medicare Advantage plan with prescription drug coverage.     Section 704(a)(3) of CARA gives the Secretary the discretion to limit the SEP for FBDE beneficiaries outlined in section 1860D- 1(b)(3)(D) of the Act. This limitation is related to, but distinct from, other changes to the duals' SEP proposed in section III.A.11 of this proposed rule (as discussed later). A limitation under a sponsor's drug management program can only be effective as long as the individual is enrolled in that plan or another plan that also has a drug management program. Therefore, this proposed SEP limitation would be an important tool to reduce the opportunities for LIS-eligible beneficiaries designated as at-risk to switch plans. If an individual is determined to be an at-risk beneficiary, and is permitted to change plans using the duals' SEP, he or she could avoid the drug management program by leaving the plan before the program can be started or by enrolling in a PDP that does not have a drug management program. This would allow the beneficiary to circumvent the lock-in program and not receive the care coordination such a program provides. Even if an-risk beneficiary joined another plan that had a drug management program in place, there would be challenges in terms of preventing a gap managing their potential or actual overutilization of frequently abused drugs due to timing of information sharing between the plans and possible difference in provider networks.     Accordingly, we are proposing to revise Sec.  423.38(c)(4), so that it is not available to potential at-risk beneficiaries or at-risk beneficiaries. Once an individual is identified as a potential at-risk beneficiary and the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, the sponsor would provide an initial notice to the beneficiary and the duals' SEP would no longer be available to the otherwise eligible individual. This means that he or she would be unable to use the duals' SEP to enroll in a different plan or disenroll from the current Part D plan. The limitation would be effective as of the date the Part D plan sponsor identifies an individual to be potentially at-risk. Limiting the duals' SEP concurrent with the plan's identification of a potential at-risk beneficiary would reduce the opportunities for such beneficiaries to use the interval between receipt of the initial notice and application of the limitation (for example, pharmacy or prescriber lock-in, beneficiary-specific POS claim edit) as an opportunity to change plans before the restriction takes effect.     Based on the 2015 data in CMS' OMS, more than 76 percent of all beneficiaries estimated to be potential at-risk beneficiaries are LIS- eligible individuals. Based on this data, without an SEP limitation at the initial point of identification, the notification of a potential drug management program may prompt these individuals to switch plans immediately after receiving the initial notice. In effect, under the current regulations, if unchanged, the dually- or other LIS-eligible individual, could keep changing plans and avoid being subject to any drug management program.     We propose that, consistent with the timeframes discussed in proposed paragraph Sec.  423.153(f)(7), if the Part D plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 90 days from the initial notice, the ``potentially at-risk'' designation and the duals' SEP limitation would expire. If the sponsor determines that the potential at-risk beneficiary is an at- risk beneficiary, the

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duals' SEP would not be available to that beneficiary until the date the beneficiary's at-risk status is terminated based on a subsequent determination, including a successful appeal, or at the end of a 12- month period calculated from the effective date the sponsor provided the beneficiary in the second notice as proposed at Sec.  423.153(f)(6) whichever is sooner.     As discussed in section III.A.11 of this proposed rule, we are also proposing to revise Sec.  423.38(c)(4) to make the SEP for FBDE or other subsidy-eligible individuals available only in certain circumstances. As further explained in section III.A.11, we also are proposing to establish a new SEP at Sec.  423.38(c)(9) to permit any beneficiary to make an enrollment change when he or she has a gain, loss, or change in Medicaid or LIS eligibility.     We propose not to limit the availability of this new SEP to potential at-risk and at-risk beneficiaries. In situations where an individual is designated as a potential at-risk beneficiary or an at- risk beneficiary and later determined to be dually-eligible for Medicaid or otherwise eligible for LIS, that beneficiary should be afforded the ability to receive the subsidy benefit to the fullest extent for which he or she qualifies and therefore should be able to change to a plan that is more affordable, or that is within the premium benchmark amount if desired. Likewise, if an individual with an ``at- risk'' designation loses dual-eligibility or LIS status, or has a change in the level of extra help, he or she would be afforded an opportunity to elect a different Part D plan, as discussed in section III.A.11 of this proposed rule. This is also a life changing event that may have a financial impact on the individual, and could necessitate an individual making a plan change in order to continue coverage.     We note that auto- and facilitated enrollment of LIS eligible individuals and plan annual reassignment processes would still apply to dual- and other LIS-eligible individuals who were identified as an at- risk beneficiary in their previous plan. This is consistent with CMS's obligation and general approach to ensure Part D coverage for LIS- eligible beneficiaries and to protect the individual's access to prescription drugs. Furthermore, we note that the proposed enrollment limitations for Medicaid or other LIS-eligible individuals designated as at-risk beneficiaries would not apply to other Part D enrollment periods, including the AEP or other SEPs. As discussed previously, we propose that the ability to use the duals' SEP, as outlined in section III.A.11 of this proposed rule, would not be permissible once the individual is enrolled in a plan that has identified him or her as a potential at-risk beneficiary or at-risk beneficiary, for a dual or other LIS-eligible who meets the definition of at-risk beneficiary or potential at-risk beneficiary under proposed Sec.  423.100 (C) Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs by Sponsor (Sec.  423.153(f)(6))     As previously noted, section 1860D-4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to provide a second written notice to at-risk beneficiaries when they limit their access to coverage for frequently abused drugs. Also, as with the initial notice, our proposed implementation of this statutory requirement for the second notice would permit the second notice to be used when the sponsor implements a beneficiary-specific POS claim edit for frequently abused drugs.     We propose to codify this requirement in Sec.  423.153(f)(6)(i). Specifically, we propose to require the sponsor to provide the second notice when it determines that the beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs. We further propose to require the second notice to include the effective and end date of the limitation. Thus, this second notice would function as a written confirmation of the limitation the sponsor is implementing with respect to the beneficiary, and the timeframe of that limitation.     We also propose that the second notice, like the initial notice, contain language required by section 1860D-4(c)(5)(B)(iii) of the Act to which we propose to add detail in the regulation text. We also propose that the second notice, like the initial notice, be approved by the Secretary and be in a readable and understandable form, as well as contain other content that CMS determines is necessary for the beneficiary to understand the information required in this notice. Finally, in Sec.  423.153(f)(6)(iii), we propose that the sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice, as we proposed with the initial notice.     Proposed Sec.  423.153(f)(6)(i) would read as follows: Second notice. Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary. Paragraph (f)(6)(ii) would require that the second notice use language approved by the Secretary and be in a readable and understandable form that contains the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary; (2) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including the limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and, if applicable, any limitation on the availability of the special enrollment period described in Sec.  423.38 et seq.; (3) The prescriber(s) and/or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor; (4) An explanation of the beneficiary's right to a redetermination under Sec.  423.580 et seq., including a description of both the standard and expedited redetermination processes, with the beneficiary's right to, and conditions for, obtaining an expedited redetermination; (5) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs; (6) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(5) of this section; and (7) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     The content of the second notice we propose in Sec.  423.153(f)(6) closely follows the content required by section 1860D-4(c)(5)(B)(iii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (2), we have proposed language that would require a sponsor to include the limitation the sponsors is placing on the beneficiary's access to coverage for frequently abused drugs, the effective and end date of the limitation, and if applicable, any limitation on the availability of the SEP. We propose an additional requirement in paragraph (6) that the sponsor include instructions how the beneficiary

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may submit information to the sponsor in response to the request described in paragraph (4). Finally, we proposed a requirement in paragraph (7) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.     We note that under our current policy, plan sponsors send only one notice to the beneficiary if they intend to implement a beneficiary- specific POS opioid claim edit, which generally provides the beneficiary with a 30-day advance written notice and opportunity to provide additional information, as well as to request a coverage determination if the beneficiary disagrees with the edit. If our proposal is finalized, the implementation of a beneficiary-specific POS claim edit or a limitation on the at-risk beneficiary's coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) would be an at-risk determination (a type of initial determination that would confer appeal rights). Also, the sponsor would generally be required to send two notices--the first signaling the sponsor's intent to implement a POS claim edit or limitation (both referred to generally as a ``limitation''), and the second upon implementation of such limitation. Under our proposal, the requirement to send two notices would not apply in certain cases involving at-risk beneficiaries who are identified as such and provided a second notice by their immediately prior plan's drug management program. (D) Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur (Sec.  423.153(f)(7))     We propose that if a sponsor does not implement the limitation on the potential at-risk beneficiary's access to coverage of frequently abused drugs it described in the initial notice, then the sponsor would be required to provide the beneficiary with an alternate second notice. Although not explicitly required by the statute, we believe this notice is consistent with the intent of the statute and is necessary to avoid beneficiary confusion and minimize unnecessary appeals. We propose generally that in such an alternate notice, the sponsor must notify the beneficiary that the sponsor no longer considers the beneficiary to be a potential at-risk beneficiary upon making such determination; will not place the beneficiary in its drug management program; will not limit the beneficiary's access to coverage for frequently abused drugs; and if applicable, that the SEP limitation no longer applies.     Specifically, we propose that Sec.  423.153(f)(7)(i) would read: Alternate second notice. (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary. Paragraph (f)(7)(ii) would require that the notice use language approved by the Secretary in a readable and understandable form containing the following information: (1) The sponsor has determined that the beneficiary is not an at-risk beneficiary; (2) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs; (3) If applicable, the SEP limitation no longer applies; (4) Clear instructions that explain how the beneficiary may contact the sponsor; and (5) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     Again, as with the initial and second notices, we propose in a paragraph (f)(7)(iii) that the Part D sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(7)(i). Also, as with the initial and second notices, we propose in paragraph (ii) that the notice use language approved by the Secretary and be in a readable and understandable form; in paragraph (ii)(C)(4) that the notice contain clear instructions that explain how the beneficiary may contact the sponsor; and in paragraph (ii)(C)(5), that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the notice. (E) Timing of Notices (Sec.  423.153(f)(8))     Section 1860D-4(c)(5)(B)(iv) of the Act requires a Part D sponsor to provide the second notice to the beneficiary on a date that is not less than 30 days after the sponsor provided the initial notice to the beneficiary. We interpret the purpose of this requirement to be that the beneficiary should have ample time to provide information to the sponsor that may alter the sponsor's intended action that is contained in the initial notice to the beneficiary, or to provide the sponsor with the beneficiary's pharmacy and/or prescriber preferences, if the sponsor's intent is to limit the beneficiary's access to coverage for frequently abused drugs from selected a pharmacy(ies) and/or prescriber(s).     In addition, we propose to impose a deadline by when a sponsor must provide the second notice or alternate second notice to the beneficiary, although not specifically required by CARA. Such a requirement should provide the sponsor with sufficient time to complete the administrative steps necessary to execute the action the sponsor intends to take that was explained in the initial notice to the beneficiary, while acknowledging that the sponsor would have already met in the case management, clinical contact and prescriber verification requirement.     In the case of an alternate second notice, the timeframe should provide the beneficiary with definitive notice that the sponsor has not identified the beneficiary as an at-risk beneficiary and that there will be no limitation on his/her access to coverage for frequently abused drugs. Accordingly, we propose that the sponsor would be required to send either the second notice or the alternate second notice, as applicable, when it makes its determination or no later than 90 calendar days after the date on the initial notice, whichever comes sooner.     Specifically, we propose to include at Sec.  423.153(f)(8) the following: Timing of Notices. (i) Subject to paragraph (ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days and not more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice described in paragraph (f)(5) of this section. We intend this proposed timeframe for the sponsor to provide either the second notice or the alternate second notice, as applicable, to be reasonable for both Part D sponsors and the relevant beneficiaries and important to ensuring clear, timely and reasonable communication between the parties.     Section 1860D-4(c)(5)(B)(iv)(II) of the Act explicitly provides for an exception to the required timeframe for issuing a second notice. Specifically, the statute permits the Secretary to identify through rulemaking concerns regarding the health or safety of a beneficiary or significant drug diversion activities that would necessitate that a Part D sponsor provide the second written notice to the beneficiary before the 30 day time period normally required has elapsed. For this reason, we included the language, ``subject to paragraph (ii),'' at the beginning of proposed Sec.  423.153(f)(8)(i).

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    We note that the proposed definition of at-risk beneficiary would include beneficiaries for whom a gaining Part D plan sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon enrollment. This proposed definition is based on the language in section 1860-D-4(c)(5)(C)(i)(II) of the Act.     Given that this provision allows an at-risk identification to carry forward to the next plan, we believe it is appropriate to propose to permit a gaining plan to provide the second notice to an at-risk beneficiary so identified by the most recent prior plan sooner than would otherwise be required. For the same reasons, we believe that it would be appropriate to permit the gaining plan to even send the beneficiary a combined initial and second notice, under certain circumstances. However, because the content of the initial notice would not be appropriate for an at-risk beneficiary, and because such beneficiary would have already received an initial notice from his or her immediately prior plan sponsor, the content of this combined notice should only consist of the required content for the second notice so as not to confuse the beneficiary. Thus, our interpretation of section 1860D-4(c)(5)(B)(iv)(II) of the Act in conjunction with section 1860D- 4(c)(5)(C)(i)(II) of the Act is that a gaining Part D sponsor may send the second notice immediately to a beneficiary for whom the sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment. This is consistent with our current policy under which a gaining sponsor may immediately implement a beneficiary-specific opioid POS claim edit, if the gaining sponsor is notified that the beneficiary was subject to such an edit in the immediately prior plan and such edit had not been terminated.\19\ ---------------------------------------------------------------------------

    \19\ See ``Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,'' August 25, 2014. ---------------------------------------------------------------------------

    We propose that sending a second notice to an at-risk beneficiary so identified in the most recent plan would be permissible only if the new sponsor is implementing a beneficiary-specific POS claim edit for a frequently abused drug, or if the sponsor is implementing a limitation on access to coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) and has the same location of pharmacy(ies) and/or the same prescriber(s) in its provider network, as applicable, that the beneficiary used to obtain frequently abused drugs in the most recent plan. Otherwise, we propose that the new sponsor would be required to provide the initial notice to the at-risk beneficiary, even though the initial notice is generally intended for potential at-risk beneficiaries, and could not provide the second notice until at least 30 days had passed. This is because even though there would also be a concern for the at-risk beneficiary's health and safety in this latter case as well, this concern would be outweighed by the fact that the beneficiary had not been afforded a chance to submit his or her preference for a pharmacy(ies) and/or prescriber(s), as applicable, from which he or she would have to obtain frequently abused drugs to obtain coverage under the new plan's drug management program.     We propose to codify this policy by adding a paragraph (ii) to Sec.  423.153(f)(8), as noted earlier, to read as follows: Immediately upon the beneficiary's enrollment in the gaining plan, the gaining plan sponsor may provide a second notice described in paragraph (f)(6) to a beneficiary for whom the gaining sponsor received notice that the beneficiary was identified as an at-risk beneficiary by his or her most recent prior plan and such identification had not been terminated in accordance with Sec.  423.153(f)(14), if the sponsor is implementing either of the following: (A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i); or (B) A limitation on access to coverage as described in paragraph(f)(3)(ii), if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under (f)(9).     Some stakeholders commented that sponsors should be allowed to expedite the second notice in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court. However, given the importance of a beneficiary having advance notice of a pending limit on his or her access to coverage for frequently abused drugs and sufficient time to respond and/or prepare, we believe exceptions to the timing of the notices should be very narrow. Therefore, we have only included a proposal for an exception to shorten the 30 day timeframe between the initial and second notice that is based on a beneficiary's status as an at-risk beneficiary in an immediately preceding plan. We note that is a status the drug management provisions of CARA explicitly requires to be shared with the next plan sponsor, if a beneficiary changes plans, which means there would be a concrete data point for this proposed exception to the timing of the notices. We discuss such sharing of information later in the preamble. (viii) Provisions Specific to Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers (Sec. Sec.  423.153(f)(4), 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423,153(f)(13))     Some of the drug management program provisions in CARA are only relevant to ``lock-in''. We propose several regulatory provisions to implement these provisions, as follows: (A) Special Requirement To Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s) (Sec.  423.153(f)(4))     We believe prescriber lock-in should be a tool of last resort to manage at-risk beneficiaries' use of frequently abused drugs, meaning when a different approach has not been successful, whether that was a ``wait and see'' approach or the implementation of a beneficiary specific POS claim edit or a pharmacy lock-in. Limiting an at-risk beneficiary's access to coverage for frequently abused drugs from only selected prescribers impacts the beneficiary's relationship with his or her health care providers and may impose burden upon prescribers in terms of prescribing frequently abused drugs.     As a result, we propose that a sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary. We propose that this date be the date of the first OMS report that identified the beneficiary, so long as the beneficiary was also reported in the most recent OMS report that the sponsor received. This is because limiting the beneficiary's access to coverage of frequently abused drugs from a selected prescriber would only be necessary if the beneficiary continues to meet the clinical guidelines despite any existing

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intervention or limitation. We discuss OMS reports in more detail later.     We expect that the 6-month waiting period will provide the sponsor additional time to assess whether case management or another tool, such as a beneficiary-specific POS claim edit or pharmacy lock-in has failed to resolve the beneficiary's overutilization of frequently abused drugs. Sponsors have indicated in comments on the current policy that the case management process can take 3 to 6 months. Also, sponsors would need time to determine whether the beneficiary still meets the clinical guidelines and is thus continuing to be reported by OMS. Therefore, the time period we propose was chosen to account for time needed for the case management process and to align with the 6 month measurement period of the proposed clinical guidelines.     We seek comment on whether this 6-month waiting period would reduce provider burden sufficiently to outweigh the additional case management, clinical contact and prescriber verification that providers may experience if a sponsor believes a beneficiary's access to coverage of frequently abused drugs should be limited to a selected prescriber(s). Comments should include the additional operational considerations for sponsors to implement this proposal.     Given our proposal, we propose adding a paragraph (iv) to Sec.   423.153(f)(4) that would state: (f)(4)(iv) A Part D sponsor must not limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers under Sec.  423.153(f)(3)(ii)(A) unless--(A) At least 6 months has passed from the date the beneficiary was first identified as a potential at-risk beneficiary from the date of the applicable CMS identification report; and (B) The beneficiary meets the clinical guidelines and was reported by the most recent CMS identification report.     We note that in conducting the case management required under Sec.   423.153(f)(4)(i)(A) in anticipation of implementing a prescriber lock- in, the sponsor would be expected to update any case management it had already conducted. Also, even if a sponsor had already obtained the prescriber's agreement to implement a limitation on the beneficiary's coverage of frequently abused drugs to a selected pharmacy to comply with Sec.  423.153(f)(4)(i)(B), for example, the sponsor would have to obtain the agreement of the prescriber who would be selected to implement a limitation on a beneficiary's coverage of frequently abused drugs to a selected prescriber. Finally, we note that even if a sponsor had already provided the beneficiary with the required notices to comply with Sec.  423.153(f)(4)(i)(C), the sponsor would have to provide them again in order to remain compliant, because the beneficiary would not have been notified about the specific limitation on his or her access to coverage for frequently abused drugs to a selected prescriber(s) and has an opportunity to select the prescriber(s).     We foresee a scenario in which a sponsor may wish to implement a limitation on a beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) when the sponsor's first round of case management, clinical contact and prescriber verification resulted only in sending the prescribers of frequently abused drugs a written report about the beneficiary's utilization of frequently abused drugs and taking a ``wait and see'' approach, which did not result in the prescribers' adjusting their prescriptions for frequently abused drugs for their patient. In such a scenario, assuming the patient still meets the clinical guidelines and continues to be reported by OMS, the sponsor would need to try another intervention to address the opioid overuse. Another scenario could be that the sponsor implemented a pharmacy lock-in, but after 6-months, the beneficiary still meets the clinical guidelines due to receiving frequently abused drugs from additional prescribers. (B) Selection of Pharmacies and Prescribers (Sec. Sec.  423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423.153(f)(13)) (1) Beneficiary Preferences (Sec.  423.153(f)(9))     Section 1860D-4(c)(5)(D) of the Act provides that, if a sponsor intends to impose, or imposes, a limit on a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) or prescriber(s), and the potential at-risk beneficiary or at-risk beneficiary submits preferences for a pharmacy(ies) or prescriber(s), the sponsor must select the pharmacy(ies) and prescriber(s) for the beneficiary based on such preferences, unless an exception applies, which we will address later in the preamble. We further propose that such pharmacy(ies) or prescriber(s) must be in-network, except if the at-risk beneficiary's plan is a stand-alone prescription drug benefit plan and the beneficiary's preference involves a prescriber. Because stand-alone Part D plans (PDPs) do not have provider networks, and thus no prescriber would be in-network, the plan sponsor must generally select the prescriber that the beneficiary prefers, unless an exception applies. We discuss exceptions in the next section of this preamble. In our view, it is essential that an at-risk beneficiary must generally select in-network pharmacies and prescribers so that the plan is in the best possible position to coordinate the beneficiary's care going forward in light of the demonstrated concerns with the beneficiary's utilization of frequently abused drugs.     Accordingly, we propose Sec.  423.153(f)(9) to read: Beneficiary preferences. Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following--(i) Review such preferences and (ii) If the beneficiary is--(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s) or (B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s). If the beneficiary submits preferences for a non-network pharmacy(ies), or in the case of a Medicare Advantage prescription drug benefit plan a non-network prescriber(s), or both, the sponsor does not have to select or change the selection for the beneficiary to a non-network pharmacy or prescriber except if necessary to provide reasonable access.     In a paragraph (iii), we propose that the sponsor must inform the beneficiary of the selection in the second notice, or if not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission. Thus, this section would require a Part D plan sponsor to honor an at-risk beneficiary's preferences for in-network prescribers and pharmacies from which to obtain frequently abused drugs, unless the plan was a stand-alone PDP and the selection involves a prescriber. In other words, a stand-alone PDP or MA-PD does not have to honor a beneficiary's selection of a non-network pharmacy, except as necessary

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to provide reasonable access, which we discuss later in this section. Also, under our proposal, the beneficiary could submit preferences at any time. Finally, the sponsor would be required to confirm the selection in writing either in the second notice, if feasible, or within 14 days of receipt of the beneficiary's submission. (2) Exception to Beneficiary Preferences (Sec.  423.153(f)(10))     Section 1860D-4(c)(5)(D)(iv) of the Act, provides for an exception to an at-risk beneficiary's preference of prescriber or pharmacy from which the beneficiary must obtain frequently abused drugs, if the beneficiary's allowable preference of prescriber or pharmacy would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary. Section 1860-D-4(c)(5)(D)(iv) of the Act requires the sponsor to provide the at-risk beneficiary with at least 30 days written notice and a rationale for not honoring his or her allowable preference for pharmacy or prescriber from which the beneficiary must obtain frequently abused drugs under the plan.     A few commenters asserted there should be limits to how many times beneficiaries can submit their preferences. Other commenters stated there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection.     We are not proposing to place a limit on how many times beneficiaries can submit their preferences, but we are open to additional comments on this topic. We agree with commenters who stated that there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection, but we note that because such a situation would often involve a network pharmacy or prescriber, we would expect that the sponsor would also take appropriate action with respect to the pharmacy or prescriber, such as termination from the network.     Given the foregoing, we propose to add the following: Sec.   423.153(f)(10) Exception to Beneficiary Preferences. (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy or beneficiary. (ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with (A) At least 30 days advance written notice of the change; and (B) A rationale for the change. (3) Reasonable Access (Sec. Sec.  423.100, 423.153(f)(11), 423.153(f)(12))     If a potential at-risk beneficiary or at-risk beneficiary does not submit pharmacy or prescriber preferences, section 1860-D-4(c)(5)(D)(i) of the Act provides that the Part D sponsor shall make the selection. Section 1860-D-4(c)(5)(D)(ii) of the Act further provides that, in making the selection, the sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time.     We propose to add the following at Sec.  423.153(f)(11): Reasonable access. In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure both of the following: (i) That the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, the beneficiary's predominant usage of a prescriber or pharmacy or both, impact on cost-sharing, and reasonable travel time; and (ii) reasonable access to frequently abused drugs in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.     Since the statute explicitly allows the beneficiary to submit preferences, we interpret the additional reference to beneficiary preference in the context of reasonable access to mean that a beneficiary allowable preference should prevail over a sponsor's evaluation of geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy impact on cost-sharing and reasonable travel time. In the absence of a beneficiary preference for pharmacy and/or prescriber, however, a Part D plan sponsor must take into account geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy, impact on cost-sharing and reasonable time travel in selecting a pharmacy and/or prescriber, as applicable, from which the at-risk beneficiary will have to obtain frequently abused drugs under the plan. Thus, absent a beneficiary's allowable preference, or the beneficiary's selection would contribute to prescription drug abuse or drug diversion, the sponsor must ensure reasonable access by choosing the network pharmacy or prescriber that the beneficiary uses most frequently to obtain frequently abused drugs, unless the plan is a stand-alone PDP and the selection involves a prescriber(s). In the latter case, the prescriber will not be a network provider, because such plans do not have provider networks. In urgent circumstances, we propose that reasonable access means the sponsor must have reasonable policies and procedures in place to ensure beneficiary access to coverage of frequently abused drugs without a delay that may seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function.     Determining reasonable access may be complicated when an enrollee has multiple addresses or his or her health care necessitates obtaining frequently abused drugs from more than one prescriber and/or more than one pharmacy. Section 1860D-4(c)(5) addresses this issue by requiring the Part D plan sponsor to select more than one prescriber to prescribe frequently abused drugs and more than one pharmacy to dispense them, as applicable, when it reasonably determines it is necessary to do so to provide the at-risk beneficiary with reasonable access.     Given the foregoing, we propose the following at Sec.   423.153(f)(12): Selection of Prescribers and Pharmacies. (i) A Part D plan sponsor must select, as applicable--(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP and the selection involves a prescriber(s), in which case, the prescriber need not be a network prescriber; and (B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary.     We also propose to address chain pharmacies and group practices by adding a paragraph (ii) that states: (ii) (A) For purposes of this subsection (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy; and (B) For purposes of this subsection (f)(12), in the case of a group practice, all prescribers of the group practice shall be treated as one prescriber.     We would interpret these provisions to mean that a sponsor would be required to select more than one prescriber of frequently abused drugs, if more than one prescriber has asserted

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during case management that multiple prescribers of frequently abused drugs are medically necessary for the at-risk beneficiary. We further propose that if no prescribers of frequently abused drugs were responsive during case management, and the beneficiary does not submit preferences, the sponsor would be required to select the pharmacy or prescriber that the beneficiary predominantly uses to obtain frequently abused drugs. (4) Confirmation of Pharmacy and Prescriber Selection (Sec.   423.153(f)(13))     Section 1860D-4(c)(5)(D)(v) of the Act requires that, before selecting a prescriber or pharmacy, a Part D plan sponsor must notify the prescriber and/or pharmacy that the at-risk beneficiary has been identified for inclusion in the drug management program which will limit the beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s) and that the prescriber and/or pharmacy has been selected as a designated prescriber and/or pharmacy for the at-risk beneficiary.     We propose that plan sponsors can obtain a network provider's confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries' selected prescriber or pharmacy, as applicable. In these cases, the network provider would agree to forgo providing specific confirmation if selected under a drug management program to serve an at-risk beneficiary. However, the contract between the sponsor and the network provider would need to specify how the sponsor will notify the provider of its selection. Absent a provision in the network contract, however, the sponsor would be required to receive confirmation from the prescriber(s) and/or pharmacy(ies) that the selection is accepted before conveying this information to the at-risk beneficiary. Otherwise, the plan would need to make another selection and seek confirmation.     We propose Sec.  423.153(f)(13) to read: Confirmation of Selections(s). (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is (are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs. (ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both that the selection is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the prescriber or pharmacy will be notified by the sponsor of its selection. (ix) Drug Management Program Appeals (Sec. Sec.  423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, 423.638, 423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126)     Section 1860D-4(c)(5)(E) of the Act specifies that the identification of an individual as an at-risk beneficiary for prescription drug abuse under a Part D drug management program, a coverage determination made under such a program, the selection of a prescriber or pharmacy, and information sharing for subsequent plan enrollments shall be subject to reconsideration and appeal under section 1860D-4(h) of the Act. This provision also permits the option of an automatic escalation to external review to the extent provided by the Secretary.     As discussed earlier in this preamble, we are proposing to integrate the lock-in provisions with existing Part D Opioid DUR Policy/OMS. Determinations made in accordance with any of those processes, proposed at Sec.  423.153(f), and discussed previously, are interrelated issues that we collectively refer to as an ``at-risk determination'' made under a drug management program. The at-risk determination includes prescriber and/or pharmacy selection for lock- in, beneficiary-specific POS claim edits for frequently abused drugs, and information sharing for subsequent plan enrollments. Given the concomitant nature of the at-risk determination and associated aspects of the drug management program applicable to an at-risk beneficiary, we expect that any dispute under a plan's drug management program will be adjudicated as a single case involving a review of all aspects of the drug management program for the at-risk beneficiary. While a beneficiary who is subject to a Part D plan sponsor's drug management program always retains the right to request a coverage determination under existing Sec.  423.566 for any Part D drug that the beneficiary believes may be covered by their plan, we believe that appeals of an at-risk determination made under proposed Sec.  423.153(f) should involve consideration of all relevant elements of that at-risk determination. For example, if a Part D plan determines that a beneficiary is at-risk, implements a beneficiary-specific claim edit on 2 drugs that beneficiary is taking and locks that beneficiary into a specific pharmacy, the affected beneficiary should not be expected to raise a dispute about the pharmacy selection and about one of the claim edits in distinct appeals.     We note that, while section 1860D-4(c)(5)(B)(ii)(III) of the Act requires the initial written notice to the beneficiary, which identifies him or her as potentially being at-risk, to include ``notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h),'' we interpret ``such identification'' to refer to any subsequent identification that the beneficiary is actually at-risk. Because CARA, at section 1860D- 4(c)(5)(E) of the Act, specifically provides for appeal rights under subsection (h) but does not refer to identification as a potential at- risk beneficiary, we believe this interpretation is consistent with the statutory intent. Furthermore, when a beneficiary is identified as being potentially at-risk, but has not yet been identified as at-risk, the plan is not taking any action to limit such beneficiary's access to frequently abused drugs; therefore, the situation is not ripe for appeal. While an LIS SEP under Sec.  423.38 would be restricted at the time the beneficiary is identified as potentially at-risk under proposed Sec.  423.100, the loss of such SEP is not appealable under section 1860D-4(h) of the Act.     As noted previously, section 1860D-4(c)(5)(E) of the Act specifically refers to the Part D benefit appeals provisions in section 1860D-4(h) of the Act, which require Part D plan sponsors to meet the requirements of paragraphs (4) and (5) of section 1852(g) of the Act for benefits in a manner similar to the manner such requirements apply to MA organizations. Section 1852(g)(4) of the Act specifically provides for independent review of ``reconsiderations that affirm denial of coverage, in whole or in part (emphasis added).'' We believe section 1860D-4(c)(5)(E) of the Act broader reference to ``reconsideration and appeal'' should be interpreted to mean that individuals have a right to a plan level appeal, consistent with the reconsideration provisions under section 1860D-4(g) of the Act, followed by the right to independent review if the plan level affirms the initial adverse decision. In other words, we believe the reference to ``reconsideration'' means that a Part D plan sponsor should conduct the initial

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level of appeal following an at-risk determination under the plan sponsor's drug management program, consistent with the existing Part D drug benefit appeals process, despite the absence of a specific reference to section 1860D-4(g) of the Act.     Part D enrollees, plan sponsors, and other stakeholders are already familiar with the Part D benefit appeals process. Resolving disputes that arise under a plan sponsor's drug management program within the existing Part D benefit appeals process would allow at-risk beneficiaries to be more familiar with, and more easily access, the appeals process instead of creating a new process specific to appeals related to a drug management program. Also, allowing a plan sponsor the opportunity to review information it used to make an at-risk determination under the drug management program (and any additional relevant information submitted as part of the appeal) would be efficient for both the individual and the Medicare program because it would potentially resolve the issues at a lower level of administrative review. Conversely, permitting review by the independent review entity (IRE) before a plan sponsor has an opportunity to review and resolve any errors or omissions that may have been made during the initial at- risk determination would likely result in an unnecessary increase in costs for plan sponsors as well as CMS' Part D IRE contract costs.     As noted previously, the Secretary has the discretion under CARA to provide for automatic escalation of drug management program appeals to external review. Under existing Part D benefit appeals procedures, there is no automatic escalation to external review for adverse appeal decisions; instead, the enrollee (or prescriber, on behalf of the enrollee) must request review by the Part D IRE. Under the existing Part D benefit appeals process, cases are auto-forwarded to the IRE only when the plan fails to issue a coverage determination within the applicable timeframe. During the stakeholder call and in subsequent written comments, most commenters opposed automatic escalation to the IRE, citing support for using the existing appeals process for reasons of administrative efficiency and better outcomes for at-risk beneficiaries. The majority of stakeholders supported following the existing Part D appeals process, and some commenters specifically supported permitting the plan to review its lock-in decision prior to the case being subject to IRE review. Stakeholders cited a variety of reasons for their ***opposition***, including increased costs to plans, the IRE, and the Part D program. Stakeholders cited administrative efficiency in using the existing appeal process that is familiar to enrollees, plans, and the IRE, while other commenters expressed support for automatic escalation to the IRE as a beneficiary protection.     We are proposing that at-risk determinations made under the processes at Sec.  423.153(f) be adjudicated under the existing Part D benefit appeals process and timeframes set forth in Subpart M. However, we are not proposing to revise the existing definition of a coverage determination. The types of decisions made under a drug management program align more closely with the regulatory provisions in Subpart D than with the provisions in Subpart M related to coverage or payment for a drug based on whether the drug is medically necessary for an enrollee. Therefore, we believe it is clearer to set forth the rules for at-risk determinations as part of Sec.  423.153 and cross reference Sec.  423.153(f) in relevant provisions in Subpart M and Subpart U. While a coverage determination made under a drug management program would be subject to the existing rules related to coverage determinations, the other types of initial determinations made under a drug management program (for example, a restriction on the at-risk beneficiary's access to coverage of frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers) would be subject to the processes set forth at proposed Sec.   423.153(f). Consistent with existing rules for redeterminations at Sec.  423.582, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the second written notice to make such request, unless the enrollee shows good cause for untimely filing under Sec.  423.582(c). As previously discussed for proposed Sec.  423.153(f)(6), the second written notice is sent to a beneficiary the plan has identified as an at-risk beneficiary and with respect to whom the sponsor limits his or her access to coverage of frequently abused drugs regarding the requirements of the sponsor's drug management programs.     Also consistent with the existing Part D benefit appeals process, we are proposing that at-risk beneficiaries (or an at-risk beneficiary's prescriber, on behalf of the at-risk beneficiary) must affirmatively request IRE review of adverse plan level appeal decisions made under a plan sponsor's drug management program. In other words, under this proposal, an adverse redetermination would not be automatically escalated to the Part D IRE, unless the plan sponsor fails to meet the redetermination adjudication timeframe. We are also proposing to amend the existing Subpart M rules at Sec.  423.584 and Sec.  423.600 related to obtaining an expedited redetermination and IRE reconsideration, respectively, to apply them to appeals of a determination made under a drug management program. The right to an expedited appeal of such a determination, which must be adjudicated as expeditiously as the at-risk beneficiary's health condition requires, would ensure that the rights of at-risk beneficiaries are protected with respect to access to medically necessary drugs. While we are not proposing to adopt auto-escalation, we believe our proposed approach ensures that an at-risk beneficiary has the right to obtain IRE review and higher levels of appeal (ALJ/attorney adjudicator, Council, and judicial review). Accordingly, we also are proposing to add the reference to an ``at-risk determination'' to the following regulatory provisions that govern ALJ and Council processes: Sec. Sec.  423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126     Finally, we are also proposing a change to Sec.  423.1970(b) to address the calculation of the amount in controversy (AIC) for an ALJ hearing in cases involving at-risk determinations made under a drug management program in accordance with proposed Sec.  423.153(f). Specifically, we propose that the projected value of the drugs subject to the drug management program be used to calculate the amount remaining in controversy. For example, if the beneficiary is disputing the lock-in to a specific pharmacy for frequently abused drugs and the beneficiary takes 3 medications that are subject to the plan's drug management program, the projected value of those 3 drugs would be used to calculate the AIC, including the value of any refills prescribed for the drug(s) in dispute during the plan year.     In addition to the proposed changes related to the implementation of drug management program appeals, we are also proposing to make technical changes to Sec.  423.562(a)(1)(ii) to remove the comma after ``includes'' and replace the reference to ``Sec. Sec.  423.128(b)(7) and (d)(1)(iii)'' with a reference to ``Sec. Sec.  423.128(b)(7) and (d)(1)(iv).'' (x) Termination of a Beneficiary's Potential At-Risk or At-Risk Status (Sec.  423.153(f)(14))     Section 1860-D-4(c)(5)(F) of the Act provides that the Secretary shall develop standards for the termination of the identification of an individual as an at-risk beneficiary, which shall be the

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earlier of the date the individual demonstrates that he or she is no longer likely to be an at-risk beneficiary in the absence of limitations, or the end of such maximum period as the Secretary may specify.     Most commenters recommended a maximum 12-month period for an at- risk beneficiary to be locked-in. We also note that a 12-month lock-in period is common in Medicaid lock-in programs.\20\ A few commenters stated that a physician should be able to determine that a beneficiary is no longer an at-risk beneficiary. One commenter was opposed to an arbitrary termination based on a time period. ---------------------------------------------------------------------------

    \20\ Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug Fee-For Service Program (December 2016). ---------------------------------------------------------------------------

    Given that most commenters recommended a 12-month period and such a period is common in Medicaid ``lock-in'' program, we propose a maximum 12-month period for both a lock-in period, and also for the duration of a beneficiary-specific POS claim edit for frequently abused drugs through the addition of the following language at Sec.  423.153(f)(14): Termination of Identification as an At-Risk Beneficiary. The identification of an at-risk beneficiary as such shall terminate as of the earlier of the following--     (i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary; or     (ii) The end of a 12 calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section.     Thus, we note that if a beneficiary continues to meet the clinical guidelines and, if the sponsor implements an additional, overlapping limitation on the at-risk beneficiary's access to coverage for frequently abused drugs, the beneficiary may experience a coverage limitation beyond 12-months. The same is true for at-risk beneficiaries who were identified as such in the most recent prescription drug plan in which they were enrolled and the sponsor of his or her subsequent plan immediately implements a limitation on coverage of frequently abused drugs.     Section 1860-D-4(c)(5)(F)(ii) of the Act states that nothing in CARA shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary after such termination on the basis of additional information on drug use occurring after the date of notice of such termination. Accordingly, we note that our proposed approach to termination of an at-risk determination would not prevent an at-risk beneficiary from being subsequently identified as a potential at-risk beneficiary or at-risk beneficiary on the basis of new information on drug use occurring after the date of such termination that causes the beneficiary to once again meet the clinical guidelines. (xi) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments (Sec.  423.153(f)(15))     In order for Part D sponsors to conduct the case management/ clinical contact/prescriber verification required by proposed Sec.   423.153(f)(2), CMS must identify potential at-risk beneficiaries to sponsors who are in the sponsors' Part D prescription drug benefit plans. In addition, new sponsors must have information about potential at-risk beneficiaries and at-risk beneficiaries who were so identified by their immediately prior plan and enroll in the new sponsor's plan and such identification had not terminated before the beneficiary disenrolled from the immediately prior plan. Finally, as discussed earlier, sponsors may identify potential at-risk beneficiaries by their own application of the clinical guidelines on a more frequent basis. It is important that CMS be aware of which Part D beneficiaries sponsors identify on their own, as well as which ones have been subjected to limitations on their access to coverage for frequently abused drugs under sponsors' drug management programs for Part D program administration and other purposes. This data disclosure process would be consistent with current policy, as described earlier in this preamble.     As we also discussed earlier, under the current policy, CMS provides quarterly reports to sponsors about beneficiaries enrolled in their plans who meet the OMS criteria. In turn, Part D sponsors are expected to provide responses to CMS through the OMS for each case identified within 30 days of receiving a report that reflects the status or outcome of their case management.\21\ At the same time, also within 30 days, sponsors are expected to report additional beneficiaries to OMS that they identify using their own opioid overutilization identification criteria.\22\ ---------------------------------------------------------------------------

    \21\ See ``Medicare Part D Overutilization Monitoring System,'' July 5, 2013.     \22\ See ``Medicare Part D Overutilization Monitoring System, January 17, 2014. ---------------------------------------------------------------------------

    Regarding data disclosures, section 1860D-4(c)(5)(H) of the Act provides that, in the case of potential at-risk beneficiaries and at- risk beneficiaries, the Secretary shall establish rules and procedures to require the Part D plan sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.     Sponsors also report information to CMS' MARx system about pending, implemented and terminated beneficiary-specific POS claim edit for opioids within 7 business days of the date on the applicable beneficiary notice or of the termination.\23\ The MARx system transfers information about pending and implemented claim edits to the gaining sponsor with the beneficiary's enrollment record if the beneficiary disenrolls and enrolls in the gaining sponsor's plan. If a gaining sponsor requests case management information from the losing sponsor about the beneficiary, we expect the losing sponsor to transfer the information to the gaining sponsor as soon as possible, but no later than 2 weeks from the date of the gaining sponsor's request.\24\ ---------------------------------------------------------------------------

    \23\ Final Parts C&D 2017 Call Letter, April 4, 2016.     \24\ See ``Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,'' August 25, 2014. ---------------------------------------------------------------------------

    Section 1860-D-4(c)(5)(I) of the Act requires that the Secretary establish procedures under which Part D sponsors must share information when at-risk beneficiaries or potential at-risk beneficiaries enrolled in one prescription drug plan subsequently disenroll and enroll in another prescription drug plan offered by the next sponsor (gaining sponsor). We plan to expand the scope of the reporting to MARx under the current policy to include the ability for sponsors to report similar information to MARx about all pending, implemented and terminated limitations on access to coverage of frequently abused drugs associated with their plans' drug management programs.     We propose to codify the data disclosure and information sharing process under the current policy, with the expansion just described, by adding the following requirement to Sec.  423.153: (f)(15) Data Disclosure. (i) CMS identifies each potential at-risk beneficiary to the sponsor of the prescription drug plan in which the beneficiary is enrolled. (ii) A Part D sponsor that operates a drug management program must disclose any

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data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner, specified by CMS. The data and information disclosures must do all of the following: (A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS; (B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries; (C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs; and (D) Transfer case management information upon request of a gaining sponsor as soon as possible but no later than 2 weeks from the gaining sponsor's request when: (1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and (2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment. (xii) Summary     Our proposal is intended to be responsive to stakeholder input that CMS focus on opioids; allow for flexibility to adjust the clinical guidelines and frequently abused drugs in the future; is reflective of the importance of the provider-patient relationship; protects beneficiary's rights and access, and allows for operational manageability and consistency with the current policy to the extent possible. This proposal, if finalized, should result in effective Part D drug management programs within a regulatory framework provided by CMS, and further reduce opioid overutilization in the Part D program. 2. Flexibility in the Medicare Advantage Uniformity Requirements     We have determined that providing access to services (or specific cost sharing for services or items) that is tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the Medicare Advantage (MA) regulations at Sec.   422.100(d). This regulatory requirement is a means to implement both section 1852(d) of the Act, which requires that benefits under the MA plan be available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. We have determined that these statutory provisions and the regulation at Sec.  422.100(d) mean that we have the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. For example, reduced cost sharing flexibility would allow an MA plan to offer diabetic enrollees zero cost sharing for endocrinologist visits. Similarly, with this flexibility, a MA plan may offer diabetic enrollees more frequent foot exams as a tailored, supplemental benefit. In addition, with this flexibility, a MA plan may offer diabetic enrollees a lower deductible. Under this example, non-diabetic enrollees would not have access to these diabetic-specific tailored cost-sharing or supplemental benefits; however, any enrollee that develops diabetes would then have access to these benefits.     Such flexibility under our new interpretation of the uniformity requirement is not without limits, however, as section 1852(b)(1)(A) of the Act prohibits an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health- status related factors. MA regulations (for example, Sec. Sec.   422.100(f)(2) and 422.110(a)) reiterate and implement this non- discrimination requirement. In interpreting these obligations to protect against discrimination, we have historically indicated that the purpose of the requirements is to protect high-acuity enrollees from adverse treatment on the basis of their higher cost health conditions (79 FR 29843; 76 FR 21432; and 74 FR 54634). As MA plans consider this new flexibility in meeting the uniformity requirement, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations.\25\ MA plans that exercise this flexibility must ensure that the cost sharing reductions and targeted supplemental benefits are for health care services that are medically related to each disease condition. CMS will be concerned about potential discrimination if an MA plan is targeting cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other higher-cost conditions. We will review benefit designs to make sure that the overall impact is non- discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations. ---------------------------------------------------------------------------

    \25\ Among these responsibilities and obligations are compliance with Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act. ---------------------------------------------------------------------------

    For example, an MA plan could identify enrollees diagnosed with specific diseases, such as diabetes, chronic heart failure, and COPD, as medically vulnerable and in need of certain services, which could be offered to these enrollees in the form of tailored supplemental benefits. In identifying eligible enrollees, the MA plan must use medical criteria that are objective and measurable, and the enrollee must be diagnosed by a plan provider or have their existing diagnosis certified or affirmed by a plan provider to assure equal application of the objective criteria necessary to provide equal treatment of similarly situated individuals.     For contract year 2019, we are considering issuing guidance clarifying the flexibility MA plans have to offer targeted supplemental benefits for their most medically vulnerable enrollees. A benefit package that offers differential access to enhanced services or benefits or reduced cost sharing or different deductibles based on objective criteria, and ensures equal treatment of similarly situated enrollees, for whom such services and benefits are useful, can be priced at a uniform premium consistent with the requirements for availability and accessibility throughout the service area for all enrollees in section 1852(d)(1)(A) of the Act and for uniform bids and premiums in section 1854(c) of the Act. We believe this flexibility will help MA plans better manage health care services for the most vulnerable enrollees. The benefit and cost sharing flexibility we have discussed here applies to Part C benefits but not Part D benefits. We are requesting comments and/or questions from stakeholders about the implementation of this flexibility. We note that CMS is currently testing value based insurance design (VBID) through the use of our demonstration authority under Section 1115A of the Act (42 U.S.C 1315a, added by Section 3021 of the Affordable Care Act), which will include some of the elements we have discussed

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previously. However, there are also features of the VBID demonstration that are unique to the demonstration test. We expect the VBID demonstration to provide CMS with insights into future VBID innovations for the MA program. 3. Segment Benefits Flexibility     In reviewing section 1854(h) of the Social Security Act and Medicare Advantage (MA) regulations governing plan segments, we have determined that the statute and existing regulations may be interpreted to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. Plans segments are county-level portions of a plan's overall service area which, under current CMS policy, are permitted to have different premiums and cost sharing amounts as long as these premiums and cost sharing amounts are uniform throughout the segment. We are proposing to revise our interpretation of the existing statute and regulations to allow MA plan segments to vary by benefits in addition to premium and cost sharing, consistent with the MA regulatory requirements defining segments at Sec.  422.262(c)(2). 4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (Sec. Sec.  422.100 and 422.101)     As provided at Sec.  422.100(f)(4) and (5) and Sec.  422.101(d)(2) and (3), all Medicare Advantage (MA) plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)), must establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS. CMS added Sec. Sec.  422.100(f)(4) and (f)(5), effective for coverage in 2011, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory) (75 FR 19709-11). Section 1858(b)(2) of the Act requires a limit on in-network out-of-pocket expenses for enrollees in Regional MA Plans. In addition, Local Preferred Provider Organization (LPPO) plans, under Sec.   422.100(f)(5), and Regional PPO (RPPO) plans, under section 1858(b)(2) of the Act and Sec.  422.101(d)(3), are required to have a ``catastrophic'' limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the annual limit which is also established by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services, excluding plan premium, must be included in each plan's Maximum Out-of-Pocket (MOOP) amount subject to these limits.     As discussed in the 2010 rulemaking (75 FR 19709), CMS affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. The percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7 percent in CY 2011 to 68.1 percent in CY 2017. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51 percent in CY 2011 to 21 percent in CY 2017.     As stated in the CY 2018 final Call Letter \26\ and in the 2010 final rule (75 FR 19710), CMS currently sets MOOP limits based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare Fee-for-Service (FFS) for local and regional MA plans. The mandatory MOOP amount represents approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, 5 percent of Medicare FFS beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments, and coinsurance. The voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs. The Office of the Actuary conducts an annual analysis to help CMS determine the MOOP limits. Since the MOOP requirements for local and regional MA plans were finalized in regulation, a strict application of the 95th and 85th percentile would have resulted in MOOP limits for local and regional MA plans fluctuating from year-to-year. Therefore, CMS has exercised discretion in order to maintain stable MOOP limits from year-to-year, when the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages year over year, and does not discourage the adoption of the lower voluntary MOOP amount because of fluctuations in the amount. CMS expects to change MOOP limits if a consistent pattern of increasing or decreasing costs emerges over time. ---------------------------------------------------------------------------

    \26\ The CY 2018 final Call Letter may be accessed at [*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html*](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html) ---------------------------------------------------------------------------

    As part of the annual Call Letter process, stakeholders have suggested changes to how CMS establishes MOOP limits. Some of the comments suggested CMS use Medicare FFS and MA encounter data to inform its decision-making. Other suggestions received have included increasing the voluntary MOOP limit, increasing the number of service categories that have higher cost sharing in return for a plan offering a lower MOOP limit, and considering three levels of MOOP and service category cost sharing to encourage plan offerings with lower MOOP limits.     CMS's goal is to establish future MOOP limits based on the most relevant and available data, or combination of data, that reflects beneficiary health care costs in the MA program and maintains benefit stability over time. Medicare FFS data currently represents the most relevant and available data at this time. CMS may consider future rulemaking regarding the use of MA encounter cost data to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. Under this current proposal to revise the regulations controlling MOOP limits, CMS might change its existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending in the future. CMS expects to establish future limits by striking the appropriate balance between limiting MOOP costs and potential changes in premium, benefits, and cost sharing with the goal of making sure beneficiaries can access affordable and sustainable benefit packages. While CMS intends to continue using the 85th and 95th percentiles of projected beneficiary out-of-pocket spending for the immediate future to set MA MOOP limits, CMS proposes to amend the regulation text in Sec. Sec.  422.100(f)(4) and (5) and 422.101(d)(2) and (d)(3) to incorporate authority to balance factors discussed previously. The flexibility provided by these proposed changes will permit CMS to annually adjust mandatory and voluntary MOOP limits based on changes in market conditions and to ensure the sustainability of the MA program and benefit options.     The proposed new authority permitting changes in data and methodology related to establishing MOOP limits would be exercised by CMS in advance of each plan year; CMS would use the annual Call Letter and other guidance documents to explain its application of this proposed regulatory standard and the data used to identify MOOP limits in advance of bid

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deadlines. This will provide MA organizations adequate time to comment and prepare for changes. In addition, CMS plans to transition any significant changes under this proposal over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.     CMS proposes to codify specific requirements because of the number of comments received in the past about MOOP changes. CMS proposes to amend Sec. Sec.  422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3) to clarify that CMS may use Medicare FFS data to establish annual MOOP limits. In addition, CMS would have authority to increase the voluntary MOOP limit to another percentile level of Medicare FFS, increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount, and implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits. This proposal includes authority to increase the number of service categories that have higher cost sharing in return for offering a lower (voluntary) MOOP amount and considering more than two levels of MOOP (with associated cost sharing limits) to encourage plan offerings with lower MOOP limits. Consistent with past practice, CMS will continue to publish annual limits and a description of how the regulation standard was applied (that is, the methodology used) in the annual Call Letter prior to bid submission so that MA plans can submit bids consistent with parameters that CMS has determined to meet the cost sharing limits requirements. CMS seeks comments and suggestions on the topics discussed in this section. 5. Cost Sharing Limits for Medicare Parts A and B Services (Sec. Sec.   417.454 and 422.100)     As provided at Sec. Sec.  417.454(e), 422.100(f)(6), and 422.100(j), MA plan cost sharing for Parts A and B services specified by CMS must not exceed certain levels. Section 422.100(f)(6) provides that cost sharing must not be discriminatory and CMS determines annually the level at which certain cost sharing becomes discriminatory. Sections 417.454(e) and 422.100(j), on the other hand, are based on how section 1852(a)(1)(B)(iii) and (iv) of the Act directs that cost sharing for certain services may not exceed cost sharing levels in Medicare Fee-for-Service (FFS); under the statute and the regulations, CMS may add to that list of services. CMS reviews cost sharing set by MA organizations using parameters based on Parts A and B services that are more likely to have a discriminatory impact on beneficiaries. The review parameters are currently based on Medicare FFS data and reflect a combination of patient utilization scenarios and length of stays or services used by average to sicker patients. CMS uses multiple utilization scenarios for some services (for example, inpatient care) to guard against MA organizations distributing benefit cost sharing amounts in a manner that is discriminatory. Review parameters are also established for frequently used professional services, such as primary and specialty care services.     CMS proposes here to amend Sec.  422.100(f)(6) to clarify that it may use Medicare FFS data to establish appropriate cost sharing limits. In addition, CMS intends to use MA utilization encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory; we solicit comment on whether to codify that use of MA encounter data for this purpose in Sec.  422.100(f)(6). This proposal is not related to a statutory change.     This proposal aims to allow CMS to use the most relevant and appropriate information in determining whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory. CMS intends to continue the practice of furnishing information to MA organizations about the methodology used to establish cost sharing limits and the thresholds CMS identifies as non-discriminatory through the annual Call Letter process or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows MA organizations to prepare plan bids consistent with parameters that CMS have determined to be non-discriminatory.     As specified in section 1852(a)(1)(B)(iv) of the Act, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. Although CMS has not established a specific service category cost sharing limit for all possible services, CMS has issued guidance that MA plans must pay at least 50 percent of the contracted (or Medicare allowable) rate and that cost sharing for services cannot exceed 50 percent of the total MA plan financial liability for the benefit in order for the cost sharing for such services to be considered non-discriminatory; CMS believes that cost sharing (service category deductibles, copayments or co- insurance) that fails to cover at least half the cost of a particular service or item acts to discriminate against those for whom those services and items are medically necessary and discourages enrollment by beneficiaries who need those services and items. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Medicare FFS service category cannot exceed 50 percent of the average contracted rate of that service under this guidance (Medicare Managed Care Manual, Chapter 4, Section 50.1). Some service categories may identify specific benefits for which a unique copayment would apply, while others include a variety of services with different levels of cost which may reasonably have a range of copayments based on groups of similar services, such as durable medical equipment or outpatient diagnostic and radiological services.     CMS affords MA plans that adopt a lower, voluntary MOOP limit greater flexibility in establishing Parts A and B cost sharing than is available to plans that adopt the higher, mandatory MOOP limit. As discussed in section III.A.5, CMS intends to continue to establish more than one set of Parts A and B service cost sharing thresholds for plans choosing to offer benefit designs with either a lower, voluntary MOOP limit or the higher, mandatory MOOP limit set under Sec. Sec.   422.100(f)(4) and (5) and 422.101(d)(2) and (3). Medicare FFS data currently represents the most relevant and available data at this time and is used to evaluate cost sharing for specific services as well in applying the standard currently at Sec.  422.100(f)(6) and in considering CMS's authority to add (by regulation) categories of services for which cost sharing may not exceed levels in Medicare FFS.     As noted with regard to setting MOOP limits under Sec. Sec.   422.100 and 422.101, CMS expects that MA encounter data will be more accurate and complete in the future and may consider future rulemaking regarding the use of MA encounter to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. For reasons discussed in section III.A.5, CMS proposes to amend Sec.  422.100(f)(6) to permit use of Medicare FFS to evaluate whether cost sharing for Part A and B services is discriminatory to set the evaluation limits announced each year in the Call Letter: in addition, we propose to use MA utilization encounter data as part of that evaluation process. As with the proposal to authorize use of this data for setting MOOP limits, CMS intends to use the Advance Notice/Call Letter process to communicate its

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application of the regulation and to transition any significant changes over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.     This proposal will allow CMS to use the most relevant and appropriate information in determining cost sharing standards and thresholds. For example, analyses of MA utilization encounter data can be used with Medicare FFS data to establish the appropriate utilization scenarios to determine MA plan cost sharing standards and thresholds. CMS seeks comments and suggestions on this proposal, particularly whether additional regulation text is needed to achieve CMS's goal of setting and announcing each year presumptively discriminatory levels of cost sharing. 6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (Sec. Sec.  422.254 and 422.256)     As provided at Sec. Sec.  422.254(a)(4) and 422.256(b)(4), CMS will only approve a bid submitted by a Medicare Advantage (MA) organization if its plan benefit package is substantially different from those of other plans offered by the organization in the area with respect to key plan characteristics such as premiums, cost sharing, or benefits offered. MA organizations may submit bids for multiple plans in the same area under the same contract only if those plans are substantially different from one another based on CMS's annual meaningful difference evaluation standards. CMS proposes to eliminate this meaningful difference requirement beginning with MA bid submissions for contract year (CY) 2019. Separate meaningful difference rules were concurrently adopted for MA and stand-alone prescription drug plans (PDPs), but this specific proposal is limited to the meaningful difference provision related to the MA program. This proposal is not related to a statutory change.     This proposal aims to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation. CMS will maintain requirements that prohibit plans from misleading beneficiaries in their communication materials, provide CMS the authority to disapprove a bid if a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare- eligible individuals, and allow CMS to non-renew a plan that fails to attract a sufficient number of enrollees over a sustained period of time (Sec. Sec.  422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects organizations to continue designing plan benefit packages that, within a service area, are different from one another with respect to key benefit design characteristics, so that any potential beneficiary confusion is minimized when comparing multiple plans offered by the organization. For example, beneficiaries may consider the following factors when they make their health care decisions: plan type, Part D coverage, differences in provider network, Part B and plan premiums, and unique populations served (for example, special needs plans, or SNPs). In addition, CMS intends to continue the practice of furnishing information to MA organizations about their bid evaluation methodology through the annual Call Letter process and/or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows CMS to articulate bid requirements and MA organizations to prepare bids that satisfy CMS requirements and standards prior to bid submission in June each year.     Research studies indicate that consumers, especially elderly consumers, may be challenged by a large number of plan choices that may: (1) Result in not making a choice, (2) create a bias to not change plans, and (3) impact MA enrollment growth.\27\ Beneficiaries indicate they want to make informed and effective decisions, but do not feel qualified. As a result, they seek help from Medicare Plan Finder (MPF), brokers or plan representatives, providers, and family members. Although challenged by choices, beneficiaries do not want their plan choices to be limited and understand key decision factors such as premiums, out-of-pocket cost sharing, Part D coverage, familiar providers, and company offering the plan.\28\ CMS continues to explore enhancements to MPF that will improve the customer experience; some examples of recent updates are provided below. ---------------------------------------------------------------------------

    \27\ McWilliams JM, Afendulis CC, McGuire TG, Landon BE. Complex Medicare advantage choices may overwhelm seniors--especially those with impaired decision making. Health Aff (Millwood). 2011;30(9):1786-94.     \28\ Jacobson, G. Swoope, C., Perry, M. Slosar, M. How are seniors choosing and changing health insurance plans? Kaiser Family Foundation. 2014. ---------------------------------------------------------------------------

    As discussed later in this section, CMS believes that it is challenging to apply the current standardized meaningful difference evaluation (which is applied consistently to all plans) in a manner that accommodates and evaluates important considerations objectively. CMS is concerned that the current evaluation may create unintended consequences related to innovative benefit designs. In addition, CMS's efforts in implementing more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices. For example, in MPF, plan details have been expanded to include MA and Part D benefits and a new consumer friendly tool for the CY 2018 Medicare open enrollment period which will assist beneficiaries in choosing a plan that meets their unique and financial needs based on a set of 10 quick questions.     Prior to implementing the meaningful difference evaluation for CY 2011 bid submissions, the beneficiary weighted average number of plans per county was about 30 in 2010 compared to 18 in 2017 (these numbers do not include SNPs or employer group plans which have additional criteria for enrollment). Private-fee-for-service (PFFS) plans represented 13 of the 30 plans in 2010 and less than 1 of the 18 plans in 2017. The Medicare Improvements for Patients and Providers Act of 2008 required PFFS plans to establish contracted provider networks by 2011 and many PFFS plans non-renewed. The weighted average number of plans has remained relatively stable since the decline of PFFS options. MA enrollment continued to grow from more than 11 million in July 2010 to 18.7 million in July 2017, fueled by the continued overall acceptance of managed care, the baby boom generation aging into Medicare beginning in 2011, and decreases in average plan premium during the time period.     As stated in the October 22, 2009, proposed rule (74 FR 54670 through 73) and April 15, 2010, final rule (75 FR 19736 through 40), CMS's goal for the meaningful difference evaluation was to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. The meaningful difference evaluation was initiated when cost sharing and benefits were relatively consistent within each plan and similar plans within the same contract could be readily compared by measuring estimated out-of-pocket costs and other factors currently integrated in the evaluation's methodology.     The current meaningful difference evaluation uses estimated enrollee out-of-pocket costs based on the CMS Out-of-Pocket Cost (OOPC) model. This model uses a nationally representative cohort of beneficiaries from the Medicare Beneficiary Surveys (MCBS)

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and is intended to be objective and applied in a standardized and consistent manner across plans. MCBS data collected by CMS from beneficiaries are used to create the cohort of beneficiaries whose medical and prescription data are used to estimate out-of-pocket costs. The OOPC model generates estimated out-of-pocket costs based on utilization from the cohort of beneficiaries and each plan's benefit design entered into the Plan Benefit Package submitted to CMS as part of the bidding process. Detailed information about the meaningful difference evaluation is available in the CY 2018 Final Call Letter issued April 3, 2017 (pages 115-118) and information about the CMS OOPC model is available at: [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html) Estimated enrollee cost sharing is determined by the cost sharing amounts for Part A, B, and D services and most mandatory supplemental benefits (for example, dental services). Benefit service categories within a plan may have a range of multiple and varying cost sharing amounts. For example, the outpatient procedures, tests, labs, and radiology services benefit category includes many services that may have a wide range of cost sharing amounts. The OOPC model uses the minimum or lowest cost sharing value placed in the Plan Benefit Package (PBP) for each service category to estimate out-of-pocket costs in these situations. As discussed in the CY 2018 Final Call Letter, the differences between similar plans must have at least a $20 per member per month estimated beneficiary out-of-pocket cost difference. Differences in plan type (for example, HMO, LPPO), SNP sub-type, and inclusion of Part D coverage are considered meaningful differences which aligns with beneficiary decision-making. Premiums, risk scores, actual plan utilization and enrollment are not included in the evaluation because these factors would introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity.     Based on CMS's efforts to revisit MA standards and the implementation of the governing law to find flexibility for MA beneficiaries and plans, MA organizations are able to: (1) Tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data which was communicated in CY 2011 guidance; (2) establish Provider Specific Plans (PSPs) designed to offer enrollees benefits through a subset of the overall contracted network in a given service area, which are sometimes referred to as narrower networks, and which was collected in the PBP beginning in CY 2011; and (3) beginning in CY 2019, provide different cost sharing and/or additional supplemental benefits for enrollees based on defined health conditions within the same plan (Flexibility in the Medicare Advantage Uniformity Requirements). These flexibilities allow MA organizations to provide beneficiaries with access to health care benefits that are tailored to individual needs, but make it difficult for CMS to objectively measure meaningful differences between plans. Items 1 and 3 provide greater cost sharing flexibility to address individual beneficiary needs, but result in a much broader range of cost sharing values being entered into PBP. As discussed in the previous paragraph, the CMS OOPC model uses the lowest cost sharing value for each service category to estimate out-of-pocket costs which may or may not be a relevant comparison between different plans for purposes of evaluating meaningful difference when variable cost sharing of this type is involved.     CMS remains committed to ensuring transparency in plan offerings so that beneficiaries can make informed decisions about their health care plan choices. It is also important to encourage competition, innovation, and provide access to affordable health care approaches that address individual needs. The current meaningful difference methodology evaluates the entire plan and does not capture differences in benefits that are tied to specific health conditions. As a result, the meaningful difference evaluation would not fully represent benefit and cost sharing differences experienced by enrollees and could lead to MA organizations to focus on CMS standards, rather than beneficiary needs, when designing benefit packages.     In order to capture differences in provider network, more tailored benefit and cost sharing designs, or other innovations, the evaluation process would have to use more varied and complex assumptions to identify plans that are not meaningfully different from one another. CMS believes that such an evaluation could result in more complicated and potentially confusing benefit designs to achieve differences between plans. This process may require greater administrative resources for MA organizations and CMS, while not producing results that are useful to beneficiaries.     The current meaningful difference methodology may force MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs. To satisfy current CMS meaningful difference standards, MA organizations may have to change benefit coverage or cost sharing in certain plans to establish the necessary benefit value difference, even if substantial difference exists based on factors CMS is currently unable to incorporate into the evaluation (such as tiered cost sharing, and unique benefit packages based on enrollee health conditions). Although these changes in benefits coverage may be positive or negative, CMS is concerned the meaningful difference requirement results in organizations potentially reducing the value of benefit offerings. On the basis of bid review activities performed over the past several years, CMS is concerned that benefits may be decreased or cost sharing increased to satisfy the meaningful difference evaluation. These are unintended consequences of the existing meaningful difference evaluation and may restrict innovative benefit designs that address individual beneficiary needs and affordability.     Beneficiaries may also consider plan and Part B premiums when choosing among health plan options. Making changes to the existing meaningful difference evaluation to consider premiums differences as sufficient to distinguish among otherwise similar plans may limit the value of CMS's evaluation by introducing factors that plans can easily leverage, such as risk selection, costs, and margin, to satisfy the evaluation test without resulting in additional benefit value or choice for enrollees.     Stakeholders have expressed concern that without the meaningful difference evaluation the number of bids and plan choices will likely increase and make beneficiary decisions more difficult. The number of plan bids may increase because of a variety of factors, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but CMS does not believe the number of similar plan options offered by the same MA organization in each county will necessarily increase significantly or create confusion in beneficiary decision-making. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision-making should help

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beneficiaries, caregivers, and family members make informed plan choices among more individualized plan offerings. Based on the previously stated information, CMS does not expect a significant increase in time spent in bid review as a direct result of eliminating meaningful difference nor increased health care provider burden.     In addition, new flexibilities in benefit design may allow MA organizations to address different beneficiary needs within existing plan options and reduce the need for new plan options to navigate existing CMS requirements. In addition, MA organizations may be able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums which would allow beneficiaries to make more effective decisions if the MA organizations are not required to change benefit and cost sharing designs in order to satisfy Sec. Sec.  422.254 and 422.256 Currently, MA organizations must satisfy CMS meaningful difference standards (and other requirements), rather than solely focusing on beneficiary purchasing needs when establishing a range of plan options.     CMS supports beneficiary decision-making by providing tools and materials that focus on key beneficiary purchasing criteria, such as eligibility to enroll in SNPs, need for Part D coverage, Part D formulary and benefit coverage, plan type preference (for example, HMO vs. PPO), network providers, medical benefit coverage, premiums, and the brand or organization offering the plan options. CMS is also taking steps to improve information available through MPF and 1-800-MEDICARE to help beneficiaries, caregivers, and family members make informed plan choices.     CMS continually evaluates consumer engagement tools and outreach materials (including marketing, educational, and member materials) to ensure information is formatted consistently so beneficiaries can easily compare multiple plans. CMS also provides annual guidance and model materials to MA organizations to assist them in providing resources, such as the plan's Annual Notice of Change and Evidence of Coverage, which contain valuable information for the enrollee to evaluate and select the best plan for their needs. To reinforce informed decision making, CMS invests substantial resources in engagement strategies such as 1-800-MEDICARE, MPF, standard and electronic mail, and social media to continuously communicate with beneficiaries, caregivers, family members, providers, community resources, and other stakeholders.     CMS will continue to furnish information to MA organizations and solicit comments on bid evaluation methodology through the annual Call Letter process or HPMS memoranda, as appropriate.     In addition, CMS is maintaining requirements around plans not misleading beneficiaries in communication materials, disapproving a bid if CMS finds that a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and non-renewing plans that fail to attract a sufficient number of enrollees over a sustained period of time (Sec. Sec.   422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects these measures will continue to protect beneficiaries from discriminatory plan benefit packages and health plans that demonstrate a lack of beneficiary interest if the meaningful difference requirement is eliminated. For all these reasons, CMS proposes to remove Sec. Sec.   422.254(a)(4) and 422.256(b)(4) to eliminate the meaningful difference requirement for MA bid submissions. CMS seeks comments and suggestions on the topics discussed in this section about making sure beneficiaries have access to innovative plans that meet their unique needs. 7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (Sec. Sec.  422.66 and 422.68)     Section 1851(c)(3)(A)(ii) of the Act provides the Secretary with the authority to implement default enrollment rules for the Medicare Advantage (MA) program in addition to the statutory direction that beneficiaries who do not elect an MA plan are defaulted to original (fee-for-service) Medicare. This provision states that the Secretary may establish procedures whereby an individual currently enrolled in a non-MA health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA plan offered by the organization if he or she does not elect to receive Medicare coverage in another way.     We initially addressed default enrollment upon conversion to Medicare in rulemaking (70 FR 4606 through 4607) in 2005, indicating that we would retain the flexibility to implement this provision through future instructions and guidance to MA organizations. Such subregulatory guidance was established later that same year and was applicable to the 2006 contract year. As outlined in Chapter 2 of the Medicare Managed Care Manual, we established an optional enrollment mechanism, whereby MA organizations may develop processes and, with CMS approval, provide seamless continuation of coverage by way of enrollment in an MA plan for newly MA eligible individuals who are currently enrolled in other health plans offered by the MA organization (such as commercial or Medicaid plans) at the time of the individuals' initial eligibility for Medicare. The guidance emphasized that MA organizations not limit seamless continuation of coverage to situations in which an enrollee becomes eligible for Medicare by virtue of age, but includes all newly eligible Medicare beneficiaries, including those whose Medicare eligibility is based on disability. We did not mandate that organizations implement a process for seamless continuation of coverage but, instead, gave organizations the option of implementing such a process for its enrollees who are approaching Medicare eligibility. From its inception, the guidance has required that individuals receive advance notice of the proposed MA enrollment and have the ability to ``opt out'' of such an enrollment prior to the effective date of coverage. This guidance has been in practice for the past decade for MA organizations that requested to use this voluntary enrollment mechanism, but we have encountered complaints and heard concerns about the practice. We are proposing new regulation text to establish limits and requirements for these types of default enrollments to address these concerns and our administrative experience with seamless continuation of coverage, commonly referred to as seamless conversion.     Based on our experience with the seamless conversion process thus far, we are proposing, to be codified at Sec.  422.66(c)(2), requirements for seamless default enrollments upon conversion to Medicare. As proposed in more detail later in this section, such default enrollments would be into dual eligible special needs plans (D- SNPs) and be subject to five substantive conditions: (1) The individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (2) the state has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization; (3) the individual does not opt out of the default enrollment; (4) the MA

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organization provides a notice that meets CMS requirements to the individual; and (5) CMS has approved the MA organization to use the default enrollment process before any enrollments are processed. We are also proposing that coverage under these types of default enrollments begin on the first of the month that the individual's Part A and Part B eligibility is effective. We are also proposing changes to Sec. Sec.   422.66(d)(1) and (d)(5) and 422.68 that coordinate with the proposal for Sec.  422.66     In the Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter, we explained how entities that sponsor Medicaid managed care organizations (MCOs) and affiliated D- SNPs can promote coverage of an integrated Medicare and Medicaid benefit through existing authority for seamless continuation of coverage of Medicaid MCO members as they become eligible for Medicare. We received positive comments from state Medicaid agencies that supported this enrollment mechanism and requested that we clarify the process for approval of seamless continuation of coverage as a mechanism to promote enrollment in integrated D-SNPs that deliver both Medicare and Medicaid benefits. We also received comments from beneficiary advocates asking that additional consumer protections, including requiring written beneficiary confirmation and a special enrollment period for those individuals who transition from non- Medicare products to Medicare Advantage. We believe that our proposal, described later in this section, adequately addresses the concerns on which these requests are based, given that the default enrollment process would be permissible only for individuals enrolled in a Medicaid managed care plan in states that support this process. This means that the Medicare plan into which individuals would be defaulted would be one that is offered by the same parent organization as their existing Medicaid plan, such that much of the information needed by the MA plan would already be in the possession of the MA organization to facilitate the default enrollment process. Also, default enrollment would not be permitted if the state does not actively support this process, ensuring an accurate source of data for use by MA organizations to appropriately identify and notify individuals eligible for default enrollment.     On October 21, 2016,\29\ in response to inquiries regarding this enrollment mechanism, its use by MA organizations, and the beneficiary protections currently in place, we announced a temporary suspension of acceptance of new proposals for seamless continuation of coverage. Based on our subsequent discussions with beneficiary advocates and MA organizations approved for this enrollment mechanism, it is clear that organizations attempting to conduct seamless continuation of coverage from commercial coverage (that is, private coverage and Marketplace coverage) find it difficult to comply with our current guidance and approval parameters. This is especially true of the requirement to identify commercial members who are approaching Medicare eligibility based on disability. Also challenging for these organizations is the requirement that they have the means to obtain the individual's Medicare number and are able to confirm the individual's entitlement to Part A and enrollment in Part B no fewer than 60 days before the MA plan enrollment effective date. ---------------------------------------------------------------------------

    \29\ [*https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/HPMS\_Memo\_Seamless\_Moratorium.pdf*](https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/HPMS_Memo_Seamless_Moratorium.pdf) ---------------------------------------------------------------------------

    In addition, the ability for organizations to conduct seamless enrollment of individuals converting to Medicare will be further limited due to the statutory requirement that CMS remove Social Security Numbers (SSNs) from all Medicare cards by April 2019. A new Medicare number will replace the SSN-based Health Insurance Claim Number (HICN) on the new Medicare cards for Medicare transactions. Beginning in April 2018, we'll start mailing the new Medicare cards with the new number to all people with Medicare. Given the random and unique nature of the new Medicare number, we believe MA organizations will be limited in their ability to automatically enroll newly eligible Medicare beneficiaries without having to contact them to obtain their Medicare numbers, as CMS does not share Medicare numbers with organizations for their commercial members who are approaching Medicare eligibility. We note that contacting the individual in order to obtain the information necessary to process the enrollment does not align with the intent of default enrollment, which is designed to process enrollments and have coverage automatically shift into the MA plan without an enrollment action required by the beneficiary.     Organizations operating Medicaid managed care plans are better able to meet these requirements when states provide data, including the individual's Medicare number, on those about to become Medicare eligible. As part of coordination between the Medicare and Medicaid programs, CMS shares with states, via the State MMA file, data of individuals with Medicaid who are newly becoming entitled to Medicare; such data includes the Medicare number of newly eligible Medicare beneficiaries. MA organizations with state contracts to offer D-SNPs would be able to obtain (under their agreements with state Medicare agencies) the data necessary to process the MA enrollment submission to CMS. Therefore, we are proposing to revise Sec.  422.66 to permit default enrollment only for Medicaid managed care enrollees who are newly eligible for Medicare and who are enrolled into a D-SNP administered by an MA organization under the same parent organization as the organization that operates the Medicaid managed care plan in which the individual remains enrolled. These requirements would be codified at Sec.  422.66(c)(2)(i) (as a limit on the type of plan into which enrollment is defaulted) and (c)(2)(i)(A) (requiring existing enrollment in the affiliated Medicaid managed care plan as a condition of default MA enrollment). At paragraph (c)(2)(i)(B), we are also proposing to limit these default enrollments to situations where the state has actively facilitated and approved the MA organization's use of this enrollment process and articulates this in the agreement with the MA organization offering the D-SNP, as well as providing necessary identifying information to the MA organization.     The option of default enrollment can be particularly beneficial for Medicaid managed care enrollees who are newly eligible for Medicare, because in the case that the parent organization of the Medicaid managed care plan also offers a D-SNP, default enrollment promotes enrollment in a plan that offers some level of integration of acute care, behavioral health and, for eligible beneficiaries, long-term care services and supports, including institutional care, and home and community-based services (HCBS). This is in line with CMS' support of state efforts to increase enrollment of dually eligible individuals in fully integrated systems of care and the evidence \30\ that such systems

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improve health outcomes. Further this proposal will provide states with additional flexibility and control. States can decide if they wish to allow their contracted Medicaid managed care plans to use default enrollment of Medicaid enrollees into D-SNPs and can control which D- SNPs receive default enrollments through two means: The contracts that states maintain with D-SNPs (Sec.  422.107(b)) and by providing the data necessary for MA organizations to successfully implement the process. Under our proposal, MA organizations can process default enrollments only for dual-eligible individuals in states where the contract with the state under Sec.  422.107 approves it and the state identifies eligibility and shares necessary data with the organization. ---------------------------------------------------------------------------

    \30\ There is a growing evidence that integrated care and financing models can improve beneficiary experience and quality of care, including:      Health Management Associates, Value Assessment of the Senior Care Options (SCO) Program, July 21, 2015, available at: [*http://www.mahp.com/unify-files/HMAFinalSCOWhitePaper\_2015\_07\_21.pdf;*](http://www.mahp.com/unify-files/HMAFinalSCOWhitePaper_2015_07_21.pdf;)      MedPAC chapter ``Care coordination programs for dual- eligible beneficiaries,'' June 2012, available at:   [*http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0;*](http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0;)      Anderson, Wayne L., Zhanlian Fen, and Sharon K. Long, RTI International and Urban Institute, Minnesota Managed Care Longitudinal Data Analysis, prepared for the U.S Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE), March 2016, available at:   [*https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis*](https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis). ---------------------------------------------------------------------------

    To ensure that Medicaid beneficiaries considered for default enrollment upon their conversion to Medicare are aware of the default MA enrollment and of the changes to their Medicare and Medicaid coverage, we also propose, at Sec.  422.66(c)(2)(i)(C) and (c)(2)(iv), that the MA organization must issue a notice no fewer than 60 days before the default enrollment effective date to the enrollee. The proposed revised notice \31\ must include clear information on the D- SNP, as well as instructions to the individual on how to opt out (or decline) the default enrollment and how to enroll in Original Medicare or a different MA plan. This notice requirement aims to help ensure a smooth transition of eligible individuals into the D-SNP for those who choose not to opt out. All MA organizations currently approved to conduct seamless conversion enrollment issue at least one notice 60 days prior to the MA enrollment effective date, so our proposal would not result in any additional burden to these MA organizations using this process. Recent discussions with MA organizations currently conducting seamless conversion enrollment have revealed that several of them already include in their process additional outreach, including reminder notices and outbound telephone calls to aid in the transition. We believe that these additional outreach efforts are helpful and we would encourage their use under our proposal. ---------------------------------------------------------------------------

    \31\ Enrollment requirements and burden are currently approved by OMB under control number 0938-0753 (CMS-R-267). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number. ---------------------------------------------------------------------------

    We also propose, in paragraph (c)(2)(i)(E) and (2)(ii), that MA organizations must obtain approval from CMS before implementing default enrollment. Under our proposal in paragraph (c)(2)(i)(B), CMS approval would be granted only if the applicable state approves the default enrollment through its agreement with the MA organization. MA organizations would be required to implement default enrollment in a non-discriminatory manner, consistent with their obligations under Sec.  422.110; that is, MA organizations could not select for default enrollment only certain of the members of the affiliated Medicaid plan who were identified as eligible for default enrollment. Lastly, we propose that CMS may suspend or rescind approval at any time if it is determined that the MA organization is not in compliance with the requirements. We request comment whether this authority to rescind approval should be broader; we have considered whether a time limit on the approval (such as 2 to 5 years) would be appropriate so that CMS would have to revisit the processes and procedures used by an MA organization under this proposed regulation in order to assure that the regulation requirements are still being followed. We are particularly interested in comment on this point in conjunction with our alternative (discussed later in this section) proposal to codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non-Medicare coverage.     Under our proposal, default enrollment of individuals at the time of their conversion to Medicare would be more limited than the default enrollments Congress authorized the Secretary to permit in section 1851(c)(3)(A)(ii) of the Act. However, we are also proposing some flexibility for MA organizations that wish to offer seamless continuation of coverage to their non-Medicare members, commercial, Medicaid or otherwise, who are gaining Medicare eligibility. As discussed in more detail below, affirmative elections would be necessary for individuals not enrolled in a Medicaid managed care plan, consistent with Sec.  422.50 However, because individuals enrolled in an organization's commercial plan, for example would already be known to the parent organization offering both the non-Medicare plan and the MA plan and the statute acknowledges that this existing relationship is somewhat relevant to Part C coverage, we propose to amend Sec.   422.66(d)(5) and to establish, through subregulatory guidance, a new and simplified positive (that is, ``opt in'') election process that would be available to all MA organizations for the MA enrollments of their commercial, Medicaid or other non-Medicare plan members. To reflect our change in policy with regard to a default enrollment process and this proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same entity as the individual's non-Medicare coverage, we are also proposing to add text in Sec.  422.66(d)(5) authorizing a simplified election for purposes of converting existing non-Medicare coverage, commercial, Medicaid or otherwise, to MA coverage offered by the same organization. This new mechanism would allow for a less burdensome process for MA organizations to offer enrollment in their MA plans to their non- Medicare health plan members who are newly eligible for Medicare. As the MA organization has a significant amount of the information from the member's non-Medicare enrollment, this new simplified election process aims to make enrollment easier for the newly-eligible beneficiary to complete and for the MA organization to process. It would align with the individual's Part A and Part B initial enrollment period (and initial coordinated election period for MA coverage), provided he or she enrolled in both Medicare Parts A and B when first eligible for Medicare. This new election process would provide a longer period of time for MA organizations to accept enrollment requests than the time period in which MA organizations would be required to effectuate default enrollments, as organizations would be able to accept enrollments throughout the individual's Initial Coverage Election Period (ICEP), which for an aged beneficiary is the 7-month period that begins 3 months before the month in which the individual turns 65 and ends 3 months after the month in which the individual turns 65. We would use existing authority to create this new enrollment

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mechanism which, if implemented, would be available to MA organizations in the 2019 contract year. We solicit comments on the proposed changes to the regulation text as well as the form and manner in which such enrollments may occur.     This optional simplified election process for the enrollment of non-Medicare plan members into MA upon their initial eligibility (or initial entitlement) for Medicare would provide individuals the option to remain with the organization that offers their non-Medicare coverage. A positive election in this circumstance provides an additional beneficiary protection for non-dually eligible individuals, so that they may actively choose a Medicare plan structure similar to that of their commercial, Medicaid or other non-Medicare health plans, as there may be significant differences between an organization's commercial plans, for example, and its MA plans in terms of provider networks, drug formularies, costs and benefit structures. While these differences may result in a more restrictive network, a mandated change in a primary care physician and increased out-of-pocket costs for converting enrollees, default enrollment of a dually eligible individual enrolled in a Medicaid plan into a D-SNP, triggers no premium liability or cost sharing for medical care or prescription drugs above levels that apply under Original Medicare. Further, the individual remains in the Medicaid managed care plan and is gaining additional Medicare coverage, which is not always the case in other contexts. We solicit comment on these coordinated proposals to implement section 1851(c)(3)(A)(ii) in general as discussed below and in two particular ways: (1) To permit default MA enrollments for dually-eligible beneficiaries who are newly eligible for Medicare under certain conditions and (2) to permit simplified elections for seamless continuations of coverage for other newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers the MA plan. We further invite comments regarding whether the CMS approval of an organization's request to conduct default enrollment should be limited to a specific time frame. In addition, we are proposing amendments to Sec. Sec.  422.66(d)(1) and 422.68 that are also related to MA enrollment. Currently, as described in the 2005 final rule (70 FR 4606 through 4607), Sec.  422.66(d)(1) requires MA organizations to accept, during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, enrollment requests from an individual who is enrolled in a non-Medicare health plan offered by the MA organization and who meets MA eligibility requirements. To better reflect section 1851(c)(3)(A)(ii), we are proposing to amend Sec.  422.66(d)(1) to add text clarifying that seamless continuations of coverage are available to an individual who requests enrollment during his or her Initial Coverage Election Period. In light of our proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same parent organization as the individual's non-Medicare coverage, we are also proposing a revision to Sec.  422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made. This proposed revision would codify the subregulatory guidance that MA organizations have been following since 2006. This proposal is also consistent with the proposal at Sec.  422.66(c)(2)(iii) regarding the effective date of coverage for default enrollments into D-SNPs. We also solicit comment on these related proposals.     In conclusion, we are proposing to add regulation text at Sec.   422.66(c)(2)(i) through (iv) to set limits and requirements for a default enrollment of the type authorized under section 1851(c)(3)(A)(ii). We are proposing a clarifying amendment to Sec.   422.66(d)(1) regarding when seamless continuation coverage can be elected and revisions to Sec.  422.66(d)(5) to reflect our proposal for a new and simplified positive election process that would be available to all MA organizations. Lastly, we are proposing revisions to Sec.   422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made.     We invite comments in general on our proposal, as well as on the alternatives presented. We recognize that our proposal narrows the scope of default enrollments compared to what CMS approved under section 1851(c)(3)(A) of the Act in the past. As we contemplated the future of the seamless conversion mechanism, we considered retaining processes similar to how the seamless conversion mechanism is outlined currently in section 40.1.4 of Chapter 2 of the Medicare Managed Care Manual and had been in practice through October 2016. We considered proposing regulations to codify that guidance as follows--      Articulating the requirements for an MA organization's proposal to use the seamless conversion mechanism, including identifying eligible individuals in advance of Medicare eligibility;      Establishing timeframes for processing and the effective date of the enrollment; and      Requiring notification to individuals at least 60 days prior to the conversion of their right to opt-out or decline the enrollment.     In considering this alternative, we contemplated adding additional beneficiary protections, including the issuance of an additional notice to ensure that individuals understood the implication of taking no action. While this alternative would have led to increased use of the seamless conversion enrollment mechanism than what had been used in the past, the operational challenges, particularly in relation to the new Medicare Beneficiary Identification number may be significant for MA organizations to overcome at this time.     We also considered proposing regulations to limit the use of default enrollment to only the aged population. While this alternative would simplify a MA organization's ability to identify eligible individuals, we have concerns about disparate treatment among newly eligible individuals based on their reason for obtaining Medicare entitlement.     We invite comments on our proposal and the alternate approaches, including the following:      Codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non- Medicare coverage.      Codify the existing parameters for this type of seamless conversion default enrollment, as described previously, but allow that use of default enrollment be limited to only the aged population.     If commenters recommend one or more alternate approaches, we ask for suggested solutions that address the concerns noted in this discussion, particularly related to the requirement that plans identify commercial members who are approaching Medicare eligibility based on disability, as well as how plans could confirm MA eligibility and process enrollments without access to the individual's Medicare number.

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8. Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (Sec.  422.60(g))     Beneficiaries who are dually eligible for both Medicare and Medicaid typically face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in unnecessary, duplicative, or missed services. One method for overcoming this challenge is through integrated care, which provides dually eligible beneficiaries with the full array of Medicaid and Medicare benefits for which they are eligible through a single delivery system, thereby improving quality of care, beneficiary satisfaction, care coordination, and reducing administrative burden.     Integrated care options are increasingly available for dually eligible beneficiaries, which include a variety of integrated D-SNPs. D-SNPs can provide greater integrated care than enrollees would otherwise receive in other MA plans or Medicare Fee-For-Service (FFS), particularly when an individual is enrolled in both a D-SNP and Medicaid managed care organization offered by the same organization. D- SNPs that meet higher standards of integration, quality, and performance benchmarks--known as highly integrated D-SNPs--are able to offer additional supplemental benefits to support integrated care pursuant to Sec.  422.102(e). D-SNPs that are fully integrated--known as Fully Integrated Dual-Eligible (FIDE) SNPs, as defined at Sec.   422.2 provide for a much greater level of integration and coordination than non-integrated D-SNPs, providing all primary, acute, and long-term care services and supports under a single entity.     While enrollment in integrated care options continues to grow, there are instances in which beneficiaries may face disruptions in coverage in integrated care plans. These disruptions can result from numerous factors, including market forces that impact the availability of integrated D-SNPs and state re-procurements of Medicaid managed care organizations. Such disruptions can result in beneficiaries being enrolled in two separate organizations for their Medicaid and Medicare benefits, thereby losing the benefits of integration achieved when the same entity offers both benefit packages. In an effort to protect the continuity of integrated care for dually eligible beneficiaries, we are proposing a limited expansion of our regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries in instances where integrated care coverage would otherwise be disrupted.     Section 1851(c)(1) of the Act authorizes us to develop mechanisms for beneficiaries to elect MA enrollment, and we have used this authority to create passive enrollment. The current regulation at Sec.   422.60(g) limits the use of passive enrollment to two scenarios: (1) In instances where there is an immediate termination of an MA contract; or (2) in situations in which we determine that remaining enrolled in a plan poses potential harm to beneficiaries. The passive enrollment defined in Sec.  422.60(g) requires beneficiaries to be provided prior notification and a period of time prior to the effective date to opt out of enrollment from a plan. Current Sec.  422.60(g)(3) provides every passively enrolled beneficiary with a special election period to allow for election of different Medicare coverage: Selecting a different managed care plan or opting out of MA completely and, instead, receiving services through Original Medicare (a FFS delivery system). A beneficiary who is offered a passive enrollment is deemed to have elected enrollment in the designated plan if he or she does not elect to receive Medicare coverage in another way.     Our proposal is a limited expansion of this regulatory authority to promote continued enrollment of dually eligible beneficiaries in integrated care plans to preserve and promote care integration under certain circumstances. The proposal includes use of these existing opt- out procedures and special election period. Therefore, we are proposing to redesignate these requirements from (g)(1) through (3) to (g)(3) through (g)(5) respectively, with minor revisions in proposed paragraph (g)(5) to describe the application of special election period and in proposed paragraph (g)(4) to make minor grammatical changes to the text to improve its readability and clarity.     Our proposal is to add authority to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP under certain circumstances. We anticipate that these proposed regulations would permit passive enrollments only when all the following conditions are met:      When necessary to promote integrated care and continuity of care;      Where such action is taken in consultation with the state Medicaid agency;      Where the D-SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and      Where certain other conditions are met to promote continuity and quality of care.     We expect that these factors would all occur in situations when affected beneficiaries would otherwise be experiencing an involuntary disruption in either their Medicare or Medicaid coverage. We anticipate using this new proposed authority exclusively in such situations.     All individuals would be provided with a special election period (which, as established in subregulatory guidance, lasts for 2 months), as described in Sec.  422.62(b)(4), provided they are not otherwise eligible for another SEP (for example, under proposed Sec.   423.38(c)(4)(ii)).     For illustrative purposes we have outlined two scenarios in which this proposed regulatory authority could be used to promote continued access to integrated care and maintain continuity of care for dually eligible individuals:      State Re-Procurement of Medicaid Managed Care Contracts: In several states, dually eligible beneficiaries receive Medicaid services through managed care plans that the state selects through a competitive procurement process. Some states also require that the sponsors of Medicaid health plans also offer a D-SNP in the same service area to promote opportunities for integrated care. Dually eligible beneficiaries can face disruptions in coverage due to routine state re-procurements of Medicaid managed care contracts. Individuals enrolled in Medicaid managed care plans that are not renewed are typically transitioned to a separate Medicaid managed care plan. In such a scenario, dually eligible beneficiaries enrolled in the non- renewing Medicaid managed care plan's corresponding D-SNP product would now be enrolled in two separate organizations for their Medicaid and Medicare services, resulting in non-integrated coverage. Under this proposed regulation, CMS would have the ability, in consultation with the state Medicaid agency that contracts with integrated D-SNPs, to passively enroll dually eligible beneficiaries facing such a disruption into an integrated D-SNP that corresponds with their new Medicaid managed care plan, thereby promoting continuous enrollment in integrated care.

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     Non-Renewal of D-SNP Contracts: Beneficiaries enrolled in an integrated D-SNP that non-renews its MA contract at the end of the contract year can face disruptions in integrated care coverage, requiring them to actively select a new MA plan or default into Original Medicare and a standalone prescription drug plan. While states are permitted to passively enroll beneficiaries for Medicaid coverage as defined in Sec.  438.54(c), CMS is not permitted to do so for Medicare coverage when an MA plan non-renews at the end of the contract year, as current authority for passive enrollment is limited to midyear terminations. Rather, beneficiaries in the D-SNP that is non-renewing its contract would need to actively select and enroll in an MA plan that integrates their Medicare and Medicaid coverage in order to continue the same level of integrated care. Permitting CMS the ability to passively enroll D-SNP enrollees into other integrated D-SNP plans in consultation with the state Medicaid agency would support beneficiaries remaining in integrated care.     With a limited expansion of our passive enrollment regulatory authority, we can better promote integrated care and continuity of care for dually eligible beneficiaries. Therefore, we are proposing to redesignate the introductory text in Sec.  422.60(g) as paragraph (g)(1), with a new heading, technical revisions to the existing text that specifies when passive enrollments may be implemented by CMS designated as (g)(1)(i) and (ii), and a new paragraph (iii). This new (g)(1)(iii) would authorize CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D-SNP into another integrated D-SNP, after consulting with the state Medicaid agency that contracts with the D-SNP or other integrated managed care plan, to promote continuity of care and integrated care.     We also propose to add a new paragraph (g)(2) to include a number of requirements that an MA plan would have to meet in order to qualify to receive passive enrollments under paragraph (g)(1)(iii). We also propose to include in paragraph (g)(1)(iii) a reference to new paragraph (g)(2) to make it clear that a contract with the state is also necessary for a D-SNP to be eligible to receive these passive enrollments. Specifically, we propose that in order to receive passive enrollments under the new authority, MA plans must be highly integrated, thereby restricting passive enrollment to those MA plans that operate as a FIDE SNP or meet the integration standard for a highly-integrated D-SNP, as defined in Sec.  422.2 and described in Sec.  422.102(e) respectively. In an effort to ensure continuity of care, acquiring MA plans would also be required to have substantially similar provider and facility networks and Medicare- and Medicaid- covered benefits as the integrated MA plan (or plans) from which beneficiaries are passively enrolled. MA plans receiving passive enrollment would also be required to not have any prohibition on new enrollment imposed by CMS and have appropriate limits on premium and cost-sharing for beneficiaries. If our proposed paragraphs (g)(1) and (g)(2) are finalized, we would describe in subregulatory guidance the procedure through which CMS would determine qualification for passive enrollment. We also propose that to receive these passive enrollments, that D-SNP must meet minimum quality standards based on MA Star Ratings; we direct the reader to the proposal at section III.A.12 of this rule regarding the MA Star Rating System. Our proposed regulation text refers to a requirement to have a minimum overall MA Star Rating of at least 3 stars, which represents average or above-average performance. The rating for the year prior to receipt of passive enrollment would be used in order to provide sufficient time for CMS, states, and MAOs to prepare for the passive enrollment process. Low- enrollment contracts or new plans without MA Star Ratings as defined in Sec.  422.252 would also be eligible for passive enrollment under our proposal, as long as the plan meets all other proposed requirements.     Our goal with this proposed requirement is to ensure that the D-SNP plans receiving these passive enrollments provide high-quality care, coverage and administration of benefits. As passive enrollments, in some sense, are a benefit to a plan, by providing an enrollee and associated payments without the plan having successfully marketed to the enrollee, we believe that it is important that these enrollments are limited to plans that have demonstrated commitment to quality. Further, it is important to ensure that when we are making an enrollment decision for a beneficiary who does not make an alternative coverage choice that we are guided by the beneficiary's best interests, which are likely served by a plan that is rated as having average or above-average performance on the MA Stars Rating System. However, we recognize that MA Star Ratings do not capture performance for those services that would be covered under Medicaid, including community behavioral health treatment and long-term services and supports. We welcome comments on the process for determining qualification for passive enrollment under this proposal and particularly on the minimum quality standards. We request that commenters identify specific measures and minimum ratings that would best serve our goals in this proposal and are specific or especially relevant to coverage for dually eligible beneficiaries.     In addition to the proposed minimum quality standards and other requirements for a D-SNP to receive passive enrollments, we are considering limiting our exercise of this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs. We seek comment on this potential further limitation on exercise of the proposed passive enrollment regulatory authority to better promote integrated care and continuity of care. In particular, we seek stakeholder feedback how to calculate the projected impact on Medicare and Medicaid costs from exercise of this authority.     The intent of the proposed passive enrollment regulatory authority is to better promote integrated care and continuity of care--including with respect to Medicaid coverage--for dually eligible beneficiaries. As such, we would implement this authority in consultation with the state Medicaid agencies that are contracting with these plan sponsors for provision of Medicaid benefits.     We considered proposing new beneficiary notification requirements for passive enrollments that occur under proposed paragraph (g)(1)(iii). We considered requiring MA organizations receiving the passive enrollment to provide two notifications to all potential enrollees prior to their enrollment effective date. We acknowledge that under the Financial Alignment Initiative demonstrations, states are required to provide two passive enrollment notices. Under the passive enrollment authority proposed here, we would continue to encourage, but not require, a second notice or additional outreach to impacted individuals. Given the existing beneficiary notifications that are currently required under Medicare regulations and concerns regarding the quantity of notifications sent to beneficiaries, we are not proposing to modify the existing notification requirements, so these existing standards would apply for existing passive enrollments and for the newly proposed passive enrollment authority.

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However, we solicit comment on alternatives regarding beneficiary notices, including comments about the content and timing of such notices. Our proposal redesignates the notice requirements to paragraph (g)(4) with minor grammatical revisions.     Finally, we propose a technical correction to a citation in Sec.   422.60(g), which discusses situations involving an immediate termination of an MA plan as provided in Sec.  422.510(a)(5). This citation is outdated, as the regulatory language at Sec.  422.510(a)(5) has been moved to Sec.  422.510(b)(2)(i)(B). We propose to replace the current citation with a reference to Sec.  422.510(b)(2)(i)(B). 9. Part D Tiering Exceptions (Sec. Sec.  423.560, 423.578(a) and (c)) a. Background     Section 1860D-4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering prescription drug benefits for Part D drugs through the use of a tiered formulary may request an exception to the plan sponsor's tiered cost-sharing structure. The statute requires such plan sponsors to have a process in place for making determinations on such requests, consistent with guidelines established by the Secretary. At the start of the Part D program, we finalized regulations at Sec.  423.578(a) that require plan sponsors to establish and maintain reasonable and complete exceptions procedures. These procedures permit enrollees, under certain circumstances, to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing applicable to alternative drugs on a lower cost-sharing tier of the plan sponsor's formulary. Such an exception is granted when the plan sponsor determines that the non-preferred drug is medically necessary based on the prescriber's supporting statement. The tiering exceptions regulations establish the general scope of issues that must be addressed under the plan sponsor's tiering exceptions process. Our goal with the exceptions rules codified in the Part D final rule (70 FR 4352) was to allow plan sponsors sufficient flexibility in benefit design to obtain pricing discounts necessary to offer optimal value to beneficiaries, while ensuring that beneficiaries with a medical need for a non-preferred drug are afforded the type of drug access and favorable cost-sharing called for under the law.     At the start of the program, most Part D formularies included no more than four cost-sharing tiers, generally with only one generic tier. For the 2006 and 2007 plan years respectively, about 83 percent and 89 percent of plan benefit packages (PBPs) that offered drug benefits through use of a tiered formulary had 4 or fewer tiers. Since that time, there have been substantial changes in the prescription drug landscape, including increasing costs of some generic drugs, as well as the considerable impact of high-cost drugs on the Part D program. Plan sponsors have responded by modifying their formularies and PBPs, resulting in the increased use of two generic-labeled drug tiers and mixed drug tiers that include brand and generic products on the same tiers. The flexibilities CMS permits in benefit design enable plan sponsors to continue to offer comprehensive prescription drug coverage with reasonable controls on out of pocket costs for enrollees, but increasingly complex PBPs with more variation in type and level of cost-sharing. For the 2017 plan year, about 91 percent of all Part D PBPs offer drug benefits through use of a tiered formulary. Over 98 percent of those tiered PBPs use a formulary containing 5 or 6 tiers; of those, about 98 percent contain two generic-labeled tiers.     These changes and increased complexities, and more than a decade of program experience, lead us to believe that our current regulations are no longer sufficient to ensure that tiering exceptions are understood by beneficiaries and adjudicated by plan sponsors in the manner the statute contemplates. For this reason, we propose to amend Sec. Sec.   423.560, 423.578(a) and 423.578(c) to revise and clarify requirements for how tiering exceptions are to be adjudicated and effectuated.     While section 1860D-4(g)(2) of the Act uses the terms ``preferred'' and ``non-preferred'' drug, rather than ``brand'' and ``generic'', it also gives the Secretary authority to establish guidelines for making a determination with respect to a tiering exception request. The statute further specifies that ``a non-preferred drug could be covered under the terms applicable for preferred drugs'' (emphasis added) if the prescribing physician determines that the preferred drug would not be as effective or would have adverse effects for the individual. The statute therefore contemplates that tiering exceptions must allow for an enrollee with a medical need to obtain favorable cost-sharing for a non-preferred product, but that such access be subject to reasonable limitations. Establishing regulations that allow plans to impose certain limitations on tiering exceptions helps ensure that all enrollees have access to needed drugs at the most favorable cost- sharing terms possible. b. General Rules     We are proposing to revise Sec.  423.578(a)(2) to read as follows: ``Part D plan sponsors must establish criteria that provide for a tiering exception consistent with paragraphs Sec.  423.578(a)(3) through (a)(6) of this section.'' We believe that inserting a cross- reference to paragraph (a)(6), which establishes allowable limitations on tiering exceptions, and which we are also proposing to revise, would streamline and clarify the requirements for such exceptions. The proposed revisions would establish rules that more definitively base eligibility for tiering exceptions on the lowest applicable cost sharing for the tier containing the preferred alternative drug(s) for treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug, and not based on tier labels. c. Limitations on Tiering Exceptions     We are also proposing to revise the regulations at Sec.   423.578(a)(6) to specify when a Part D plan sponsor may limit tiering exceptions. We believe the current text, which permits a plan sponsor to exempt any dedicated generic tier from its tiering exceptions procedures, is being applied in a manner that restricts tiering exceptions more stringently than is appropriate. Specifically, Part D sponsors have been considering any tier that is labeled ``generic'' to be exempt from tiering exceptions even if the tier also contains brand name drugs. This has become even more problematic with the increase in the number of PBPs with more than one tier labeled ``generic''. Based on an analysis of 2017 plan data entered into the Health Plan Management System (HPMS), for all Part D plans using a tiered formulary, 62 percent have indicated at least two tiers that contain only generic drugs, and 7 percent have three such tiers. Combined with the allowable exemption of a specialty tier (used by 99.8 percent of tiered Part D plans in 2017), almost two-thirds of all tiered PBPs could exempt 3 of their 5 or 6 tiers from tiering exceptions without any consideration of medical need or placement of preferred alternative drugs. To ensure appropriate enrollee access to tiering exceptions, we are proposing to revise Sec.  423.578(a)(6) to specify that a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives. Under this proposal, however, plans would be required to approve tiering exceptions for non-preferred generic drugs when

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the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives. In other words, plans would not be permitted to exclude a tier containing alternative drug(s) with more favorable cost-sharing from their tiering exceptions procedures altogether just because that lower-cost tier is dedicated to generic drugs. As described in the following paragraph, we are also proposing at Sec.  423.578(a)(6) to establish specific tiering exceptions policy for biological products.     Proposed Sec.  423.578(a)(6)(iii) would specify that, ``If a Part D plan sponsor maintains a specialty tier, as defined in Sec.  423.560, the sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception.'' We also propose to add the following definition to Subpart M at Sec.  423.560:     Specialty tier means a formulary cost-sharing tier dedicated to very high cost Part D drugs and biological products that exceed a cost threshold established by the Secretary. We note that, while the proposed definition of specialty tier does not refer to ``unique'' drugs as existing Sec.  423.578(a)(7) does, we do not intend to change the criteria for the specialty tier, which has always been based on the drug cost. This proposal would retain the current regulatory provision that permits Part D plan sponsors to disallow tiering exceptions for any drug that is on the plan's specialty tier. This policy is currently codified at Sec.  423.578(a)(7), which would be revised and redesignated as Sec.  423.578(a)(6)(iii). We believe that retaining the existing policy limiting the availability of tiering exceptions for drugs on the specialty tier is important because of the beneficiary protection that limits cost-sharing for the specialty tier to 25 percent coinsurance (up to 33 percent for plans that have a reduced or $0 Part D deductible), ensuring that these very high cost drugs remain accessible to enrollees at cost sharing equivalent to the defined standard benefit.     We also clarify that, if the specialty tier has cost sharing more preferable than another tier, then a drug placed on such other non- preferred tier is eligible for a tiering exception down to the cost sharing applicable to the specialty tier if an applicable alternative drug is on the specialty tier and the other requirements of Sec.   423.578(a) are met. In other words, while plans are not required to allow tiering exceptions for drugs on the specialty tier to a more preferable cost-sharing tier, the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exceptions.     We believe a shift in regulatory policy that establishes a distinction between non-preferred branded drugs, biological products, and non-preferred generic and authorized generic drugs, achieves needed balance between limitations in plans' exceptions criteria and beneficiary access, and aligns with how many plan sponsors already design their tiering exceptions criteria. Accordingly, we are proposing to revise Sec.  423.578(a)(6) to clarify and establish additional limitations plans would be permitted to place on tiering exception requests. First, we are proposing new paragraphs (i) and (ii), which would permit plans to limit the availability of tiering exceptions for the following drug types to a preferred tier that contains the same type of alternative drug(s) for treating the enrollee's condition:      Brand name drugs for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(b)(2)); and      Biological products, including follow-on biologics, licensed under section 351 the Public Health Service Act.     With the proposed revisions, that approved tiering exceptions for brand name drugs would generally be assigned to the lowest applicable cost-sharing associated with brand name alternatives, and approved tiering exceptions for biological products would generally be assigned to the lowest applicable cost-sharing associated with biological alternatives. Similarly, tiering exceptions for non-preferred generic drugs would be assigned to the lowest applicable cost-sharing associated with alternatives that are either brand or generic drugs (see further discussion later in this section related to assignment of cost-sharing for approved tiering exceptions to the lowest applicable tier). Given the widespread use of multiple generic tiers on Part D formularies, and the inclusion of generic drugs on mixed, higher-cost tiers, we believe these changes are needed to ensure that tiering exceptions for non-preferred generic drugs are available to enrollees with a demonstrated medical need. Procedures that allow for tiering exceptions for higher-cost generics when medically necessary promote the use of generic drugs among Part D enrollees and assist them in managing out of pocket costs.     We are also proposing at Sec.  423.578(a)(6)(i) to codify that plans are not required to offer tiering exceptions for brand name drugs or biological products at the cost-sharing level of alternative drug(s) for treating the enrollee's condition, where the alternatives include only the following drug types:      Generic drugs for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)), or      Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(t)(3)).     As discussed in the Call Letter, CMS collects Part D plan formulary data based on the National Library of Medicare RxNorm concept unique identifier (RxCUI), and not at the manufacturer-specific National Drug Code (NDC) level. This process does not allow us to clearly identify whether a plan sponsor includes coverage of authorized generic NDCs or not. We believe this position is consistent with how plans currently administer their formularies. Under this regulatory proposal, a plan sponsor could not completely exclude a lower tier containing only generic and authorized generic drugs from its tiering exception procedures, but would be permitted to limit the cost sharing for a particular brand drug or biological product to the lowest tier containing the same drug type. Plans would be required to grant a tiering exception for a higher cost generic or authorized generic drug to the cost sharing associated with the lowest tier containing generic and/or authorized generic alternatives when the medical necessity criteria is met. d. Alternative Drugs for Treatment of the Enrollee's Condition     In response to the 2018 Call Letter and RFI, we received comments from plan sponsors and PBMs requesting that CMS provide additional guidance on how to determine what constitutes an alternative drug for purposes of tiering exceptions, including establishment of additional limitations on when such exceptions are approvable. The statutory language for tiering and formulary exceptions at sections 1860D-4(g)(2) and 1860D-4(h)(2) of the Act, respectively, specifically refers to a preferred or formulary drug ``for treatment of the same condition.'' We interpret this language to be referring to the condition as it affects the enrollee--that is, taking into consideration the individual's overall clinical condition,

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including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen, which can factor into which drugs are appropriate alternative therapies for that enrollee. The Part D statute at Sec.  1860D-4(g)(2) requires that coverage decisions subject to the exceptions process be based on the medical necessity of the requested drug for the individual for whom the exception is sought. We believe that requirement reasonably includes consideration of alternative therapies for treatment of the enrollee's condition, based on the facts and circumstances of the case. e. Approval of Tiering Exception Requests     We are proposing to revise Sec.  423.578(c)(3) by renumbering the provision and adding a new paragraph (ii) to codify our current policy that cost sharing for an approved tiering exception request is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers. Under this proposal, assignment of cost sharing for an approved tiering exception must be at the most favorable cost- sharing tier containing alternative drugs, unless such alternative drugs are not applicable pursuant to limitations set forth under proposed Sec.  423.578(a)(6). We are also proposing to ***delete*** similar language from existing (c)(3) that proposed new paragraph (c)(3)(ii) would replace. f. Additional Technical Changes and Corrections     Finally, we are proposing various technical changes and corrections to improve the clarity of the tiering exceptions regulations and consistency with the regulations for formulary exceptions. Specifically, we are proposing the following:      Revise the introductory text of Sec.  423.578(a) to clarify that a ``requested'' non-preferred drug for treatment of an enrollee's health condition may be eligible for an exception.      Revise Sec.  423.578(a)(1) to include ``tiering'' when referring to the exceptions procedures described in this subparagraph.      Revise Sec.  423.578(a)(4) by making ``conditions'' singular and by adding ``(s)'' to ``drug'' to account for situations when there are multiple alternative drugs.      Revise Sec.  423.578(a)(5) by removing the text specifying that the prescriber's supporting statement ``demonstrate the medical necessity of the drug'' to align with the existing language for formulary exceptions at Sec.  423.578(b)(6). The requirement that the supporting statement address the enrollee's medical need for the requested drug is already explained in the introductory text of Sec.   423.578(a).      Redesignate paragraphs Sec.  423.578(c)(3)(i) through (iii) as paragraphs Sec.  423.578(c)(3)(i)(A) through (C), respectively. This proposed change would improve consistency between the regulation text for tiering and formulary exceptions.     We anticipate that the proposed changes to the tiering exceptions regulations will make this process more accessible and transparent for enrollees and less cumbersome for plan sponsors to administer. We also believe that, by helping plan sponsors ensure their tiering exceptions processes comply with CMS requirements, IRE overturn rates for tiering exception requests will remain low. 10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (Sec.  423.38)     As discussed in section III.A.2 of this proposed rule, the MMA added section 1860D-1(b)(3)(D) to the Act to establish a special election period (SEP) for full-benefit dual eligible (FBDE) beneficiaries under Part D. This SEP, codified at Sec.  423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by regulation (75 FR 19720). The SEP allows eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA-PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the annual enrollment period (AEP) each fall.     The MMA sought to strike a balance of promoting beneficiary plan choice, but also ensuring that FBDE beneficiaries who did not make an active election would still have Part D coverage. The statute directed the Secretary to enroll FBDE beneficiaries into a PDP if they did not enroll in a Part D plan on their own. (As noted previously, CMS extended the SEP through rulemaking to make it available to all other subsidy-eligible beneficiaries.) When the automatic enrollment of subsidy-eligible beneficiaries was originally proposed in rulemaking, we noted that beneficiaries would have the option to use the SEP if they determined there was a better plan option for them, and codified a continuous SEP (that is, that was available monthly).     At the time, we did not know on what factors FBDE beneficiaries would rely to make their plan choice. Now, with over 10 years of programmatic experience, we have observed certain enrollment trends in terms of FBDE and other LIS beneficiaries:      Most LIS beneficiaries do not make an active choice to join a PDP. For plan year 2015, over 71 percent of LIS individuals in PDPs were placed into that plan by CMS.      Once in a plan, whether it was a CMS-initiated enrollment or a choice they made on their own, most LIS beneficiaries do not make changes during the year. Of all LIS beneficiaries who were eligible for the SEP in 2016, less than 10 percent utilized it. Overall, we have seen slight growth of SEP usage over the past 5 years (for example, less than 8 percent in 2012, approximately 9 percent in 2014).      A small subset (0.8 percent) of LIS beneficiaries use the SEP to actively enroll in a plan of their choice and then disenroll within 2 months.     While we know that the majority of LIS-eligible beneficiaries do not take advantage of the SEP, we have seen the Medicare and Medicaid environment evolve in such a way that it may be disadvantageous to beneficiaries if they changed plans during the year, let alone if they made multiple changes. States and plans have noted that they are best able to provide or coordinate care if there is continuity of enrollment, particularly if the beneficiary is enrolled in an integrated product (as discussed later in this section). We now know that in addition to choice, there are other critical issues that must be considered in determining when and how often beneficiaries should be able to change their Medicare coverage during the year, such as coordination of Medicare-Medicaid benefits, beneficiary care management, and public health concerns such as the national opioid epidemic (and the drug management programs discussed in section II.A.1). In addition, there are different care models available now such as dual eligible special needs plans (D-SNPs), Fully Integrated Dual Eligible (FIDE) SNPs, and Medicare-Medicaid Plans (MMPs) that are discussed later in this section and specifically designed to meet the needs of high risk, high needs beneficiaries.     Current enrollment trends demonstrate that while a majority of subsidy-eligible beneficiaries still receive their Part D coverage through standalone PDPs, an increasing percentage of beneficiaries are enrolled in MA-PDs and other capitated managed care products, including over one in three dually eligible beneficiaries. A smaller but rapidly growing subset are enrolled in capitated

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Medicare managed care products that also integrate Medicaid services. For example:      The MMA established D-SNPs to provide coordinated care to dually eligible beneficiaries. Between 2007 and 2016, growth in D-SNPs has increased by almost 150 percent.      FIDE SNPs are a type of SNP created by the Affordable Care Act (ACA) in 2010 designed to promote full integration and coordination of Medicare and Medicare benefits for dually eligible beneficiaries by a single managed care organization. In 2017, there are 39 FIDE SNPs providing coverage to approximately 155,000 beneficiaries.      MMPs, which operate as part of a model test under Section 1115(A) of the Act, are fully-capitated health plans that serve dually eligible beneficiaries though demonstrations under the Financial Alignment Initiative. The demonstrations are designed to promote full access to seamless, high quality integrated health care across both Medicare and Medicaid. In 2017, there are 58 MMPs providing coverage to nearly 400,000 beneficiaries.     The current SEP, especially in the context of these products that integrate Medicare and Medicaid, highlights differences in Medicare and Medicaid managed care enrollment policies. Bringing Medicare and Medicaid enrollment policies into greater alignment, even partially, is a mechanism to reduce complexity in the health care system and better partner with states. Both are important priorities for CMS.     In addition, the application of the continuous SEP carries different service delivery implications for enrollees of MA-PD plans and related products than for standalone enrollees of PDPs. At the outset of the Part D program, when drug coverage for dually eligible beneficiaries was transitioned from Medicaid to Medicare, there were concerns about how CMS would effectively identify, educate, and enroll dually eligible beneficiaries. While processes (for example, auto- enrollment, reassignment) were established to facilitate coverage, the continuous SEP served as a fail-safe to ensure that the beneficiary was always in a position to make a choice that best served their healthcare needs. Unintended consequences have resulted from this flexibility, including, as noted by the Medicare Payment Advisory Commission (MedPAC \32\), opportunities for marketing abuses. ---------------------------------------------------------------------------

    \32\ Medicare Payment Advisory Commission, ``Report to Congress: Medicare Payment Policy,'' March 2008. ---------------------------------------------------------------------------

    Among the key obstacles the SEP (and resulting plan movement) can present are--      Interfering with the coordination of care among the providers, health plans, and states;      Hindering the ability for beneficiaries to benefit from case management and disease management;      Wasting the effort and resources needed to conduct enrollee needs assessments and developing plans of care for services covered by Medicare and Medicaid;      Limiting a plan's opportunity for continuous treatment of chronic conditions; and      Diminishing incentives for plans to innovate and invest in serving potentially high-cost members.     While we still support in the underlying principle that LIS beneficiaries should have the ability to make an active choice, we find that plan sponsors are better able to administer benefits to beneficiaries, including coordination of Medicare and Medicaid benefits, and maximize care management and positive health outcomes, if dual and other LIS-eligible beneficiaries are held to the similar election period requirements as all other Part D-eligible beneficiaries. Therefore, we are proposing to amend Sec.  423.38(c)(4) to make the SEP for FBDE and other subsidy-eligible individuals available only in certain circumstances. These circumstances would be considered separate and unique from one another, so there could be situations where a beneficiary could still use the SEP multiple times if he or she meets more than one of the conditions proposed as follows. Specifically, we are proposing to revise to Sec.  423.38(c) to specify that the SEP is available only as follows:      In new paragraph (c)(4)(i), eligible beneficiaries (that is, those who are dual or other LIS-eligible and meet the definition of at-risk beneficiary or potential at-risk beneficiary under proposed Sec.  423.100) would be able to use the SEP once per calendar year.      In new paragraph (c)(4)(iii), eligible beneficiaries who have been assigned to a plan by CMS or a State would be able to use the SEP before that election becomes effective (that is, opt out and enroll in a different plan) or within 2 months of their enrollment in that plan.      In new paragraph (c)(9), dual and other LIS-eligible beneficiaries who have a change in their Medicaid or LIS-eligible status would have an SEP to make an election within 2 months of the change, or of being notified of such change, whichever is later. This SEP would be available to beneficiaries who experience a change in Medicaid or LIS status regardless of whether they have been identified as potential at-risk beneficiaries or at-risk beneficiaries under proposed Sec.  423.100 In addition, we are also proposing to remove the phrase ``at any time'' in the introductory language of Sec.   423.38(c) for the sake of clarity.     The onetime annual SEP opportunity would be able to be used at any time of the year to enroll in a new plan or disenroll from the current plan, provided that their eligibility for the SEP has not been limited consistent with section 1860D-1(b)(3)(D) of the Act, as amended by CARA (as discussed in section III.A.2 of this proposed rule). We believe that the onetime annual SEP would still provide dually eligible beneficiaries adequate opportunity to change their coverage during the year if desired, but is also responsive to consistent feedback we have received from States and plans that have noted that the current SEP, which allows month-to-month movement, can disrupt continuity of care, especially in integrated care plans. They specifically noted that effective care management can best be achieved through continuous enrollment.     Beneficiaries who have been enrolled in a plan by CMS or a state (that is, through processes such as auto enrollment, facilitated enrollment, passive enrollment, default enrollment (seamless conversion), or reassignment), would be allowed a separate, additional use of the SEP, provided that their eligibility for the SEP has not been limited consistent with section 1860D-1(b)(3)(D) of the Act, as amended by CARA. These beneficiaries would still have a period of time before the election takes effect to opt out and choose their own plan or they would be able to use the SEP to make an election within 2 months of the assignment effective date. Once a beneficiary has made an election (either prior to or after the effective date) it would be considered ``used'' and no longer would be available. If a beneficiary wants to change plans after 2 months, he or she would have to use the onetime annual election opportunity discussed previously, provided that it has not been used yet. If that election has been used, the beneficiary would have to wait until they are eligible for another election period to make a change.

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    Under a new proposed SEP, individuals who have a change in their Medicaid or LIS-eligible status would have an election opportunity that is separate from, and in addition to, the two scenarios discussed previously. (As discussed in section III.A.2 of this rule, and unlike the other two conditions discussed previously, individuals identified as ``at risk'' would be able to use this SEP.) This would apply to individuals who gain, lose, or change Medicaid or LIS eligibility. We believe that in these instances, it would be appropriate to give these beneficiaries an opportunity to re-evaluate their Part D coverage in light of their changing circumstances. Beneficiaries eligible for this SEP would need to use it within 2 months of the change or of being notified of the change, whichever is later.     We considered multiple alternatives related to the SEP proposal. We describe two such alternatives in the following discussion:     Limit of two or three uses of the SEP per year. In 2016, 1.2 million beneficiaries used the SEP for FBDE or other subsidy-eligible individuals, including over 27,000 who used the SEP three or more times, and over 1,700 who used the SEP five or more times during the year. These SEP changes are in addition to changes made during the AEP and any other election periods for which a beneficiary may qualify. We believe that any overuse of the SEP creates significant inefficiencies and impedes meaningful continuity of care and care coordination. As such, we considered applying a simple numerical limit to the number of times the LIS SEP could be used by any beneficiary within each calendar year. We specifically considered limits of either two or three uses of the SEP per year.     Compared to our proposal to limit the use of the SEP to one time per calendar year, this alternative would permit more opportunities for midyear changes. However, it could still allow for a high level of membership churning. Relative to our proposal, it would also be less effective in limiting the opportunities for aggressive marketing to LIS beneficiaries outside of the AEP. We welcome comments on this alternative.     Limits on midyear MA-PD plan switching. We also considered a more complex option, drawing heavily on earlier MedPAC recommendations.\33\ Under this alternative we would: ---------------------------------------------------------------------------

    \33\ Medicare Payment Advisory Commission, ``Report to Congress: Medicare Payment Policy,'' March 2008. ---------------------------------------------------------------------------

     Modify the SEP to prohibit its use to elect a non- integrated MA-PD plan. As such, the SEP would not be used for switching between MA-PD plans, movement from integrated products to a non- integrated MA-PD plan, or movement from Medicare FFS to an MA-PD plan. Beneficiaries would still be able to select non-integrated MA-PD plans during other enrollment periods, such as the AEP, the open enrollment period (OEP) outlined in section III.C.2 of this proposed rule, and any other SEP for which they may be eligible; and      Allow continuous use of the dual SEP to allow eligible beneficiaries to enroll into FIDE SNPs or comparably integrated products for dually eligible beneficiaries through model tests under section 1115(A) of the Act.     This alternative would still permit continuous election of Medicare FFS with a standalone PDP throughout the year and a continuous option to change between standalone PDPs.     We believe this alternative would create greater stability among plans and limit the opportunities for misleading and aggressive marketing to dually-eligible individuals. It would also maintain the opportunity for continuous enrollment into integrated products to reflect our ongoing partnership with states to promote integrated care. However, this alternative would be more complex to administer and explain to beneficiaries, and it encourages enrollment into a limited set of MA plans compared to all the plans available to the beneficiary under the MA program. We welcome comments on this alternative.     We believe that our proposed approach to narrowing of the scope of the SEP preserves a dual or other LIS-eligible beneficiary's ability to make an active choice. As noted previously, less than 10 percent of the LIS population used the dual SEP in 2016. We acknowledge that even though this is a small percentage of the population, given the number of beneficiaries who receive Extra Help, this equates to over a million elections. We note, though, that of this group, the majority (74.5 percent) used the SEP one time. Under our proposal, this population would still be able to make an election, thus, we believe that the majority of beneficiaries would not be negatively impacted by these changes. We opted for our proposed approach, as opposed to the alternatives, because we believe it encourages continuity of enrollment and care, without overcomplicating both beneficiary understanding of how the SEP is available to them, as well as plan sponsor operational responsibilities.     If the proposal is finalized, we would revise our messaging and beneficiary education materials as necessary to ensure that dual and other LIS-eligible beneficiaries understand that the SEP is no longer an unlimited opportunity. We would also need to ensure that beneficiaries who are assigned to a plan by CMS or the State understand that they must use the SEP within 2 months after the new coverage begins if they wish to change from the plan to which they were assigned.     We note that other election periods, including the AEP, the new OEP, or other SEPs (for example, when moving to a new service area), would still be available to individuals. In addition, the proposed limitations would also apply to the Part C SEP established in sub- regulatory guidance for dual-eligible individuals or individuals who lose their dual-eligibility.     We welcome public comment on this proposal and the considered alternatives. Specifically, we seek input on the following areas:      Are there other limited circumstances where the dual SEP should be available?      Are there special considerations CMS should keep in mind if we finalize this policy?      Are there other alternative approaches we should consider in lieu of narrowing the scope of the SEP?      In addition to CMS outreach materials, what are the best ways to educate the affected population and other stakeholders of the new proposed SEP parameters? 11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System a. Introduction     We are committed to transforming the health care delivery system-- and the Medicare program--by putting a strong focus on person-centered care, in accordance with the CMS Quality Strategy, so each provider can direct their time and resources to each beneficiary and improve their outcomes. As part of this commitment, one of our most important ***strategic*** goals is to improve the quality of care for Medicare beneficiaries. The Part C and D Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by health and drug plans, physicians, hospitals, and other Medicare providers. We currently publicly report the quality and performance of health and drug plans on the Medicare Plan Finder tool on [*www.medicare.gov*](http://www.medicare.gov) in the form of summary and overall ratings for the contracts under which each MA plan (including MA-PD plans) and Part D plan is offered, with drill downs to

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ratings for domains, ratings for individual measures, and underlying performance data. We also post additional measures on the display page \34\ at [*www.cms.gov*](http://www.cms.gov) for informational purposes. The goals of the Star Ratings are to display quality information on Medicare Plan Finder for public accountability and to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance. In addition, CMS has started to incorporate efforts to recognize the challenges of serving high risk, high needs populations while continuing the focus on improving health care for these important groups. ---------------------------------------------------------------------------

    \34\ [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings) (under the downloads). ---------------------------------------------------------------------------

    In this rule as part of the Administration's efforts to improve transparency, we propose to codify the existing Star Ratings System for the MA and Part D programs with some changes. As noted later in this section in more detail, the proposed changes include more clearly delineating the rules for adding, updating, and removing measures and modifying how we calculate Star Ratings for contracts that consolidate. Although the rulemaking process will create a longer lead time for changes, codifying the Star Ratings methodology will provide plans with more stability to plan multi-year initiatives, because they will know the measures several years in advance. We have received comments for the past several years from MA organizations and other stakeholders asking that CMS use Federal Register rulemaking for the Star Ratings System; we discuss in section III.12.c (regarding plans for the transition period before the codified rules are used) how section 1832(b) authorizes CMS to establish and annually modify the Star Ratings System using the Advance Notice and Rate Announcement process because the system is an integral part of the policies governing Part C payment. We think this is an appropriate time to codify the methodology, because the rating system has been used for several years now and is relatively mature so there is less need for extensive changes every year; the smaller degree of flexibility in having codified regulations rather than using the process for adopting payment methodology changes may be appropriate. Further, by adopting and codifying the rules that govern the Star Ratings System, we are demonstrating a commitment to transparency and predictability for the rules in the system so as to foster investment. b. Background     We originally acted upon our authority to disseminate information to beneficiaries as the basis for developing and publicly posting the 5-star ratings system (sections 1851(d) and 1852(e) of the Act). The MA statute explicitly requires that information about plan quality and performance indicators be provided to beneficiaries in an easy to understand language to help them make informed plan choices. These data are to include disenrollment rates, enrollee satisfaction, health outcomes, and plan compliance with requirements.     The Part D statute (at section 1860D-1(c)) imposes a parallel information dissemination requirement with respect to Part D plans, and refers specifically to comparative information on consumer satisfaction survey results as well as quality and plan performance indicators. Part D plans are also required by regulation (Sec.  423.156) to make Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data available to CMS and are required to submit pricing and prescription drug event data under statutes and regulations specific to those data. Regulations require plans to report on quality improvement and quality assurance and to provide data which CMS can use to help beneficiaries compare plans (Sec. Sec.  422.152 and 423.153). In addition we may require plans to report statistics and other information in specific categories (Sec. Sec.  422.516 and 423.514).     Currently, for similar reasons of providing information to beneficiaries to assist them in plan enrollment decisions, we also review and rate section 1876 cost plans on many of the same measures and publish the results. We also propose to continue to include 1876 cost contracts in the MA and Part D Star Rating system to provide comparative information to Medicare beneficiaries making plan choices. We propose specific text, to be codified at Sec.  417.472(k), noting that 1876 cost contracts must agree to be rated under the quality rating system specified at subpart D of part 422. Cost contracts are also required by regulation (Sec.  17.472(j)) to make CAHPS survey data available to CMS. As is the case today, no quality bonus payments (QBP) would be associated with the ratings for 1876 cost contracts.     In line with Sec. Sec.  422.152 and 423.153, CMS uses the Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), CAHPS data, Part C and D Reporting requirements and administrative data, and data from CMS contractors and oversight activities to measure quality and performance of contracts. We have been displaying plan quality information based on that and other data since 1998.     Since 2007, we have published annual performance ratings for stand- alone Medicare PDPs. In 2008, we introduced and displayed the Star Ratings for Medicare Advantage Organizations (MAOs) for both Part C only contracts (MA-only contracts) and Part C and D contracts (MA-PDs). Each year since 2008, we have released the MA Star Ratings. An overall rating combining health and drug plan measures was added in 2011, and differential weighting of measures (for example, outcomes being weighted 3 times the value of process measures) began in 2012. The measurement of year to year improvement began in 2013, and an adjustment (Categorical Adjustment Index) was introduced in 2017 to address the within-contract disparity in performance revealed in our research among beneficiaries that are dual eligible, receive a low income subsidy, and/or are disabled.     The MA and Part D Star Ratings measure the quality of care and experiences of beneficiaries enrolled in MA and Part D contracts, with 5 stars as the highest rating and 1 star as the lowest rating. The Star Ratings provide ratings at various levels of a hierarchical structure based on contract type, and all ratings are determined using the measure-level Star Ratings. Contingent on the contract type, ratings may be provided and include overall, summary (Part C and D), and domain Star Ratings. Information about the measures, the hierarchical structure of the ratings, and the methodology to generate the Star Ratings is detailed in the annually updated Medicare Part C and D Star Ratings Technical Notes, referred to as Technical Notes, available at [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings).     The MA and Part D Star Ratings System is designed to provide information to the beneficiary that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care. The information included in the ratings is selected based on its relevance and importance such that it can meet the data needs of beneficiaries using it to inform plan choice. While encouraging improved health outcomes of beneficiaries in an efficient, person centered, equitable, and high quality manner is one of the

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primary goals of the ratings, they also provide feedback on specific aspects of care that directly impact outcomes, such as process measures and the beneficiary's perspective. The ratings focus on aspects of care that are within the control of the health plan and can spur quality improvement. The data used in the ratings must be complete, accurate, reliable, and valid. A delicate balance exists between measuring numerous aspects of quality and the need for a small data set that minimizes reporting burden for the industry. Also, the beneficiary or his or her representative must have enough information to make an informed decision without feeling overwhelmed by the volume of data.     The Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Healthcare and Education Reconciliation Act (Pub. L. 111-152), provides for quality ratings, based on a 5-star rating system and the information collected under section 1852(e) of the Act, to be used in calculating payment to MA organizations beginning in 2012. Specifically, sections 1853(o) and 1854(b)(1)(C) of the Act provide, respectively, for an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and benchmark available to the MA organization to use as a rebate. Under the Act, Part D plan sponsors are not eligible for quality based payments or rebates. We finalized a rule on April 15, 2011 to implement these provisions and to use the existing Star Ratings System that had been in place since 2007 and 2008. (76 FR 21485-21490).\35\ In addition, the Star Ratings measures are tied in many ways to responsibilities and obligations of MA organizations and Part D sponsors under their contracts with CMS. We believe that continued poor performance on the measures and overall and summary ratings indicates systemic and wide-spread problems in an MA plan or Part D plan. In April 2012, we finalized a regulation to use consistently low summary Star Ratings--meaning 3 years of summary Star Ratings below 3 stars--as the basis for a contract termination for Part C and Part D plans. (Sec. Sec.  422.510(a)(14) and 423.509(a)(13)). Those regulations further reflect the role the Star Ratings have had in CMS' oversight, evaluation, and monitoring of MA and Part D plans to ensure compliance with the respective program requirements and the provision of quality care and health coverage to Medicare beneficiaries. ---------------------------------------------------------------------------

    \35\ The ratings were first used as part of the Quality Bonus Payment Demonstration for 2012 through 2014 and then used for payment purposes as specified in sections 1853(o) and 1854(b)(1)(C) and the regulation at 42 CFR 422.258(d)(7). ---------------------------------------------------------------------------

    The true potential of the use of the MA and Part D Star Ratings System to reach our goals and to serve as a catalyst for change can only be realized by working in tandem with our many stakeholders including beneficiaries, industry, and advocates. The following guiding principles have been used historically in making enhancements to the MA and Part D Star Ratings:      Ratings align with the current CMS Quality Strategy.      Measures developed by consensus-based organizations are used as much as possible.      Ratings are a true reflection of plan quality and enrollee experience; the methodology minimizes risk of misclassification.      Ratings are stable over time.      Ratings treat contracts fairly and equally.      Measures are selected to reflect the prevalence of conditions and the importance of health outcomes in the Medicare population.      Data are complete, accurate, and reliable.      Improvement on measures is under the control of the health or drug plan.      Utility of ratings is considered for a wide range of purposes and goals.     ++ Accountability to the public.     ++ Enrollment choice for beneficiaries.     ++ Driving quality improvement for plans and providers.      Ratings minimize unintended consequences.      Process of developing methodology is transparent and allows for multi-stakeholder input.     We are using these goals to guide our proposal and how we interpret and apply the proposed regulations once finalized. For each provision we are proposing, we solicit comment on whether our specific proposed regulation text best serves these guiding principles. We also solicit comment on whether additional or other principles are better suited for these roles in measuring and communicating quality in the MA and Part D programs in a comparative manner.     As we continue to consider making changes to the MA and Part D programs in order to increase plan participation and improve benefit offerings to enrollees, we would also like to solicit feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. We welcome all comments on those topics, and will consider them for changes through this or future rulemaking or in connection with interpreting our regulations (once finalized) on the Star Rating system measures. However, we are particularly interested in receiving stakeholder feedback on the following topics:      Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.      Whether CMS' current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality.      How CMS should measure overall improvement across the Star Ratings measures. We are requesting input on additional improvement adjustments that could be implemented, and the effect that these adjustments could have on new entrants (that is, new MA organizations and/or new plans offered by existing MA organizations).      Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.      In order to further encourage plan participation and new market entrants, whether CMS should consider implementing a demonstration to test alternative approaches for putting new entrants (that is, new MA organizations) on a level playing field with renewing plans from a Star Ratings perspective for a pre-determined period of time.      Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.      Including survey measures of physicians' experiences. (Currently, we measure beneficiaries' experiences with their health and drug plans through the CAHPS survey.) Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services, and we would welcome comments.

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c. Basis, Purpose and Applicability of the Quality Star Ratings System     We propose to codify regulation text, at Sec. Sec.  422.160 and 423.180, that identifies the statutory authority, purpose, and applicability of the Star Ratings System regulations we are proposing to add to part 422 subpart D and part 423 subpart D. Under our proposal, the existing purposes of the quality rating system--to provide comparative information to Medicare beneficiaries pursuant to sections 1851(d) and 1860D-1(c) of the Act, to identify and apply the payment consequences for MA plans under sections 1853(o) and 1854(b)(1)(C) of the Act, and to evaluate and oversee overall and specific performance by plans--would continue. To reflect how the Part D ratings are used for MA-PD plan QBP status and rebate retention allowances, we also propose specific text, to be codified at Sec.   423.180(b)(2), noting that the Part D Star Rating will be used for those purposes.     We are proposing here, broadly stated, to codify the current quality Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019. We are proposing some changes, such as how we handle consolidations from the current Star Ratings program, but overall the proposal is to continue the Star Ratings System as it has been developed and has stabilized. Data will be collected and performance will be measured using these proposed rules and regulations for the 2019 measurement period; the associated quality Star Ratings will be used to assign QBP ratings for the 2022 payment year and released prior to the annual coordinated election period held in late 2020 for the 2021 contract year. Application of the final regulations resulting from this proposal will determine whether the measures proposed in section III.A.12.i of the proposed rule (Table 2) are updated, transitioned to or from the display page, and otherwise used in conjunction with the 2019 performance period.     Under our proposal, the current quality Star Ratings System and the procedures for revising it will remain in place for the 2019 and 2020 quality Star Ratings. Section 1853(b) of the Act authorizes an advance notice and rate announcement to announce and seek comment for proposed changes to the MA payment methodology, which includes the Part C and D Star Ratings program. The statute identifies specific notice and comment timeframes, but that process does not require publication in the Federal Register. We have used the draft and final Call Letter, which are attachments to the Advance Notice and final Rate Announcement respectively,\36\ to propose for comment and finalize changes to the quality Star Ratings System since the ratings became a component of the payment methodology for MA and MA-PD plans. (76 FR 214878 through 89). Because the Star Ratings System has been integrated into the payment methodology since the 2012 contract year (as a mechanism used to determine how much a plan is paid, and not the mechanism by which (or a rule about when) a plan is paid), the Star Ratings are part of the process for setting benchmarks and capitation rates under section 1853, and the process for announcing changes to the Star Ratings System falls within the scope of section 1853(b). Although not expressly required by section 1853(b), CMS has historically solicited comment on significant changes to the ratings system using a Request for Comment process before the Advance Notice and draft Call Letter are released; this Request for Comment \37\ provides MAOs, Part D sponsors, and other stakeholders an opportunity to request changes to and raise concerns about the Star Ratings methodology and measures before CMS finalizes its proposal for the Advance Notice. We intend to continue the current process at least until the 2019 measurement period that we are proposing as the first measurement period under these new regulations, but we may discontinue that process at a later date as the rulemaking process may provide sufficient opportunity for public input. In addition, CMS issues annually the Technical Notes \38\ that describe in detail how the methodology is applied from the changes in policy adopted through the Advance Notice and Rate Announcement process. We intend to continue the practice of publishing the Technical Notes during the preview periods. Under our proposal, we would also continue to use the draft and final Call Letters as a means to provide subregulatory application), interpretation, and guidance of the final version of these proposed regulations where necessary. Our proposed regulation text does not detail these plans for continued use of the current process and future for subregulatory guidance because we believe such regulation text would be unnecessary. We propose to codify the first performance period (2019) and first payment year (2022) to which our proposed regulations would apply at Sec.  422.160(c) and Sec.  423.180(c). ---------------------------------------------------------------------------

    \36\ Advance Notices and Rate Announcements are posted each year on the CMS Web site at: [*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html*](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html)     \37\ Requests for Comment are posted at   [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings) under the downloads.     \38\   [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings) (under the downloads) for the Technical Notes. ---------------------------------------------------------------------------

d. Definitions     There are a number of technical and other terms relevant to our proposed regulations. Therefore, we propose the following definitions for the respective subparts in part 422 and part 423 in paragraph (a) of Sec. Sec.  422.162 and 423.182 respectively. Some proposed definitions are discussed in more detail later in this preamble in connection with other proposed regulation text related to the definition.      CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.      Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.      Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy or have disability status in that contract (or plan as applicable).      Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure- specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify

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the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.      Consolidation means when an MA organization/Part D sponsor that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.      Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.      Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.      Domain rating means the rating that groups measures together by dimensions of care.      Dual Eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.      HEDIS is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.      Highest rating means the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.      Highly-rated contract means a contract that has 4 or more stars for their highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).      HOS means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.      Low Income Subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see Sec.  423.34 for definition of a low-income subsidy eligible individual).      Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.      Measure score means the numeric value of the measure or an assigned `missing data' message.      Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1-5 star scale.      Overall Rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.      Part C Summary Rating means a global rating that summarizes the health plan quality and performance on Part C measures.      Part D Summary Rating means a global rating of the prescription drug plan quality and performance on Part D measures.      Plan Benefit Package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by PDP sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.      Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (``signal'') rather than random variation (``noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).      Reward factor means a rating-specific factor added to the contract's summary or overall (or both) rating if a contract has both high and stable relative performance.      Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same. Although not part of the proposed regulatory definition, we clarify that CMS uses statistical tests (for example, t-test) to determine if a contract's measure value is statistically different (greater than or less than depending on the test) from the national mean for that measure, or whether conversely, the observed differences from the national mean could have arisen by chance.      Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.      Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by ***deleting*** the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place ***deleted***. e. Contract Ratings     Star Ratings and data reporting are at the contract level for most measures. Currently, data for measures are collected at the contract level including data from all PBPs under the contract, except for the following Special Needs Plan (SNP)-specific measures which are collected at the PBP level: Care for Older Adults--Medication Review, Care for Older Adults--Functional Status Assessment, and Care for Older Adults--Pain Assessment. The SNP-specific measures are rolled up to the contract level by using an enrollment-weighted mean of the SNP PBP scores. Subject to the discussion later in this section about the feasibility and burden of collecting data at the PBP (plan) level and the reliability of ratings at the plan level, we propose to continue the practice of calculating the Star Ratings at the contract level and all PBPs under the contract would have the same overall and/or summary ratings.     However, beneficiaries select a plan, rather than a contract, so we have considered whether data should be collected and measures scored at the plan level. We have explored the feasibility of separately reporting quality data for individual D-SNP PBPs, instead of the current reporting level. For example, in order for CAHPS measures to be reliably scored, the number of respondents must be at least 11 people and reliability must be at least 0.60 Our current analyses show that, at the PBP level, CAHPS measures could be reliably reported for only about one-third of D-SNP PBPs due to sample size

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issues, and HEDIS measures could be reliably reported for only about one-quarter of D-SNP PBPs. If reporting were done at the plan level, a significant number of D-SNP plans would not be rated and in lieu of a Star Rating, Medicare Plan Finder would display that the plan is ``too small to be rated.'' However, when enough data are available, plan level quality reporting would better reflect the quality of care provided to enrollees in that plan. Plan-level quality reporting would also give states that contract with D-SNPs plan-specific information on their performance and provide the public with data specific to the quality of care for dual eligible (DE) beneficiaries enrolled in these plans. For all plans as well as D-SNPs, reporting at the plan level would significantly increase plan burden for data reporting and would have to be balanced against the availability of additional clinical information available at the plan level. Plan-level ratings would also potentially increase the ratings of higher-performing plans when they are in contracts that have a mix of high and low performing plans. Similarly, plan-level ratings would also potentially decrease the ratings of lower-performing plans that are currently in contracts with a mix of high and low performing plans. Measurement reliability issues due to small sample sizes would also decrease our ability to measure true performance at the plan level and add complexities to the rating system. We are soliciting comments on balancing the improved precision associated with plan level reporting (relative to contract level reporting) with the negative consequences associated with an increase in the number of plans without adequate sample sizes for at least some measures; we ask for comments about this for D-SNPs and for all plans as we continue to consider whether rating at the plan level is feasible or appropriate. In particular, we are interested in feedback on the best balance and whether changing the level at which ratings are calculated and reported better serves beneficiaries and our goals for the Star Ratings System.     We are also exploring whether some measure data could be reported at a higher level (parent organization versus contract) to ease and simplify reporting and still remain useful (for example, call center measures as we anticipate that parent organizations use a consolidated call center to serve all contracts and plans) to incorporate into the Star Ratings. Further, we are exploring if contract market area reporting is feasible when a contract covers a large geographic area. For example, when HEDIS reporting began in 1997, there were contract- specific market areas that evolved into reporting by market area for five states with large Medicare populations.\39\ We are planning to continue work in this area to determine the best reporting level for each measure that most accurately reflects performance and minimizes to the extent possible plan reporting burden. As we consider alternative reporting units, we welcome comments and suggestions about requiring reporting at different levels (for example, parent organization, contract, plan, or geographic area) by measure. ---------------------------------------------------------------------------

    \39\ The following states were divided into multiple market areas: CA, FL, NY, OH, and TX. ---------------------------------------------------------------------------

    We propose to continue at this time calculating the same overall and/or summary Star Ratings for all PBPs offered under an MA-only, MA- PD, or PDP contract. We propose to codify this policy in regulation text at Sec. Sec.  422.162(b) and 423.182(b). We also propose a cost plan regulation at Sec.  417.472(k) to require cost contracts to be subject to the part 422 and part 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System as they are measured and rated like an MA plan. Specifically, we propose, at paragraph (b)(1) that CMS will calculate overall and summary ratings at the contract level and propose regulation text that cross-references other proposed regulations regarding the calculation of measure scoring and rating, and domain, summary and overall ratings. Further, we propose to codify, at (b)(2) of each section, that data from all PBPs offered under a contract will continue to be used to calculate the ratings for the contract. For SNP specific measures collected at the PBP level, we propose that the contract level score would be an enrollment-weighted mean of the PBP scores using enrollment in each PBP as reported as part of the measure specification, which is consistent with current practice. The proposed text is explicit that domain and measure ratings, other than the SNP-specific measures, are based on data from all PBPs under the contract. f. Contract Consolidations     We are proposing a change in how contract-level Star Ratings are assigned in the case of contract consolidations. We have historically permitted MAOs and Part D sponsors to consolidate contracts when a contract novation occurs or to better align business practices. As noted in MedPAC's March 2016 Report to Congress ([*https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*](https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs)), there has been a continued increase in the number of enrollees being moved from lower Star Rating contracts that do not receive a QBP to higher Star Rating contracts that do receive a QBP as part of contract consolidations, which increases the size of the QBPs that are made to MAOs due to the large enrollment increase in the higher rated, surviving contract. We are worried that this practice results in masking low quality plans under higher rated surviving contracts. This does not provide beneficiaries with accurate and reliable information for enrollment decisions, and it does not truly reward higher quality contracts. We propose here to modify from the current policy the calculation of Star Ratings for surviving contracts that have consolidated. Instead of assigning the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, we propose to assign and display on Medicare Plan Finder Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Under this proposal, the calculation of the measure, domain, summary, and overall ratings would be based on these enrollment-weighted mean scores. The number of contracts this would impact is small relative to all contracts that qualify for QBPs. During the period from 1/1/2015 through 1/1/2017 annual consolidations for MA contracts ranged from a low of 7 in 2015 to a high of 19 in 2016 out of approximately 500 MA contracts. As proposed in Sec. Sec.  422.162(b)(3)(i)-(iii) and 423.182(b)(3)(i)-(iii), CMS will use enrollment-weighted means of the measure scores of the consumed and surviving contracts to calculate ratings for the first and second plan years following the contract consolidations. We believe that use of enrollment-weighted means will provide a more accurate snapshot of the performance of the underlying plans in the new consolidated contract, such that both information to beneficiaries and QBPs are not somehow inaccurate or misleading. We also propose, however, that the process of weighting the enrollment of each contract and applying this general rule would vary depending on the specific types of measures involved in order to take into account the measurement period and

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data collection processes of certain measures. Our proposal would also treat ratings for determining quality bonus payment (QBP) status for MA contracts differently than displayed Star Ratings for the first year following the consolidation for consolidations that involve the same parent organization and plans of the same plan type.     We propose to codify our new policy at Sec. Sec.  422.162(b)(3) and 423.182(b)(3). First, we propose generally, at paragraph (b)(3)(i) of each regulation, that CMS will assign Star Ratings for consolidated contracts using the provisions of paragraph (b)(3). We are proposing in Sec.  422.162(b)(3) both a specific rule to address the QBP rating following the first year after the consolidation and a rule for subsequent years. As Part D plan sponsors are not eligible for QBPs, the Part D regulation text is proposed without the QBP aspect. We propose in Sec.  422.162(b)(3)(iv) and Sec.  423.182(b)(3)(ii) the process for assigning Star Ratings for posting on the Medicare Plan Finder for the first 2 years following the consolidation.     For the first contract year following a consolidation, as proposed at paragraphs Sec.  422.162(b)(3)(iv) and Sec.  423.182(b)(3)(ii), we propose to use the enrollment-weighted means as calculated below to set Star Ratings for publication (and, in Sec.  422.162(b)(3)(iii), use of certain enrollment-weighted means for establishing QBP status:      The Star Ratings measure scores for the consolidated entity's first plan year would be based on enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey- based and call center measures.      The survey-based measures (that is, CAHPS, HOS, and HEDIS measures collected through CAHPS or HOS) would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. For example, for a contract consolidation that is effective January 1, 2021 the CAHPS sample for the 2021 Star Ratings would be pulled in January 2020 so enrollment in January 2020 would be used. The call center measures would use mean enrollment during the study period. We believe that these proposals for survey-based measures are more nuanced and account for how the data underlying those measures are gathered. By using the enrollment-weighted means we are reflecting the true underlying performance of both the surviving and consumed contracts.     For the second year following the consolidation, for all MA and Part D Sponsors, the Star Ratings would be calculated as follows:      The enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts would be used for all measures except HEDIS, CAHPS, and HOS.      The current reporting requirements for HEDIS and HOS already combine data from the surviving and consumed contract(s) following the consolidation, so we are not proposing any modification or averaging of these measure scores. For example, for HEDIS if an organization consolidates one or more contracts during the change over from measurement to reporting year, then only the surviving contract is required to report audited summary contract-level data but it must include data on all members from all contracts involved. For this reason, we are proposing regulation text that HEDIS and HOS measure data will be used as reported in the second year after consolidation.      The CAHPS survey sample that would be selected following the consolidation would be modified to include enrollees in the sample universe from which the sample is drawn from both the surviving and consumed contracts. If there are two contracts (that is, Contract A is the surviving contract and Contract B is the consumed contract) that consolidate, and Contract A has 5,000 enrollees eligible for the survey and Contract B has 1,000 eligible for the survey, the universe from which the sample would be selected would be 6,000.     After applying these rules for calculating the measure scores in the first and second year after consolidation, CMS would use the other rules proposed in Sec. Sec.  422.166 and 423.186 to calculate the measure, domain, summary, and overall Star Ratings for the consolidated contract. In the third year after consolidation and subsequent years, the performance period for all the measures would be after the consolidation, so our proposal is limited to the Star Ratings issued the first 2 years after consolidation.     When consolidations involve two or more contracts for health and/or drug services of the same plan type under the same parent organization combining into a single contract at the start of a contract year, we propose to calculate the QBP rating for that first year following the consolidation using the enrollment-weighted mean, using traditional rounding rules, of what would have been the QBP ratings of the surviving and consumed contracts using the contract enrollment in November of the year the Star Ratings were released. In November of each year following the release of the ratings on Medicare Plan Finder, the preliminary QBP ratings are displayed in the Health Plan Management System (HPMS) for the year following the Star Ratings year. For example, the first year the consolidated entity is in operation is plan year 2020; the 2020 QBP rating displayed in HPMS in November 2018 would be based on the 2019 Star Ratings (which are released in October 2018) and calculated using the weighted mean of the November 2018 enrollment of the surviving and consumed contracts. Because the same parent organization is involved in these situations, we believe that many administrative processes and procedures are identical in the Medicare health plans offered by the sponsoring organization, and using a weighted mean of what would have been their QBP ratings accurately reflects their performance for payment purposes. In subsequent years after the first year following the consolidation, QBPs status would be determined based on the consolidated entity's Star Rating posted on Medicare Plan Finder. Under our proposal, the measure, domain, summary, and in the case of MA-PD plans the overall Star Ratings posted on Medicare Plan Finder for the second year following consolidation would be based on the enrollment-weighted measure scores so would include data from all contracts involved. Consequently, the ratings used for QBP status determinations would reflect the care provided by both the surviving and consumed contracts.     In conclusion, we are proposing a new set of rules regarding the calculation of Star Ratings for consolidated contracts to be codified at paragraphs (b)(3)(i) through (iv) of Sec. Sec.  422.162 and 423.182 In most cases, we propose that the Star Ratings for the first and second year following the consolidation to be an enrollment-weighted mean of the scores at the measure level for the consumed and surviving contracts. For the QBP rating for the first year following the consolidation, we propose to use the enrollment-weighted mean of the QBP rating of the surviving and consumed contracts (which would be the overall or summary rating depending on the plan type) rather than averaging measure scores. We solicit comment on this proposal and whether our separate treatment of different measure types during the first and second year adequately addresses the differences in how data are collected (and submitted) for those measures during the different

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periods. We would also like to know whether sponsoring organizations believe that the special rule for consolidations involving the same parent organization and same plan types adequately addresses how those situations are different from cases where an MA organization buys or sells a plan or contract from or to a different entity and whether these rules should be extended to situations where there are different parent organizations involved. For commenters that support the latter, we also request comment on how CMS should determine that the same administrative processes are used and whether attestations from sponsoring organizations or evidence from prior audits should be required to support such determinations. g. Data Sources     Under 1852(e) of the Act, MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. The Star Ratings System is based on information collected consistent with section 1852(e) of the Act. Section 1852(e)(3)(B) of the Act prohibits the collection of data on quality, outcomes, and beneficiary satisfaction other than the types of data that were collected by the Secretary as of November 1, 2003; there is a limited exception for SNPs to collect, analyze, and report data that permit the measurement of health outcomes and other indicia of quality. The statute does not require that only the same data be collected, but that we do not change or expand the type of data collected until after submission of a Report to Congress (prepared in consultation with MA organizations and accrediting bodies) that explains the reason for the change(s). We clarify here that the types of data included under the Star Ratings System are consistent with the types of data collected as of November 1, 2003. Since 1997, Medicare managed care organizations have been required to annually report quality of care performance measures through HEDIS. We have also been conducting the CAHPS survey since 1997 to measure beneficiaries' experiences with their health plans, and since 2007 we have been measuring experiences with drug plans with CAHPS. HOS began in 1998 to capture changes in the physical and mental health of MA enrollees. To some extent, these surveys have been revised and updated over time, but the same types of data--clinical measures, beneficiary experiences, and changes in physical and mental health, respectively--have remained the focus of these surveys. In addition, there are several measures in the Stars Ratings System that are based on performance that address telephone customer service, members' complaints, disenrollment rates, and appeals; however these additional measures are not collected directly from the sponsoring organizations for the primary purpose of quality measurement. These additional measures are calculated from information that CMS has gathered as part of the administration of the Medicare program, such as information on appeals forwarded to the Independent Review Entity under subparts M, enrollment, and compliance and enforcement actions.     The Part D program was implemented in 2006, and while there is no parallel provision regarding applicable Part D sources of data, we have used similar datasets, for example CAHPS survey data, for beneficiaries' experiences with prescription drug plans. Section 1860D- 4(d) of the Act specifically directs the administration and collection of data from consumer surveys in a manner similar to those conducted in the MA program. All of these measures reflect structure, process, and outcome indices of quality that form the measurement set under Star Ratings. Since 2007, we have publicly reported a number of measures related to the drug benefit as part of the Star Ratings. For MA organizations that offer prescription drug coverage, we have developed a series of measures focusing on administration of the drug benefit. Similar to MA measures of quality relative to health services, the Part D measures focus on customer service and beneficiary experiences, effectiveness, and access to care relative to the drug benefit. We believe that the Part D Star Ratings are consistent with the limitation expressed in section 1852(e) of the Act even though the limitation does not apply to our collection of Part D quality data from Part D sponsors.     We intend to continue to base the types of information collected in the Part C Star Ratings on section 1852(e) of the Act, and we propose at Sec.  422.162(c)(1) that the type of data used for Star Ratings will be data consistent with the section 1852(e) limits and data gathered from CMS administration of the MA program. In addition, we propose in Sec.  422.162(c)(1) and in Sec.  423.182(c)(1) to include measures that reflect structure, process, and outcome indices of quality, including Part C measures that reflect the clinical care provided, beneficiary experience, changes in physical and mental health, and benefit administration, and Part D measures that reflect beneficiary experiences and benefit administration. The measures encompass data submitted directly by MA organizations (MAOs) and Part D sponsors to CMS, surveys of MA and Part D enrollees, data collected by CMS contractors, and CMS administrative data. We also propose, primarily so that the regulation text is complete on this point, a regulatory provision at Sec. Sec.  422.162(c)(2) and 423.182(c)(2) that requires MA organizations and Part D plan sponsors to submit unbiased, accurate, and complete quality data as described in paragraph(c)(1) of each section. Our authority to collect quality data is clear under the statute and existing regulations, such as section 1852(e)(3)(A) and 1860D-4(d) and Sec. Sec.  422.12(b)(2) and 423.156 We propose the paragraph (c)(2) regulation text to ensure that the quality ratings system regulations include a regulation on this point for readers and to avoid confusion in the future about the authority to collect this data. In addition, it is important that the data underlying the ratings are unbiased, accurate, and complete so that the ratings themselves are reliable. This proposed regulation text would clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance. h. Adding, Updating, and Removing Measures     We are committed to continuing to improve the Part C and D Star Ratings System by focusing on improving clinical and other outcomes. We anticipate that new measures will be developed and that existing measures will be updated over time. NCQA and the Pharmacy Quality Alliance (PQA) continually work to update measures as clinical guidelines change and develop new measures focused on health and drug plans. To address these anticipated changes, we propose in Sec. Sec.   422.164 and 423.184 specific rules to govern the addition, update, and removal of measures. We also propose to apply these rules to the measure set proposed in this rulemaking, to the extent that there are changes between the final rule and the Star Ratings based on the performance periods beginning on or after January 2019.     As discussed in more detail in the following paragraphs, we propose the following general rules to govern adding, updating, and removing measures:      For data quality issues identified during the calculation of the Star Ratings for a given year, we propose to continue our current practice of

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removing the measure from the Star Ratings.      That new measures and substantive updates to existing measures would be added to the Star Ratings System based on future rulemaking but that prior to such a rulemaking, CMS would announce new measures and substantive updates to existing measures and solicit feedback using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act (that is the Call Letter attachment to the Advance Notice and Rate Announcement).      That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be updated with regular updates from the measure stewards through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act when the changes are not substantive.      That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be removed from use in the Star Ratings when there has been a change in clinical guidelines associated with the measure or reliability issues identified in advance of the measurement period; CMS would announce the removal using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Removal might be permanent or temporary, depending on the basis for the removal.     We are proposing specific rules for updating and removal that would be implemented through subregulatory action, so that rulemaking will not be necessary for certain updates or removals. Under this proposal, CMS would announce application of the regulation standards in the Call Letter attachment to the Advance Notice and Rate Announcement process under section 1853(b) of the Act.     First, we propose to codify, at Sec. Sec.  422.164(a) and 423.184(a), regulation text stating the general rule that CMS would add, update, and remove measures used to calculate Star Ratings as provided in Sec. Sec.  422.164 and 423.184 In each paragraph regarding addition, updating, and removal of measures and the use of improvement measures, we also propose rules to identify when these types of changes would not involve rulemaking based on application of the standards and authority in the regulation text. Under our proposal, CMS would solicit feedback of its application of the rules using the draft and final Call Letter each year.     Second, we propose, in paragraph (b) of these sections, that CMS would review the quality of the data on which performance, scoring, and rating of measures is done each year. We propose to continue our current practice of reviewing data quality across all measures, variation among organizations and sponsors, and measures' accuracy, reliability, and validity before making a final determination about inclusion of measures in the Star Ratings. The intent is to ensure that Star Ratings measures accurately measure true plan performance. If a systemic data quality issue is identified during the calculation of the Star Ratings, we would remove the measure from that year's rating under proposed paragraph (b).     Third, we propose to address the addition of new measures in paragraph (c).     In identifying whether to add a measure, we will be guided by the principles we listed in section III.A.12.b of the proposed rule. Measures should be aligned with best practices among payers and the needs of the end users, including beneficiaries. Our strategy is to continue to adopt measures when they are available, nationally endorsed, and in alignment with the private sector, as we do today through the use of measures developed by NCQA and the PQA, and the use of measures that are endorsed by the National Quality Forum (NQF). We propose to codify this standard for adopting new measures at Sec. Sec.   422.164(c)(1) and 423.184(c)(1). We do not intend this standard to require that a measure be adopted by an independent measure steward or endorsed by NQF in order for us to propose its use for the Star Ratings, but that these are considerations that will guide us as we develop such proposals. We also propose that CMS may develop its own measures as well when appropriate to measure and reflect performance in the Medicare program.     For the 2021 Star Ratings, we propose (at section III.A.12 ) of the proposed rule to have measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures. It is important to have a mix of different types of measures in the Star Ratings program to understand how all of the different facets of the provision of health and drug services interact. For example, process measures are evidence-based best practices that lead to clinical outcomes of interest. Process measures are generally easier to collect, while outcome measures are sometimes more challenging requiring in some cases medical record review and more sophisticated risk-adjustment methodologies.     Over time new measures will be added and measures will be removed from the Star Ratings program to meet our policy goals. As new measures are added, our general guidelines for deciding whether to propose new measures through future rulemaking will use the following criteria:      Importance: The extent to which the measure is important to making significant gains in health care processes and experiences, access to services and prescription medications, and improving health outcomes for MA and Part D enrollees.      Performance Gap: The extent to which the measure demonstrates opportunities for performance improvement based on variation in current health and drug plan performance.      Reliability and Validity: The extent to which the measure produces consistent (reliable) and credible (valid) results.      Feasibility: The extent to which the data related to the measure are readily available or could be captured without undue burden and could be implemented by the majority of MA and Part D contracts.      Alignment: The extent to which the measure or measure concept is included in one or more existing federal, State, and/or private sector quality reporting programs.     We would balance these criteria as part of our decision making process so that each new measure proposed for addition to the Star Ratings meets each criteria in some fashion or to some extent. We intend to apply these criteria to identify and adopt new measures for the Star Ratings, which will be done through future rulemaking that includes explanations for how and why we propose to add new measures. When we identify a measure that meets these criteria, we propose to follow the process in our proposed paragraphs (c)(2) through (4) of Sec. Sec.  422.164 and 423.184 We would initially solicit feedback on any potential new measures through the Call Letter.     As new performance measures are developed and adopted, we propose, at Sec. Sec.  422.164(c)(3) and (4) and 423.184(c)(3) and (4), that they would initially be incorporated into the display page for at least 2 years but that we would keep a new measure on the display page for a longer period if CMS finds there are reliability or validity issues with the measure. As noted in the

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Introduction, the rulemaking process will create a longer lead time for changes, in particular to add a new measure to the Star Ratings or to make substantive changes to measures as discussed later in this section. Here is an example timeline for adding a new measure to the Star Ratings. In this scenario, the new measure has already been developed by the NCQA and the PQA, and endorsed by the NQF. Otherwise, that process may add an extra 3 to 5 years to the timeline.      January 2019: Solicit feedback on whether to add the new measure in the draft 2020 Call Letter.      April 2019: Summarize feedback on adding the new measure in the 2020 Call Letter.      2020/2021: Propose adding the new measure to the 2024 Star Ratings (2022 measurement period) in a proposed rule; finalize through rulemaking (for 1/1/2022 effective date).      2020: Performance period and collection of data for the new measure and collection of data for posting on the 2022 display page.      2021: Performance period and collection of data for the new measure and collection of data for posting on the 2023 display page.      Fall 2021: Publish new measure on the 2022 display page (2020 measurement period).      January 1, 2022: Applicability date of new measure for Star Ratings.      2022: Performance period and collection of data for the new measure and collection of data for inclusion in the 2024 Star Ratings.      Fall 2022: Publish new measure on the 2023 display page (2021 measurement period).      Fall 2023: Publish new measure in the 2024 Star Ratings (2022 measurement period).      2025: QBP status and rebate retention allowances are determined for the 2025 payment year.     Fourth, at Sec. Sec.  422.164(d) and 423.184(d) we propose to address updates to measures based on whether an update is substantive or non-substantive. Since quality measures are routinely updated (for example, when clinical codes are updated), we propose to adopt rules for the incorporation of non-substantive updates to measures that are part of the Star Ratings System without going through new rulemaking. As proposed in paragraphs (d)(1) of Sec. Sec.  422.164 and 423.184, we would only incorporate updates without rulemaking for measure specification changes that do not substantively change the nature of the measure.     Substantive changes (for example, major changes to methodology) to existing measures would be proposed and finalized through rulemaking. In paragraphs (d)(2) of Sec. Sec.  422.164 and 423.184, we propose to initially solicit feedback on whether to make the substantive measure update through the Call Letter prior to the measurement period for which the update would be initially applicable. For example, if the change announced significantly expands the denominator or population covered by the measure (for example, the age group included in the measures is expanded), the measure would be moved to the display page for at least 2 years and proposed through rulemaking for inclusion in Star Ratings. We intend this process for substantive updates to be similar to the process we would use for adopting new measures under proposed paragraph (c). As appropriate, the legacy measure may remain in the Star Ratings while the updated measure is on the display page if, for example, the updated measure expands the population covered in the measure and the legacy measure would still be relevant and measuring a critical topic to continue including in the Star Ratings while the updated measure is on display. Adding the updated measure to the Star Ratings would be proposed through rulemaking.     We propose to adopt rules to incorporate specification updates that are non-substantive in paragraph (d)(1). Non-substantive updates that occur (or are announced by the measure steward) during or in advance of the measurement period will be incorporated into the measure and announced using the Call Letter. We propose to use such updated measures to calculate and assign Star Ratings without the updated measure being placed on the display page. This is consistent with current practice.     In paragraph (d)(1)(i-v) of Sec. Sec.  422.164 and paragraph (d)(1)(i-v) of 423.184, we propose to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period and how we would treat them under our proposal. The list includes updates in the following circumstances:      If the change narrows the denominator or population covered by the measure with no other changes, the updated measure would be used in the Star Ratings program without interruption. For example, if an additional exclusion--such as excluding nursing home residents from the denominator--is added, the change would be considered non- substantive and would be incorporated automatically. In our view, changes to narrow the denominator generally benefit Star Ratings of sponsoring organizations and should be treated as non-substantive for that reason.      If the change does not meaningfully impact the numerator or denominator of the measure, the measure would continue to be included in the Star Ratings. For example, if additional codes are added that increase the number of numerator hits for a measure during or before the measurement period, such a change would not be considered substantive because the sponsoring organization would generally benefit from that change. This type of administrative (billing) change has no impact on the current clinical practices of the plan or its providers, and thus would not necessitate exclusion from the Star Ratings System of any measures updated in this way.      The clinical codes for quality measures (such as HEDIS measures) are routinely revised as the code sets are updated. For updates to address revisions to the clinical codes without change in the intent of the measure and the target population, the measure would remain in the Star Ratings program and would not move to the display page. Examples of clinical codes that might be updated or revised without substantively changing the measure include:     ++ ICD-10-CM (``ICD-10'') code sets. Annually, there are new ICD 10 coding updates, which are effective from October 1 through September 30th of any given year.     ++ Current Procedural Terminology (CPT) codes. These codes are published and maintained by the American Medical Association (AMA) to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient.     ++ Healthcare Common Procedure Coding System (HCPCS) codes. These codes cover items, supplies, and non-physician services not covered by CPT codes.     ++ National Drug Code (NDC). The PQA updates NDC lists biannually, usually in January and July.      If the measure specification change is providing additional clarifications such as the following, the measure would also not move to the display page since this does not change the intent of the measure but provides more information about how to meet the measure specifications:     ++ Adding additional tests that would meet the numerator requirements.     ++ Clarifying documentation requirements (for example, medical record documentation).

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    ++ Adding additional instructions to identify services or procedures that meet (or do not meet) the specifications of the measure.      If the measure specification change is adding additional data sources, the measure would also not move to the display page because we believe such changes are merely to add alternative ways to collect the data to meet the measure specifications without changing the intent of the measure.     We solicit comment on our proposal to add non-substantive updates to measures and using the updated measure (replacing the legacy measure) to calculate Star Ratings. In particular, we are interested in stakeholders' views whether only non-substantive updates that have been adopted by a measure steward after a consensus-based or notice and comment process should be added to the Star Ratings under this proposed authority. Further, we solicit comment on whether there are other examples or situations involving non-substantive updates that should be explicitly addressed in the regulation text or if our proposal is sufficiently extensive.     In addition to updates and additions of measures, we are proposing rules to address the removal of measures from the Star Ratings to be codified in Sec. Sec.  422.164(e) and 423.184(e). In paragraph (e)(1) of each section, we propose the two circumstances under which a measure would be removed entirely from the calculation of the Star Ratings. The first circumstance would be changes in clinical guidelines that mean that the measure specifications are no longer believed to align with or promote positive health outcomes. As clinical guidelines change, we would need the flexibility to remove measures from the Star Ratings that are not consistent with current guidelines. We are proposing to announce such subregulatory removals through the Call Letter so that removals for this reason are accomplished quickly and as soon as the disconnect with positive clinical outcomes is definitively identified. We note that this proposal is consistent with our current practice. For example, previously we retired the Glaucoma Screening measure for HEDIS 2015 after the U.S Preventive Services Task Force concluded that the clinical evidence is insufficient to assess the balance of benefits and harms of screening for glaucoma in adults.     In addition to removal of measures because of changes in clinical guidelines, we currently review measures continually to ensure that the measure remains sufficiently reliable such that it is appropriate to continue use of the measure in the Star Ratings. We propose, at paragraph (e)(1)(ii), that we would also have authority to subregulatorily remove measures that show low statistical reliability so as to move swiftly to ensure the validity and reliability of the Star Ratings, even at the measure level. We will continue to analyze measures to determine if measure scores are ``topped out'' (that is, showing high performance across all contracts decreasing the variability across contracts and making the measure unreliable) so as to inform our approach to the measure, or if measures have low reliability. Although some measures may show uniform high performance across contracts and little variation between them, we seek evidence of the stability of such high performance, and we want to balance how critical the measures are to improving care, the importance of not creating incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures. If, for example, performance in a given measure has just improved across all contracts, or if no other measures capture a key focus in Star Ratings, a ``topped out'' measure which would have lower reliability may be retained in Star Ratings. Under our proposal to be codified at paragraph (e)(2), we would announce application of this rule through the Call Letter in advance of the measurement period.     We request comment on these proposals regarding the processes to add, update, and remove Star Ratings measures. i. Measure Set for Performance Periods Beginning on or After January 1, 2019     We are proposing the measures included in Table 2 to be collected for performance periods beginning on or after January 1, 2019 for the 2021 Part C and D Star Ratings. The CAHPS measure specification, including case-mix adjustment, is described in the Technical Notes and at ma-pdpcahps.org The HOS measure specification, including case-mix adjustment, is described at ([*http://hosonline.org/globalassets/hos-online/survey-results/hos\_casemix\_coefficient\_tables\_c17.pdf*](http://hosonline.org/globalassets/hos-online/survey-results/hos_casemix_coefficient_tables_c17.pdf)). These specifications are part of our proposal.     We are not proposing to codify this list of measures and specifications in regulation text in light of the regular updates and revisions contemplated by our proposals at Sec. Sec.  422.164 and 423.184 We intend, as proposed in paragraph (a) of these sections, that the Technical Notes for each year's Star Ratings would include the applicable full list of measures. BILLING CODE 4120-01-P

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[GRAPHIC] [TIFF OMITTED] TP28NO17.000

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[GRAPHIC] [TIFF OMITTED] TP28NO17.001

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[GRAPHIC] [TIFF OMITTED] TP28NO17.002

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[GRAPHIC] [TIFF OMITTED] TP28NO17.003

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[GRAPHIC] [TIFF OMITTED] TP28NO17.004

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[GRAPHIC] [TIFF OMITTED] TP28NO17.007

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j. Improvement Measures     In the 2013 Part C and D Star Ratings, we implemented the Part C and D improvement measures (CY2013 Rate Announcement, [*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf*](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf)). The improvement measures address the overall improvement or decline in individual measure scores from the prior to the current year. We propose to continue the current methodology detailed in the Technical Notes for calculating the improvement measures and to codify it at Sec. Sec.  422.164(f) and 423.184(f). For a measure to be included in the improvement calculation, the measure must have numeric value scores in both the current and prior year and not have had a substantive specification change during those years. In addition, the improvement measure will not include any data on measures that are already focused on improvement (for example, HOS measures focused on improving or maintaining physical or mental health). The Part C improvement measure includes only Part C measure scores, and the Part D improvement measure includes only Part D measure scores. All measures meeting these criteria would be included in the improvement measures under our proposal at paragraph (f)(1)(i) through (iv) of Sec. Sec.  422.164 and 423.184     Annually, the subset of measures to be included in the improvement measures following these criteria would be announced through the Call Letter, similar to our proposal for regular updates and removal of measures. Under our proposal, once the measures to be used for the improvement measures are identified, CMS would determine which contracts have sufficient data for purposes of applying and scoring the improvement measure(s). Following current practices, the improvement measure score would be calculated only for contracts that have numeric measure scores for both years for at least half of the measures identified for use in the improvement measure. We propose this standard for determining contracts eligible for an improvement measure at paragraph (f)(2).     We propose at part Sec. Sec.  422.164(f)(3) and (4) and 423.184(f)(3) and (4) the process for calculating the improvement measure score(s) and a special rule for any identified improvement measure for a contract that received a measure-level Star Rating of 5 in each of the 2 years examined, but whose associated measure score indicates a statistically significant decline in the time period. The improvement measure would be calculated in a series of distinct steps:      The improvement change score (the difference in the measure scores in the 2-year period) would be determined for each measure that has been identified as part of an improvement measure and for which a contract has a numeric score for each of the 2 years examined.      Each contract's improvement change score would be categorized as a significant change or not by employing a two tailed t- test with a level of significance of 0.05      The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.      The improvement measure score would then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.      The improvement measure score would be converted to a measure-level Star Rating using the hierarchical clustering algorithm.     The improvement measure score cut points would be determined using two separate clustering algorithms. Improvement measure scores of zero and above would use the clustering algorithm to determine the cut points for the Star Rating levels of 3 and above. Improvement measure scores below zero would be clustered to determine the cut points for 1 and 2 stars. The Part D improvement measure thresholds for MA-PDs and PDPs would be reported separately.     We propose a special rule in paragraph (f)(3) to hold harmless sponsoring organizations that have 5-star ratings for both years on a measure used for the improvement measure calculation. This hold harmless provision was added in 2014 to avoid the unintended consequence for contracts that score 5 stars on a subset of measures in each of the 2 years. For any identified improvement measure for which a contract received a rating of 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change. The measure will be included in the count of measures used to determine eligibility for the improvement measure and in the denominator of the improvement measure score. The intent of the hold harmless provision for a contract that receives a measure rating of 5 stars for each year is to prevent the measure from lowering a contract's improvement measure when the contract still demonstrates high performance. We propose in section III.A.12 of this proposed rule another hold harmless provision to be codified at Sec. Sec.  422.166(g)(1) and 423.186(g)(1).     We request comment on the methodology for the improvement measures, including rules for determining which measures are included, the conversion to a Star Rating, and the hold harmless provision for individual measures that are used for the determination of the improvement measure score. k. Data Integrity     The data underlying a measure score and rating must be complete, accurate, and unbiased for it to be useful for the purposes we have proposed at Sec. Sec.  422.160(b) and 423.180(b). As part of the current Star Ratings methodology, all measures and the associated data have multiple levels of quality assurance checks. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's measure data are incomplete, inaccurate, or biased. Data validation is a shared responsibility among CMS, CMS data providers, contractors, and Part C and D sponsors. When applicable (for example, data from the IRE, PDE, call center), CMS expects sponsoring organizations to routinely monitor their data and immediately alert CMS if errors or anomalies are identified so CMS can address these errors.     We propose to codify at Sec. Sec.  422.164(g) and 423.184(g) specific rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures. Data may be determined to be incomplete, inaccurate, or biased based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that impacted specific measure(s). One example of such situations that give rise to such determinations includes a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements. Our modifications to measure-specific ratings due to data integrity issues are separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies. This policy and

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these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when deficiencies have been identified that show we cannot objectively evaluate a sponsor's performance in an area.     As a standard practice, we check for flags that indicate bias or non-reporting, check for completeness, check for outliers, and compare measures to the previous year to identify significant changes which could be indicative of data issues. CMS has developed and implemented Part C and Part D Reporting Requirements Data Validation standards to assure that data reported by sponsoring organizations pursuant to Sec. Sec.  422.516 and 423.514 satisfy the regulatory obligation. Sponsor organizations should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications is posted on: [*http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx*](http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx) Information about Data Validation of Reporting Requirements data is posted on:   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html) and   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting\_ReportingOversight.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html)     We propose, in paragraphs (g)(1)(i) through (iii), rules for specific circumstances where we believe a specific response is appropriate. First, we propose a continuation of a current policy: To reduce HEDIS measures to 1 star when audited data are submitted to NCQA with an audit designation of ``biased rate'' or BR based on an auditor's review of the data if a plan chooses to report; this proposal would also apply when a plan chooses not to submit and has an audit designation of ``non-report'' or NR. Second, we propose to continue to reduce Part C and D Reporting Requirements data, that is, data required pursuant to Sec. Sec.  422.514 and 423.516, to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with data validation standards/ sub-standards for data directly used to calculate the associated measure. In our view, data that do not reach at least 95 percent on the data validation standards are not sufficiently accurate, impartial, and complete for use in the Star Ratings. As the sponsoring organization is responsible for these data and submits them to CMS, we believe that a negative inference is appropriate to conclude that performance is likely poor. Third, we propose a new specific rule to authorize scaled reductions in Star Ratings for appeal measures in both Part C and Part D.     The data downgrade policy was adopted to address instances when the data that would be used for specific measures are not reliable for measuring performance due to their incompleteness or biased/erroneous nature. For instances where the integrity of the data is compromised because of the action or inaction of the sponsoring organization (or its subcontractors or agents), this policy reflects the underlying fault of the sponsoring organization for the lack of data for the applicable measure. Without some policy for reduction in the rating for these measures, sponsoring organizations could ``game'' the Star Ratings and merely fail to submit data that illustrate poor performance. We believe that removal of the measure from the ratings calculation would unintentionally reward poor data compilation and submission activities such that our only recourse is to reduce the rating to 1 star for affected measures.     For verification and validation of the Part C and D appeals measures, we propose to use statistical criteria to determine if a contract's appeals measure-level Star Ratings would be reduced for missing IRE data. The criteria would allow us to use scaled reductions for the appeals measures to account for the degree to which the data are missing. The completeness of the IRE data is critical to allow fair and accurate measurement of the appeals measures. All plans are responsible and held accountable for ensuring high quality and complete data to maintain the validity and reliability of the appeals measures.     In response to stakeholder concerns about CMS' prior practice of reducing measure ratings to one star based on any finding of data inaccuracy, incompleteness, or bias, CMS initiated the Timeliness Monitoring Project (TMP) in CY 2017.\40\ The first submission for the TMP was for the measurement year 2016 related to Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. The timeframe for the submitted data was dependent on the enrollment of the contract with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period.\41\ ---------------------------------------------------------------------------

    \40\ This project was discussed in the November 28, 2016 HPMS memo, ``Industry-wide Appeals Timeliness Monitoring.'' [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf),   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf)     \41\ Contracts with a mean annual enrollment of less than 50,000 are required to submit data for a three-month time period. Contracts with a mean enrollment of at least 50,000 but at most 250,000 are required to submit data for a two-month time period. Contracts with a mean enrollment greater than 250,000 are required to submit data for a one-month period. ---------------------------------------------------------------------------

    We propose to use multiple data sources whenever possible, such as the TMP data or information from audits to determine whether the data at the Independent Review Entity (IRE) are complete. Given the financial and marketing incentives associated with higher performance in Star Ratings, safeguards are needed to protect the Star Ratings from actions that inflate performance or mask deficiencies.     CMS is proposing to reduce a contract's Part C or Part D appeal measures Star Ratings for IRE data that are not complete or otherwise lack integrity based on the TMP or audit information. The reduction would be applied to the measure-level Star Ratings for the applicable appeals measures. There are varying degrees of data issues and as such, we are proposing a methodology for reductions that reflects the degree of the data accuracy issue for a contract instead of a one-size fits all approach. The methodology would employ scaled reductions, ranging from a 1-star reduction to a 4-star reduction; the most severe reduction for the degree of missing IRE data would be a 4-star reduction which would result in a measure-level Star Rating of 1 star for the associated appeals measures (Part C or Part D). The data source for the scaled reduction is the TMP or audit data, however the specific data used for the determination of a Part C IRE data completeness reduction are independent of the data used for the Part D IRE data completeness reduction. If a contract receives a reduction due to missing Part C IRE data, the reduction would be applied to both of the contract's Part C appeals measures. Likewise, if a contract receives a reduction due to missing Part D IRE data, the reduction would be applied to both of the contract's Part D appeals measures. We solicit comment on this proposal and its scope; we are looking in particular for comments related to how to use the process we are proposing

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in this proposal to account for data integrity issues discovered through means other than the TMP and audits of sponsoring organizations.     CMS' proposed scaled reduction methodology is a three-stage process using the TMP or audit information to determine: First, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, the basis for the estimate of the error rate; and finally, whether the estimated error rate is significantly greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars.     Once the scaled reduction for a contract is determined using this methodology, the reduction would be applied to the contract's associated appeals measure-level Star Ratings. The minimum measure- level Star Rating is 1 star. If the difference between the associated appeals measure-level Star Rating (before the application of the reduction) and the identified scaled reduction is less than one, the contract would receive a measure-level Star Rating of 1 star for the appeals measure.     The error rate for the Part C and Part D appeals measures using the TMP or audit data and the projected number of cases not forwarded to the IRE for a 3-month period would be used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. A minimum error rate is proposed to establish a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold allows the focus of the possible reductions on contracts with error rates that have the greatest potential to distort the signal of the appeals measures. Since the timeframe for the TMP data is dependent on the enrollment of the contract, with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a 2-month period, and larger contracts submitting data from a one-month period, the use of a projected number of cases allows a consistent time period for the application of the criteria proposed.     The calculated error rate formula (Equation 1) for the Part C measures is proposed to be determined by the quotient of the number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during TMP or audit data collection period and the number of cases not forwarded to the IRE during the same period. [GRAPHIC] [TIFF OMITTED] TP28NO17.008

    The calculated error rate formula (Equation 2) for the Part D measures is proposed to be determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases. [GRAPHIC] [TIFF OMITTED] TP28NO17.009

    The projected number of cases not forwarded to the IRE in a 3-month period would be calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the TMP time period. Contracts with mean annual enrollments greater than 250,000 that submitted data from 1-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 3.0 Contracts with mean enrollments of 50,000 but at most 250,000 that submitted data from a 2-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.5 Small contracts with mean enrollments less than 50,000 that submitted data for a 3-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.0     Under this proposal, contract ratings would be subject to a possible reduction due to lack of IRE data completeness if both following conditions are met The calculated error rate is 20 percent or more.      The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.     The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions, the contract would not be subject to reductions for IRE data completeness issues.     If a contract is subject to a possible reduction based on the aforementioned conditions, a confidence interval estimate for the true error rate for the contract would be calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent.     The midpoint of the score interval would be determined using Equation 3. [GRAPHIC] [TIFF OMITTED] TP28NO17.010

    The z score that corresponds to a level of statistical significance of 0.05, commonly denoted as z[alpha]/2 but for ease of presentation represented here as z. (The z value that will be used for the purpose of the calculation of the interval is 1.959964 ).     For the Part C appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 1. The total number of cases in Equation 3 is the number of cases that should have been in the IRE for the Part C TMP data.     For the Part D appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 2. The total number of cases in

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Equation 3 is the total number of untimely cases for the Part D appeals measures.     Letting the calculated error rate be represented by and the total number of cases represented as n, Equation 3 can be streamlined as Equation 4: [GRAPHIC] [TIFF OMITTED] TP28NO17.011

    The lower bound of the confidence interval estimate for the error rate is calculated using Equation 5 below: [GRAPHIC] [TIFF OMITTED] TP28NO17.012

    For each contract subject to a possible reduction, the lower bound of the interval estimate of the error rate would be compared to each of the thresholds in Table 3. If the contract's calculated lower bound is higher than the threshold, the contract would receive the reduction that corresponds to the highest threshold that is less than the lower bound. In other words, the contract's lower bound is being employed to determine whether the contract's error rate is significantly greater than the thresholds of 20 percent, 40 percent, 60 percent, and 80 percent. The proposed scaled reductions are in Table 3, and would be codified in narrative form at paragraph (g)(1)(iii)(D) of both regulations.     The reductions due to IRE data completeness issues would be applied after the calculation of the measure-level Star Rating for the appeals measures. The reduction would be applied to the Part C appeals measures and/or the Part D appeals measures.     It is important to note that a contract's lower bound could be statistically significantly greater than more than one threshold. The reduction would be determined by the highest threshold that the contract's lower bound exceeds. For example, if the lower bound for a contract is 64.560000 percent, the contract's estimated value is significantly greater than the thresholds of 20 percent, 40 percent, and 60 percent because the lower bound value 64.560000 percent is greater than each of these thresholds. The lower bound for the contract's confidence interval is not greater than 80 percent. The contract would be subject to the reduction that corresponds to the 60 percent threshold, which is three stars.

 Table 3--Appeals Measure Star Ratings Reductions by the Incomplete Data                                Error Rate ------------------------------------------------------------------------                                                            Reduction for Proposed thresholds using the lower bound of  confidence    incomplete         interval  estimate of the error rate (%)             IRE data                                                               (stars) ------------------------------------------------------------------------ 20......................................................               1 40......................................................               2 60......................................................               3 80......................................................               4 ------------------------------------------------------------------------

    We propose regulation text at Sec.  422.164(g)(1)(iii)(A) through (N) and Sec.  423.184(g)(1)(iii)(A) through (K) to codify these parameters and formulas for the scaled reductions. We note that the proposed text for the Part C regulation includes specific paragraphs related to MA and MA-PD plans that are not included in the proposed text for the Part D regulation but that the two are otherwise identical.     In addition, we propose in Sec. Sec.  422.164(g)(2) and 423.184(g)(2) to authorize reductions in a Star Rating for a measure when there are other data accuracy concerns (that is, those not specified in paragraph (g)(1)). We propose an example in paragraph (g)(2) of another circumstance where CMS would be authorized to reduce ratings based on a determination that performance data are incomplete, inaccurate, or biased. We also propose this other situation would result in a reduction of the measure rating to 1 star.     We have taken several steps in past years to protect the integrity of the data we use to calculate Star Ratings. However, we welcome comments about alternative methods for identifying inaccurate or biased data and comments on the proposed policies for reducing stars for data accuracy and completeness issues. Further, we welcome comments on the proposed methodology for scaled reductions for the Part C and Part D appeals measures to address the degree of missing IRE data. l. Measure-Level Star Ratings     We propose in Sec. Sec.  422.166(a) and 423.186(a) the methods for calculating Star Ratings at the measure level. As part of the Part C and D Star Ratings System, Star Ratings are currently calculated at the measure level. To separate a distribution of scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is a set of cut points. We propose to continue to determine cut points by applying either clustering or a relative distribution and significance testing methodology; we propose to codify this policy in paragraphs (a)(1) of each section. We propose in paragraphs (a)(2) and (a)(3) of each section that for non-CAHPS measures, we would use a clustering methodology and that for CAHPS measures, we would use relative distribution and significance testing. Measure scores would be converted to a 5-star scale ranging from 1 to 5, with whole star increments for the cut points. A rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Consistent with current policy, we propose to use the two methodologies described as follows to convert measure scores to measure-level Star Ratings.     The clustering method would be applied to all Star Ratings measures, except for the CAHPS measures. For each individual measure, we would determine the measure cut points using all measure scores for all contracts required to report that do not have missing, flagged as biased, or erroneous data. For the Part D measures, we propose to determine MA-PD and PDP cut points separately. The scores would

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be grouped such that scores within the same rating (that is 1 star, 2 stars, etc.) are as similar as possible, and scores in different ratings are as different as possible. The hierarchical clustering algorithm and the associated tree and cluster assignments using SAS (a statistical software package) are currently used to determine the cut points for the assignment of the measure-level Star Ratings. We intend to continue use of this software under this proposal, but improvements in statistical analysis will not result in rulemaking or changes in these proposed rules. Rather, we believe that the software used to apply the clustering methodology is generally irrelevant.     Conceptually, the clustering algorithm identifies natural gaps within the distribution of the scores and creates groups (clusters) that are then used to identify the cut points that result in the creation of a pre-specified number of categories. The Euclidean distance between each pair of contracts' measure scores serves as the input for the clustering algorithm. The hierarchical clustering algorithm begins with each contract's measure score being assigned to its own cluster. Ward's minimum variance method is used to separate the variance of the measure scores into within-cluster and between-cluster sum of squares components in order to determine which pairs of clusters to merge. For the majority of measures, the final step in the algorithm is done a single time with five categories specified for the assignment of individual scores to cluster labels. The cluster labels are then ordered to create the 1 to 5-star scale. The range of the values for each cluster (identified by cluster labels) is examined and would be used to determine the set of cut points for the Star Ratings. The measure score that corresponds to the lower bound for the measure-level ratings of 2 through 5 would be included in the star-specific rating category for a measure for which a higher score corresponds to better performance. For a measure for which a lower score is better, the process would be the same except that the upper bound within each cluster label would determine the set of cut points. The measure score that corresponds to the cut point for the ratings of 2 through 5 would be included in the star-specific rating category. In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters. Under our proposal to use clustering to set cut points, we would not require the same number of observations (contracts) within each rating and instead would use a data-driven approach.     As proposed in paragraphs (a)(2)(ii) of each section the improvement measures for Part C and Part D would require the clustering algorithm to be done twice for the identification of the cut points that would allow the conversion of the improvement measure scores to the star scale. The Part D improvement measure score clustering for MA- PDs and PDPs would be reported separately. Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating, while improvement scores less than zero would be assigned either 1 or 2 stars. The clustering would be conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero. For contracts with improvement scores greater than or equal to zero, the clustering process would result in three clusters with measure-level Star Ratings of 3, 4, or 5 with the lower bound of each cluster serving as the cut point for the associated Star Rating. For those contracts with improvement scores less than zero, the clustering algorithm would result in two clusters with measure-level Star Ratings of 1 or 2.     We propose in paragraphs (a)(3) of each section to use percentile standing relative to the distribution of scores for other contracts, measurement reliability standards, and statistical significance testing to determine star assignments for the CAHPS measures. This method would combine evaluating the relative percentile distribution of scores with significance testing and measurement reliability standards in order to maximize the accuracy of star assignments based on scores produced from the CAHPS survey. For CAHPS measures, contracts are first classified into base groups by comparisons to percentile cut points defined by the current-year distribution of case-mix adjusted contract means. Percentile cut points would then be rounded to the nearest integer on the 0-100 reporting scale, and each base group would include those contracts whose rounded mean score is at or above the lower limit and below the upper limit. Then, the number of stars assigned would be determined by the base group assignment, the statistical significance and direction of the difference of the contract mean from the national mean, an indicator of the statistical reliability of the contract score on a given measure (based on the ratio of sampling variation for each contract mean to between-contract variation), and the standard error of the mean score. Table 4, which we propose to codify at Sec. Sec.   422.166(a)(3) and 423.186(a)(3), details the CAHPS star assignment rules for each rating. All statistical tests, including comparisons involving standard error, would be computed using unrounded scores.     We propose that if the reliability of a CAHPS measure score is very low for a given contract, less than 0.60, the contract would not receive a Star Rating for that measure. For purposes of applying the criterion for 1 star on Table 3, at item (c), low reliability scores would be defined as those with at least 11 respondents and reliability greater than or equal to 0.60 but less than 0.75 and also in the lowest 12 percent of contracts ordered by reliability. The standard error would be considered when the measure score is below the 15th percentile (in base group 1), significantly below average, and has low reliability: In this case, 1 star would be assigned if and only if the measure score is at least 1 standard error below the unrounded cut point between base groups 1 and 2. Similarly, when the measure score is at or above the 80th percentile (in base group 5), significantly above average, and has low reliability, 5 stars would be assigned if and only if the measure score is at least 1 standard error above the unrounded cut point between base groups 4 and 5.

                  Table 4--CAHPS Star Assignment Rules ------------------------------------------------------------------------           Star                  Criteria for assigning star ratings ------------------------------------------------------------------------ 1.......................  A contract is assigned one star if both                            criteria (a) and (b) are met plus at least                            one of criteria (c) and (d):                           (a) Its average CAHPS measure score is lower                            than the 15th percentile; AND                           (b) its average CAHPS measure score is                            statistically significantly lower than the                            national average CAHPS measure score;                           (c) the reliability is not low; OR                           (d) its average CAHPS measure score is more                            than one standard error (SE) below the 15th                            percentile.

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  2.......................  A contract is assigned two stars if it does                            not meet the one[dash]star criteria and meets                            at least one of these three criteria:                           (a) Its average CAHPS measure score is lower                            than the 30th percentile and the measure does                            not have low reliability; OR                           (b) its average CAHPS measure score is lower                            than the 15th percentile and the measure has                            low reliability; OR                           (c) its average CAHPS measure score is                            statistically significantly lower than the                            national average CAHPS measure score and                            below the 60th percentile. 3.......................  A contract is assigned three stars if it meets                            at least one of these three criteria:                           (a) Its average CAHPS measure score is at or                            above the 30th percentile and lower than the                            60th percentile, AND it is not statistically                            significantly different from the national                            average CAHPS measure score; OR                           (b) its average CAHPS measure score is at or                            above the 15th percentile and lower than the                            30th percentile, AND the reliability is low,                            AND the score is not statistically                            significantly lower than the national average                            CAHPS measure score; OR                           (c) its average CAHPS measure score is at or                            above the 60th percentile and lower than the                            80th percentile, AND the reliability is low,                            AND the score is not statistically                            significantly higher than the national                            average CAHPS measure score. 4.......................  A contract is assigned four stars if it does                            not meet the 5-star criteria and meets at                            least one of these three criteria:                           (a) Its average CAHPS measure score is at or                            above the 60th percentile and the measure                            does not have low reliability; OR                           (b) its average CAHPS measure score is at or                            above the 80th percentile and the measure has                            low reliability; OR                           (c) its average CAHPS measure score is                            statistically significantly higher than the                            national average CAHPS measure score and                            above the 30th percentile. 5.......................  A contract is assigned five stars if both                            criteria (a) and (b) are met plus at least                            one of criteria (c) and (d):                           (a) Its average CAHPS measure score is at or                            above the 80th percentile; AND                           (b) its average CAHPS measure score is                            statistically significantly higher than the                            national average CAHPS measure score;                           (c) the reliability is not low; OR                           (d) its average CAHPS measure score is more                            than one SE above the 80th percentile. ------------------------------------------------------------------------

    We request comments on our proposed methods to determine cut points. For certain measures, we previously published pre-determined 4- star thresholds. If commenters recommend pre-determined 4-star thresholds, we request suggestions on how to minimize generating Star Ratings that do not reflect a contract's ``true'' performance, otherwise referred to as the risk of ``misclassifying'' a contract's performance (for example, scoring a ``true'' 4-star contract as a 3- star contract, or vice versa, or creating ``cliffs'' in Star Ratings and therefore, potential benefits between plans with nearly identical Star Ratings on different sides of a fixed threshold), and how to continue to create incentives for quality improvement. We also welcome comments on alternative recommendations for revising the cut point methodology. For example, we are considering methodologies that would minimize year-to-year changes in the cut points by setting the cut points so they are a moving average of the cut points from the two or three most recent years or setting caps on the degree to which a measure cut point could change from one year to the next. We welcome comments on these particular methodologies and recommendations for other ways to provide stability for cut points from year to year. m. Hierarchical Structure of the Ratings     We propose to continue our existing policy to use a hierarchical structure for the Star Ratings. The basic building block of the MA Star Ratings System is, and under our proposal would continue to be, the measure. Because the MA Star Ratings System consists of a large collection of measures across numerous quality dimensions, the measures would be organized in a hierarchical structure that provides ratings at the measure, domain, Part C summary, Part D summary, and overall levels. The regulation text at Sec. Sec.  422.166 and 423.186 is built on this structure and provides for calculating ratings at each ``level'' of the system. The organization of the measures into larger groups increases both the utility and efficiency of the rating system. At each aggregated level, ratings are based on the measure-level stars. Ratings at the higher level are based on the measure-level Star Ratings, with whole star increments for domains and half-star increments for summary and overall ratings; a rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Half-star increments are used in the summary and overall ratings to allow for more variation at the higher hierarchical levels of the ratings system. We believe this greater variation and the broader range of ratings provide more useful information to beneficiaries in making enrollment decisions while remaining consistent with the statutory direction in sections 1853(o) and 1854(b) of the Act to use a 5-star system. These policies for the assignment of stars would be codified with other rules for the ratings at the domain, summary, and overall level. Domain ratings employ an unweighted mean of the measure-level stars, while the Part C and D summary and overall ratings employ a weighted mean of the measure-level stars and up to two adjustments. We propose to codify these policies at paragraphs (b)(2), (c)(1) and (d)(1) of Sec. Sec.  422.166 and 423.186 n. Domain Star Ratings     Groups of measures that together represent a unique and important aspect of quality and performance are organized to form a domain. Domain ratings summarize a plan's performance on a specific dimension of care. Currently the domains are used purely for purposes of displaying data on Medicare Plan Finder to organize the measures and help consumers interpret the data. We propose to continue this policy at Sec. Sec.  422.166(b)(1)(i) and 423.186(b)(1)(i).     At present, there are nine domains--five for Part C measures for MA-only and MA-PDs plans and four for Part D measures for MA-PDs. We propose to continue to group measures for purposes of display on Medicare Plan Finder and to continue use of the same domains as in current practice in Sec. Sec.  422.166(b)(1)(i) and 423.196(b)(1)(i). The current domains are listed in Tables 5 and 6.

                         Table 5--Part C Domains ------------------------------------------------------------------------                                  Domain ------------------------------------------------------------------------- Staying Healthy: Screenings, Tests and Vaccines. Managing Chronic (Long Term) Conditions. Member Experience with Health Plan.

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  Member Complaints and Changes in the Health Plan's Performance. Health Plan Customer Service. ------------------------------------------------------------------------

                         Table 6--Part D Domains ------------------------------------------------------------------------                                  Domain ------------------------------------------------------------------------- Drug Plan Customer Service. Member Complaints and Changes in the Drug Plan's Performance. Member Experience with the Drug Plan. Drug Safety and Accuracy of Drug Pricing. ------------------------------------------------------------------------

    Currently, Star Ratings for domains are calculated using the unweighted mean of the Star Ratings of the included measures. They are displayed to the nearest whole star, using a 1-5 star scale. We propose to continue this policy at paragraph (b)(2)(ii). We also propose that a contract must have stars for at least 50 percent of the measures required to be reported for that domain for that contract type to have that domain rating calculated in order to have enough data to reflect the contract's performance on the specific dimension. For example, if a contract is rated only on one measure in Staying Healthy: Screenings, Tests and Vaccines, that one measure would not necessarily be representative of how the contract performs across the whole domain so we do not believe it is appropriate to calculate and display a domain rating. We propose to continue this policy by providing, at paragraph (b)(2)(i), that a minimum number of measures must be reported for a domain rating to be calculated. o. Part C and D Summary Ratings     In the current rating system the Part C summary rating provides a rating of the health plan quality and the Part D summary rating provides a rating of the prescription drug plan quality. We are proposing, at Sec. Sec.  422.166(c) and 423.186(c), to codify regulation text governing the adoption of Part C summary ratings and Part D summary ratings. An MA-only plan and a Part D standalone plan would receive a summary rating only for, respectively, Part C measures and Part D measures.     First, in paragraphs (c)(1) of each section, we propose the overall formula for calculating the summary ratings for Part C and Part D. Under current policy, the summary rating for an MA-only contract is calculated using a weighted mean of the Part C measure-level Star Ratings with up to two adjustments: The reward factor (if applicable) and the categorical adjustment index (CAI); similarly, the current summary rating for a PDP contract is calculated using a weighted mean of the Part D measure-level Star Ratings with up to two adjustments: The reward factor (if applicable) and the CAI. We propose in Sec. Sec.   422.166(c)(1) and 423.186(c)(1) that the Part C and Part D summary ratings would be calculated as the weighted mean of the measure-level Star Ratings with an adjustment to reward consistently high performance (reward factor) and the application of the CAI, pursuant to paragraph (f) (where we propose the specifics for these adjustments) for Parts C and D, respectively.     Second, and also consistent with current policy, we propose an MA- only contract and PDP would have a summary rating calculated only if the contract meets the minimum number of rated measures required for its respective summary rating: A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated. The proposed regulation text would be codified as paragraph (c)(2)(i) of Sec. Sec.  422.166 and 423.186 The same rules would be applied to both the Part C and Part D summary ratings for the minimum number of rated measures and flags for display. We would apply this regulation to require a MA-PD to have a Part C and a Part D summary rating if the minimum requirement of rated measures for each summary rating type is met. The improvement measures are based on identified measures that are each counted towards meeting the proposed requirement for the calculation of a summary rating. We propose (at paragraph (c)(2)(ii)) that the improvement measures themselves are not included in the count of minimum number of measures for the Part C or Part D summary ratings.     Third, we propose a paragraph (c)(3) in both Sec. Sec.  422.166 and 423.186 to provide that the summary ratings are on a 1 to 5 star scale in half-star increments. Traditional rounding rules would be employed to round the summary rating to the nearest half-star. The summary rating would be displayed in HPMS and Medicare Plan Finder to the nearest half-star. As proposed in Sec. Sec.  422.166(h) and 423.186(h), if a contract has not met the measure requirement for calculating a summary rating, the display in HPMS (and on Medicare Plan Finder) for the applicable summary rating would be the flag ``Not enough data available'' or if the measurement period is less than 1 year past the contract's effective date the flag would be ``Plan too new to be measured''.     We welcome comments on the calculations for the Part C and D summary ratings. p. Overall Rating     The overall Star Rating is a global rating that summarizes the plan's quality and performance for the types of services offered by the plans under the rated contract. We propose at Sec. Sec.  422.166(d) and 423.186(d) to codify the standards for calculating and assigning overall Star Ratings for MA-PD contracts. The overall rating for an MA- PD contract is proposed to be calculated using a weighted mean of the Part C and Part D measure level Star Ratings, respectively, with an adjustment to reward consistently high performance described in paragraph (f)(1) and the application of the CAI, pursuant to described in paragraph (f)(2).     Consistent with current policy, we propose at paragraph (d)(2) that an MA-PD would have an overall rating calculated only if the contract receives both a Part C and Part D summary rating, and scores for at least 50% of the measures are required to be reported for the contract type to have the overall rating calculated. As with the Part C and D summary ratings, the Part C and D improvement measures would not be included in the count for the minimum number of measures for the overall rating. Any measure that shares the same data and is included in both the Part C and Part D summary ratings would be included only once in the calculation for the overall rating; for example, Members Choosing to Leave the Plan and Complaints about the Plan. As with summary ratings, we propose that overall MA-PD ratings would use a 1 to 5 star scale in half-star increments; traditional rounding rules would be employed to round the overall rating to the nearest half-star. These policies are proposed as paragraphs (d)(2)(i) through (iv).     In accordance with our general proposed policy at Sec. Sec.   422.166(h) and 423.186(h), the overall rating would be posted on HPMS and Medicare Plan Finder, with specific messages for lack of ratings for certain reasons. Applying that rule, if an MA-PD contract has only one of the two required summary ratings, the overall rating would not be calculated and the display in HPMS would be the flag ``Not enough data available.''     For QBP purposes, low enrollment contracts and new MA plans are defined in Sec.  422.252 Low enrollment contract

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means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcomes Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan; new MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. Low enrollment contracts and new plans do not receive an overall or summary rating because of the lack of necessary data. However, they are treated as qualifying plans for the purposes of QBPs. Section 1853(o)(3)(A)(ii)(II) of the Act, as implemented at Sec.  422.258(d)(7), provides that for 2013 and subsequent years, CMS shall develop a method for determining whether an MA plan with low enrollment is a qualifying plan for purposes of receiving an increase in payment under section 1853(o). This determination is applied at the contract level and thus determines whether a contract (meaning all plans under that contract) is a qualifying contract. The statute, at section 1853(o)(3)(A)(iii) of the Act, provides for treatment of new MA plans as qualifying plans eligible for a specific QBP. We therefore propose, at Sec. Sec.   422.166(d)(3) and 423.186(d)(3), that low enrollment contracts (as defined in Sec.  422.252 of this chapter) and new MA plans (as defined in Sec.  422.252 of this chapter) do not receive an overall and/or summary rating; they would be treated as qualifying plans for the purposes of QBPs as described in Sec.  422.258(d)(7) of this chapter and announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. This proposal would merely codify existing policy and practice. q. Measure Weights     Prior to the 2012 Part C and D Plan Ratings (now known as Star Ratings), all individual measures included in the program were weighted equally, suggesting equal importance. Based on feedback from stakeholders, including health and drug plans and beneficiary advocacy groups, we moved to provide greater weight to clinical outcomes and lesser weight to process measures. Patient experience and access measures were also given greater weight than process measures, but not as high as outcome measures. The differential weighting was implemented to help create further incentives to drive improvement in clinical outcomes, patient experience, and access. These differential weights for measures were implemented for the 2012 Ratings following a May 2011 Request for Comments and adopted in the CY2013 Rate Announcement and Final Call Letter.     In the Contract Year 2012 Final Rule for Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs rule (79 FR 21486), we stated that scoring methodologies should also consider improvement as an independent goal. To this end, we implemented in the CY 2013 Rate Announcement the Part C and D improvement measures that measure the overall improvement or decline in individual measure scores from the prior to the current year. Given the importance of recognizing quality improvement as an independent goal, for the 2015 Star Ratings, we proposed and subsequently finalized through the 2015 Rate Announcement and final Call Letter an increase in the weight of the improvement measure from 3 times to 5 times that of a process measure. This weight aligns the Part C and D Star Ratings program with value- based purchasing programs in Medicare fee-for-service which heavily weight improvement.     We are proposing in Sec. Sec.  422.166(e) and 423.186(e) to continue the current weighting of measures in the Part C and D Star Ratings program by assigning the highest weight (5) to improvement measures, followed by outcome and intermediate outcome measures (weight of 3), then by patient experience/complaints and access measures (weight of 1.5), and finally process measures (weight of 1). We are considering increasing the weight of the patient experience/complaints and access measures and are interested in stakeholder feedback on this potential change in order to reflect better the importance of these issues in plan performance. If we were to increase the weight, we are considering increasing it from a weight of 1.0 to between 1.5 and 3 similar to outcome measures. This increased weight would reflect CMS' commitment to serve Medicare beneficiaries by putting the patients first, including their assessments of the care received by plans. We solicit comment on this point, particularly the potential change in the weight of the patient experience/complaints and access measures.     Table 7 includes the proposed measure categories, the definitions of the measure categories, and the weights. In calculating the summary and overall ratings, a measure given a weight of 3 counts three times as much as a measure given a weight of 1. In section III.A.12 of this proposed rule, we propose (as Table 2) the measure set and include the category and weight for each measure; those weight assignments are consistent with this proposal. We propose that as new measures are added to the Part C and D Star Ratings, we would assign the measure category based on these categories and the regulation text proposed at Sec. Sec.  422.166(e) and 423.186(e), subject to two exceptions. We propose in paragraphs (e)(2) of each section as the first exception, to assign new measures to the Star Ratings program a weight of 1 for their first year in the Star Ratings. In subsequent years the weight associated with the measure weighting category would be used. This is consistent with current policy.

                              Table 7--Measure Categories, Definitions and Weights ----------------------------------------------------------------------------------------------------------------               Measure category                                    Definition                          Weight ---------------------------------------------------------------------------------------------------------------- Improvement.................................  Part C and Part D improvement measures are derived               5                                                through comparisons of a contract's current and                                                prior year measure scores. Outcome and Intermediate Outcome............  Outcome measures reflect improvements in a                       3                                                beneficiary's health and are central to assessing                                                quality of care. Intermediate outcome measures                                                reflect actions taken which can assist in                                                improving a beneficiary's health status.                                                Controlling Blood Pressure is an example of an                                                intermediate outcome measure where the related                                                outcome of interest would be better health status                                                for beneficiaries with hypertension. Patient Experience/Complaints...............  Patient experience measures reflect beneficiaries'             1.5                                                perspectives of the care and services they                                                received. Access......................................  Access measures reflect processes and issues that              1.5                                                could create barriers to receiving needed care.                                                Plan Makes Timely Decisions about Appeals is an                                                example of an access measure.

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  Process.....................................  Process measures capture the health care services                1                                                provided to beneficiaries which can assist in                                                maintaining, monitoring, or improving their                                                health status. ----------------------------------------------------------------------------------------------------------------

    In addition, we propose (at Sec. Sec.  422.166(e)(3) and 423.186(e)(3)) a second exception to the general weighting rule for MA and Part D contracts that have service areas that are wholly located in Puerto Rico. We recognize the additional challenge unique to Puerto Rico related to the medication adherence measures used in the Star Ratings Program due to the lack of Low Income Subsidy (LIS). For the 2017 Star Ratings, we implemented a different weighting scheme for the Part D medication adherence measures in the calculation of the overall and summary Star Ratings for contracts that solely serve the population of beneficiaries in Puerto Rico. We propose, at Sec. Sec.   422.166(e)(3) and 423.186(e)(3), to continue to reduce the weights for the adherence measures to 0 for the summary and overall rating calculations and maintain the weight of 3 for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico. We request comment on our proposed weighting strategy for Measure Weights generally and for Puerto Rico, including the weighting values themselves. r. Application of the Improvement Measure Scores     Consistent with current policy, we propose at Sec. Sec.  422.166(g) and 423.186(g) a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings. We are proposing, in paragraphs (g)(1)(i) through (iii), a series of rules that specify when the improvement measure is included in calculating overall and summary ratings.     MA-PDs would have the hold harmless provisions for highly-rated contracts applied for the overall rating. For an MA-PD that receives an overall rating of 4 stars or more without the use of the improvement measures and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded overall rating with and without the improvement measures is done. The overall rating with the improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The overall rating without the improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The higher overall rating would be used for the overall rating. For an MA-PD that has an overall rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the overall rating would exclude the improvement measure. For all others, the overall rating would include the improvement measure.     MA-only and PDPs would have the hold harmless provisions for highly-rated contracts applied for the Part C and D summary ratings, respectively. For an MA-only or PDP that receives a summary rating of 4 stars or more without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded summary rating with and without the improvement measure and up to two adjustments, the reward factor (if applicable) and CAI, is done. The higher summary rating would be used for the summary rating for the contract's highest rating. For MA-only and PDPs with a summary rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the summary rating would exclude the improvement measure. For all others, the summary rating would include the improvement measure. MA-PDs would have their summary ratings calculated with the use of the improvement measure regardless of the value of the summary rating.     In addition, at paragraph (g)(2), we also propose text to clarify that summary ratings use only the improvement measure associated with the applicable Part C or D performance.     We welcome comments on the hold harmless improvement provision we propose to continue to use, particularly any clarifications in how and when it should be applied. s. Reward Factor (Formerly Referred to as Integration Factor)     In 2011, the integration factor was added to the Star Ratings methodology to reward contracts that have consistently high performance. The integration factor was later renamed the reward factor. (The reference to either reward or integration factor refers to the same aspect of the Star Ratings.) This factor is calculated separately for the Part C summary rating, Part D summary rating for MA- PDs, Part D summary rating for PDPs, and the overall rating for MA-PDs. It is currently added to the summary (Part C or D) and overall rating of contracts that have both high and stable relative performance for the associated summary or overall rating. The contract's performance will be assessed using its weighted mean relative to all rated contracts without adjustments.     The contract's stability of performance will be assessed using its weighted variance relative to all rated contracts at the same rating level (overall, summary Part C, and summary Part D). The Part D summary thresholds for MA-PDs are determined independently of the thresholds for PDPs. We propose to codify the calculation and use of the reward factor in Sec. Sec.  422.166(f)(1) and 423.186(f)(1).     Annually, we propose to update the performance and variance thresholds for the reward factor based upon the data for the Star Ratings year, consistent with current policy. A multistep process would be used to determine the values that correspond to the thresholds for the reward factors for the summary and/or overall Star Ratings for a contract. The determination of the reward factors would rely on the contract's ranking of its weighted variance and weighted mean of the measure-level stars to the summary or overall rating relative to the distribution of all contracts' weighted variance and weighted mean to the summary and/or overall rating. A contract's weighted variance would be calculated using the quotient of the following two values: (1) The product of the number of applicable measures based on rating-type and the sum of the products of the weight of each applicable measure and its squared deviation \42\ and (2) the product of one less than the number of applicable measures and the sum of the weights of the applicable measures. A contract's weighted mean performance would be

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found by calculating the quotient of the following two values: (1) The sum of the products of the weight of a measure and its associated measure-level Star Ratings of the applicable measures for the rating- type and (2) the sum of the weights of the applicable measures for the rating type. The thresholds for the categorization of the weighted variance and weighted mean for contracts would be based upon the distribution of the calculated values of all rated contracts of the same type. Because highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean is calculated both with and without the improvement measures. ---------------------------------------------------------------------------

    \42\ A deviation is the difference between the performance measure's Star Rating and the weighted mean of all applicable measures for the contract. ---------------------------------------------------------------------------

    A contract's weighted variance is categorized into one of three mutually exclusive categories, identified in Table 8A, based upon the weighted variance of its measure-level Star Ratings and its ranking relative to all other contracts' weighted variance for the rating type (Part C summary for MA-PDs and MA-only, overall for MA-PDs, Part D summary for MA-PDs, and Part D summary for PDPs), and the manner in which the highest rating for the contract was determined--with or without the improvement measure(s). For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance for the rating type (Part C summary, Part D summary) with the improvement measure. Similarly, a contract's weighted mean is categorized into one of three mutually exclusive categories, identified in Table 8B, based on its weighted mean of all measure-level Star Ratings and its ranking relative to all other contracts' weighted means for the rating type (Part C summary for MA-PDs and MA-only, overall, Part D summary for MA-PDs, and Part D summary for PDPs) and the manner in which the highest rating for the contract was determined--with or without the improvement measure(s). For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted means for the rating type (Part C summary, Part D summary) with the improvement measure. Further, the same threshold criterion is employed per category regardless of whether the improvement measure was included or excluded in the calculation of the rating. The values that correspond to the thresholds are based on the distribution of all rated contracts and are determined with and without the improvement measure(s) and exclusive of any adjustments. Table 8A details the criteria for the categorization of a contract's weighted variance for the summary and overall ratings. Table 8B details the criteria for the categorization of a contract's weighted mean (performance) for the overall and summary ratings. The values that correspond to the cutoffs are provided each year during the plan preview and are published in the Technical Notes.

                                      Table 8A--Categorization of a Contract Based on Its Weighted Variance Ranking --------------------------------------------------------------------------------------------------------------------------------------------------------                 Variance category                                                                 Ranking -------------------------------------------------------------------------------------------------------------------------------------------------------- Low.............................................  Below the 30th percentile. Medium..........................................  At or above the 30th percentile to less than the 70th percentile. High............................................  At or above the 70th percentile. --------------------------------------------------------------------------------------------------------------------------------------------------------

                                   Table 8B--Categorization of a Contract Based on Weighted Mean (Performance) Ranking --------------------------------------------------------------------------------------------------------------------------------------------------------       Weighted mean  (performance) category                                                       Ranking -------------------------------------------------------------------------------------------------------------------------------------------------------- High............................................  At or above the 85th percentile. Relatively High.................................  At or above the 65th percentile to less than the 85th percentile. Other...........................................  Below the 65th percentile. --------------------------------------------------------------------------------------------------------------------------------------------------------

    These definitions of high, medium, and low weighted variance ranking and high, relatively high, and other weighted mean ranking would be codified in narrative form in paragraph (f)(1)(ii).     A contract's categorization for both weighted mean and weighted variance determines the value of the reward factor. Table 9 shows the values of the reward factor based on the weighted variance and weighted mean categorization; these values would be codified, as a chart, in paragraph (f)(i)(iii). The weighted variance and weighted mean thresholds for the reward factor are available in the Technical Notes and updated annually.

       Table 9--Categorization of a Contract for the Reward Factor ------------------------------------------------------------------------                                         Weighted mean          Weighted variance              (performance)     Reward  factor ------------------------------------------------------------------------ Low...............................  High................             0.4 Medium............................  High................             0.3 Low...............................  Relatively High.....             0.2 Medium............................  Relatively high.....             0.1 High..............................  Other...............             0.0 ------------------------------------------------------------------------

    We propose to continue the use of a reward factor to reward contracts with consistently high and stable performance over time. Further, we propose to continue to employ the methodology described in this subsection to categorize and determine the reward factor for contracts. As proposed in paragraphs (c)(1) and (d)(1), these reward factor adjustments would be applied at the summary and overall rating level.

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t. Categorical Adjustment Index     A growing body of evidence links the prevalence of beneficiary- level social risk factors with performance on measures included in Medicare value-based purchasing programs, including MA and Part D Star Ratings. With support from our contractors, we undertook research to provide scientific evidence as to whether MA organizations or Part D sponsors that enroll a disproportionate number of vulnerable beneficiaries are systematically disadvantaged by the current Star Ratings. In 2014, we issued a Request for Information to gather information directly from organizations to supplement the data that CMS collects, as we believe that plans and sponsors are uniquely positioned to provide both qualitative and quantitative information that is not available from other sources. In February and September 2015, we released details on the findings of our research.\43\ We have also reviewed reports about the impact of socio-economic status (SES) on quality ratings, such as the report published by the NQF posted at [*www.qualityforum.org/risk\_adjustment\_ses.aspx*](http://www.qualityforum.org/risk_adjustment_ses.aspx) and the Medicare Payment Advisory Commission's (MedPAC) Report to the Congress: Medicare Payment Policy posted at   [*http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0*](http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0). We have more recently been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE \44\) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and we have been considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use in nine Medicare value-based purchasing programs. The report also included considerations for strategies to account for social risk factors in these programs. A January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.\45\ ---------------------------------------------------------------------------

    \43\ The February release can be found at [*https://www.cms.gov/medicareprescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html*](https://www.cms.gov/medicareprescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html)     The September release can be found at   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf)     \44\   [*https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*](https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs).     \45\ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press--   [*https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social*](https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social). ---------------------------------------------------------------------------

    We have also engaged NCQA and the PQA to examine their measure specifications used in the Star Ratings program to determine if re- specification is warranted. The majority of measures used for the Star Ratings program are consensus-based. Measure specifications can be changed only by the measure steward (the owner and developer of the measure). Thus, measure scores cannot be adjusted for differences in enrollee case mix unless required by the measure steward. Measure re- specification is a multiyear process. For example, NCQA has a standard process for reviewing any measure and determining whether a measure requires re-specification. NCQA's re-evaluation process is designed to ensure any resulting measure updates have desirable attributes of relevance, scientific soundness, and feasibility:      Relevance describes the extent to which the measure captures information important to different groups, for example, consumers, purchasers, policymakers. To determine relevance, NCQA assesses issues such as health importance, financial importance, and potential for improvement among entities being measured.      Scientific soundness captures the extent to which the measure adheres to clinical evidence and whether the measure is valid, reliable, and precise.      Feasibility captures the extent to which a measure can be collected at reasonable cost and without undue burden. To determine feasibility, NCQA also assesses whether a measure is precisely specified and can be audited. The overall process for assessing the value of re-specification emphasizes multi-stakeholder input, use of evidence-based guidelines and data, and wide public input.     Beginning with 2017 Star Ratings, we implemented the CAI that adjusts for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy and/or are dual eligible (LIS/DE) and/or have disability status. We developed the CAI as an interim analytical adjustment while we developed a long-term solution. The adjustment factor varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and beneficiaries with disabilities. By design, the CAI values are monotonic in at least one dimension (LIS/DE or disability status) and thus, contracts with larger LIS/DE and/or disability percentages realize larger positive adjustments. MA-PD contracts can have up to three rating-specific CAI adjustments--one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). MA-only contracts can have one adjustment for the Part C summary rating. PDPs can have one adjustment for the Part D summary rating. We propose to codify the calculation and use of the reward factor and the CAI in Sec. Sec.  422.166(f)(2) and 423.186(f)(2), while we consider other alternatives for the future.     As is currently done today, the adjusted measure scores of a subset of the Star Ratings measures would serve as the foundation for the determination of the index values. Measures would be excluded as candidates for adjustment if the measures are already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures), if the focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures), if the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied, or if the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). We propose to codify these paragraphs for determining the measures for CAI values at paragraph (f)(2)(ii).The categorization of a beneficiary as LIS/DE for the CAI would rely on the monthly indicators in the enrollment file. For the determination of the CAI values, the measurement period would correspond to the previous Star Ratings year's measurement period. For the identification of a contract's final adjustment category for its application of the CAI in the current year's Star Ratings Program, the measurement period would align with the Star Ratings year. If a beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period, the

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beneficiary would be categorized as LIS/DE. For the categorization of a beneficiary as disabled, we would employ the information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems. Disability status would be determined using the variable original reason for entitlement (OREC) for Medicare. The percentages of LIS/DE and disability per contract would rely on the Medicare enrollment data from the applicable measurement year. The counts of beneficiaries for enrollment and categorization of LIS/DE and disability would be restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. Further, a beneficiary would be assigned to the contract based on the December file of the applicable measurement period. We propose to codify these paragraphs for determining the enrollment counts at paragraph (f)(2)(i)(B).     Using the subset of the measures that meet the basic inclusion requirements, we propose to select the measure set for adjustment based on the analysis of the dispersion of the LIS/DE within-contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. For the selection of the Part D measures, MA-PDs and PDPs would be independently analyzed. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately, and the difference between the LIS/DE and non-LIS/DE performance rates per contract would be calculated. CMS would use a logistic mixed effects model for estimation purposes that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract and LIS/DE.     Using the analysis of the dispersion of the within-contract disparity of all contracts included in the modelling, the measures for adjustment would be identified employing the following decision criteria: (1) A median absolute difference between LIS/DE and non-LIS/ DE beneficiaries for all contracts analyzed is 5 percentage points or more or \46\ (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts. We propose to codify these paragraphs for the selection criteria for the adjusted measures for the CAI at paragraph (f)(2)(iii). ---------------------------------------------------------------------------

    \46\ The use of the word `or' in the decision criteria implies that if one condition or both conditions are met, the measure would be selected for adjustment. ---------------------------------------------------------------------------

    The Part D measures for PDPs would be analyzed separately. In order to apply consistent adjustments across MA-PDs and PDPs, the Part D measures would be selected by applying the selection criteria to MA-PDs and PDPs independently and, then, selecting measures that met the criteria for either delivery system. The measure set for adjustment of Part D measures for MA-PDs and PDPs would be the same after applying the selection criteria and pooling the Part D measures for MA-PDs and PDPs. We propose to codify these paragraphs for the selection of the adjusted measure set for the CAI for MA-PDs and PDPs at (f)(2)(iii)(C). We also seek comment on the proposed methodology and criteria for the selection of the measures for adjustment. Further, we seek comment on alternative methods or rules to select the measures for adjustment for future rulemaking.     Annually, while the CAI is being developed using the rules we are proposing here, we would release on CMS.gov an updated analysis of the subset of the Star Ratings measures identified for adjustment using this rule as ultimately finalized. Basic descriptive statistics would include the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences. The set of measures for adjustment for the determination of the CAI would be announced in the draft Call Letter.     We propose, at paragraph (f)(2)(iv) of each regulation, to determine the adjusted measure scores for LIS/DE and disability status from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts. The approach employed to determine the adjusted measure scores approximates case-mix adjustment using a beneficiary-level, logistic regression model with contract fixed effects and beneficiary- level indicators of LIS/DE and disability status, similar to the approach currently used to adjust CAHPS patient experience measures. However, unlike CAHPS case-mix adjustment, the only adjusters would be LIS/DE and disability status.     The sole purpose of the adjusted measure scores is for the determination of the CAI values. The adjusted measure scores would be converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.     All contracts would have their adjusted summary rating(s) and for MA-PDs, an adjusted overall rating, calculated employing the standard methodology proposed at Sec. Sec.  422.166 and 423.186 (which would also be outlined in the Technical Notes each year), using the subset of adjusted measure-level Star Ratings and all other unadjusted measure- level Star Ratings. In addition, all contracts would have their summary rating(s) and for MA-PDs, an overall rating, calculated using the traditional methodology and all unadjusted measure-level Star Ratings.     For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled). The initial categories would be created using all groups formed by the initial LIS/DE and disabled groups. The total number of initial categories would be the product of the number of initial groups for LIS/DE and the number of initial groups for the disabled dimension.     The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled). The mean difference within each final adjustment category by rating-type (Part C, Part D for MA-PD, Part D for PDPs, or overall) would be the CAI values for the next Star Ratings year.     The percentage of LIS/DE is a critical element in the categorization of contracts into the final adjustment category to identify a contract's CAI. Starting with the 2017 Star Ratings, we applied an additional adjustment for contracts that solely serve the population of beneficiaries in Puerto Rico to address the lack of LIS in Puerto Rico. The adjustment results in a modified percentage of LIS/ DE beneficiaries that is subsequently used to categorize contracts into the final adjustment category for the CAI.     We propose to continue this adjustment and to calculate the contract-level modified LIS/DE percentage for Puerto Rico using the following sources of information: The most recent data available at the time of the development of the model of both the 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL, and

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the Medicare enrollment data from the same measurement period used for the Star Ratings year.     The data to develop the model would be limited to the 10 states, drawn from the 50 states plus the District of Columbia, with the highest proportion of people living below the FPL as identified by the 1-year ACS estimates. Further, the Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states. A linear regression model would be developed using the known LIS/DE percentage and the corresponding DE percentage from the subset of MA contracts.     The estimated slope from the linear regression approximates the expected relationship between LIS/DE for each contract in Puerto Rico and its DE percentage. The intercept term is adjusted for use with Puerto Rico contracts by assuming that the Puerto Rico model will pass through the point (x, y) where x is the observed average DE percentage in the Puerto Rico contracts based on the enrollment data, and y is the expected average percentage of LIS/DE in Puerto Rico. The expected average percentage of LIS/DE in Puerto Rico (the y value) is not observable, but is estimated by multiplying the observed average percentage of LIS/DE in the 10 highest poverty states by the ratio based on the most recent 5-year ACS estimates of the percentage living below 150 percent of the FPL in Puerto Rico compared to the corresponding percentage in the set of 10 states with the highest poverty level. (Further details of the methodology can be found in the CAI Methodology Supplement available at [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings).)     Using the model developed from this process, the estimated modified LIS/DE percentage for contracts operating solely in Puerto Rico would be calculated. The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent. All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.     We propose to continue to employ the LIS/DE indicator for contracts operating solely in Puerto Rico while the CAI is being used as an interim analytical adjustment. Further, we propose that the modeling results would continue to be detailed in the appendix of the Technical Notes and the modified LIS/DE percentages would be available for contracts to review during the plan previews.     We propose to continue the use of the CAI while the measure stewards continue their examination of the measure specifications and ASPE completes their studies mandated by the IMPACT Act and formalizes final recommendations. Contracts would be categorized based on their percentages of LIS/DE and disability using the data as outlined previously. The CAI value would be the same for all contracts within each final adjustment category. The CAI values would be determined using data from all contracts that meet reporting requirements from the prior year's Star Rating data. The CAI calculation for the PDPs would be performed separately and use the PDP specific cut points. Under our proposal, CMS would include the CAI values in the draft and final Call Letter attachment of the Advance Notice and Rate Announcement each year while the interim solution is applied. The values for the CAI value would be displayed to 6 decimal places. Rounding would take place after the application of the CAI value and if applicable, the reward factor; standard rounding rules would be employed. (All summary and overall Star Ratings are displayed to the nearest half-star.)     While we consider the recommendations from the ASPE report, findings from measure developers, and work by NQF on risk adjustment for quality measures, we are continuing to collaborate with stakeholders. We are seeking to balance accurate measurement of genuine plan performance, effective identification of disparities, and maintenance of incentives to improve the outcomes for disadvantaged populations. Keeping this in mind, we continue to seek public comment on whether and how we should account for low SES and other social risk factors in the Part C and D Star Ratings.     We look forward to continuing to work with stakeholders as we consider the issue of accounting for LIS/DE, disability and other social risk factors and reducing health disparities in CMS programs. As we have stated previously, we are continuing to consider options to how to measure and account for social risk factors in our Star Ratings program. What we discovered though our research to date is, although a sponsoring organization's administrative costs may increase as a result of enrolling significant numbers of beneficiaries with LIS/DE status or disabilities, the impacts of SES on the quality ratings are quite modest, affect only a small subset of measures, and do not always negatively impact the measures. However, CMS would like to better understand whether, how, and to what extent a sponsoring organization's administrative costs differ for caring for low-income beneficiaries and we welcome comment on that topic. Administrative costs may include non- medical costs such as transportation costs, coordination costs, marketing, customer service, quality assurance and costs associated with administering the benefit. We continue our commitment toward ensuring that all beneficiaries have access to and receive excellent care, and that the quality of care furnished by plans is assessed fairly in CMS programs. u. High and Low Performing Icons     Consistent with our current practice, we are proposing regulation text to govern assignment of high and low performing icons at Sec. Sec.  422.166(i) and 423.186(i). We propose to continue current policy that a contract would receive a high performing icon as a result of its performance on the Part C and D measures. The high performing icon would be assigned to an MA-only contract for achieving a 5-star Part C summary rating, a PDP contract for a 5-star Part D summary rating, and an MA-PD contract for a 5-star overall rating.     We propose that a contract would receive a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon would be calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years (for example, the 2016, 2017, and 2018 Star Ratings). If the contract had any combination of Part C and Part D summary ratings of 2.5 or lower in all 3 years of data, it would be marked with a low performing icon. A contract must have a summary rating in either Part C or Part D for all 3 years to be considered for this icon. These rules would be codified at Sec. Sec.  422.166(i)(2)(i) and 423.186(i)(2)(i).     We also propose, at paragraph (i)(2)(ii), to continue our policy of disabling the Medicare Plan Finder online enrollment function for Medicare health and prescription drug plans with the low-performing icon to ensure that beneficiaries are fully aware that they are enrolling in a plan with low quality and performance ratings; we believe this is an important beneficiary protection to ensure that the decision to enroll in a low rated and low performing plan has been thoughtfully considered. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in ***geographical*** areas with limited plans) will be warned, via explanatory

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messaging of the plan's poorly rated performance and directed to contact the plan directly to enroll. v. Plan Preview of Star Ratings     We propose in Sec. Sec.  422.166(i)(3) and 423.186(i)(3) that CMS have plan preview periods before each Star Ratings release, consistent with current practice. Part C and D sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the first plan preview, we expect Part C and D sponsors to closely review the methodology and their posted numeric data for each measure. The second plan preview would include any revisions made as a result of the first plan preview. In addition, our preliminary Star Ratings for each measure, domain, summary score, and overall score would be displayed. During the second plan preview, we expect Part C and D sponsors to again closely review the methodology and their posted data for each measure, as well as their preliminary Star Rating assignments. As part of this regulation, we are proposing that CMS continue to offer plan preview periods, but are not codifying the details of each period because over time the process has evolved to provide more data to sponsors to help validate their data. We envision it to continue to evolve in the future and do not believe that codifying specific display content is necessary.     It is important that Part C and D sponsors regularly review their underlying measure data that are the basis for the Part C and D Star Ratings. For measures that are based on data reported directly from sponsors, any issues or problems should be raised well in advance of CMS' plan preview periods. A draft version of the Technical Notes would be available during the first plan preview. The draft is then updated for the second plan preview and finalized when the ratings data have been posted to Medicare Plan Finder.     We welcome comments on the proposed plan preview process. w. Technical Changes     We also propose a number of technical changes to other existing regulations that refer to the quality ratings of MA and Part D plans; we propose to make technical changes to refer to the proposed new regulation text that provides for the calculation and assignment of Star Ratings. Specifically, we propose:      In Sec.  422.258(d)(7), to revise paragraph (d)(7) to read: Increases to the applicable percentage for quality. Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to the 5-star rating system (based on the data collected under section 1852(e) of the Act) specified in subpart D of this part 422. Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.      In Sec.  422.260(a), to revise the paragraph to read: Scope. The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA-PDs and Part C summary rating for MA-only contracts for the contract assigned pursuant to subpart 166 of this part 422.      In Sec.  422.260(b), to revise the definition of ``quality bonus payment (QBP) determination methodology'' to read: Quality bonus payment (QBP) determination methodology means the quality ratings system specified in subpart 166 of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP.      In Sec.  422.504(a)(18), to revise paragraph (a)(18) to read: To maintain a Part C summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 166 of this part 422. A Part C summary plan rating is calculated as provided in Sec.  422.166      In Sec.  423.505(b)(26), to revise paragraph (b)(26) to read: Maintain a Part D summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in Sec.  423.186     We welcome comment on these technical changes and whether there are additional changes that should be made to account for our proposal to codify the Star Ratings methodology and measures in regulation text. 12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (Sec. Sec.  423.100, 423.505)     Section 1860D-4(b)(1)(A) of the Act and Sec.  423.120(a)(8)(i) require a Part D plan sponsor to contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. Section 423.505(b)(18) requires Part D plan sponsors to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.     In the preamble to final rule published on January 28, 2005 (January 2005 final rule) (70 FR 4194) which implemented Sec.   423.120(a)(8)(i) and Sec.  423.505(b)(18), we indicated that standard terms and conditions, particularly for payment terms, could vary to accommodate geographic areas or types of pharmacies, so long as all similarly situated pharmacies were offered the same terms and conditions. We also stated that we viewed these standard terms and conditions as a ``floor'' of minimum requirements that all similarly situated pharmacies must abide by, but that Part D plans could modify some standard terms and conditions to encourage participation by particular pharmacies. We believe this approach strikes an appropriate balance between the any willing pharmacy requirement at section 1860D- 4(b)(1)(A) of the Act and the provisions of section 1860D-4(b)(1)(B) of the Act, which permits Part D plan sponsors to offer reduced cost sharing at preferred pharmacies.     The balancing of these goals has led to the development of preferred pharmacy networks in which certain pharmacies agree to additional or different terms from the standard terms and conditions. This has resulted in the development of ``standard'' terms and conditions that in some cases has had the effect, in our view, of circumventing the any willing pharmacy requirements and inappropriately excluding pharmacies from network participation. This section is intended to clarify or modify our interpretation of the existing regulations to ensure that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement.     First, we intend to clarify that the any willing pharmacy requirement applies to all pharmacies, regardless of how they have organized one or more lines of pharmacy business. Second, we propose to revise the definition of retail pharmacy and define mail-order pharmacy. Third, we propose to clarify our regulatory requirements for what constitutes ``reasonable and relevant'' standard contract terms and conditions. Finally, we propose to codify our existing guidance with respect to when a pharmacy must be provided with a

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Part D plan sponsor's standard terms and conditions. a. Any Willing Pharmacy Required for All Pharmacy Business Models     With the pharmaceutical distribution and pharmacy practice landscape evolving rapidly, and because pharmacies now frequently have multiple lines of business, many pharmacies no longer fit squarely into traditional pharmacy type classifications. For example, compounding pharmacies and specialty pharmacies, including but not limited to manufacturer-limited-access pharmacies, and those that may specialize in certain drugs, disease states, or both, are increasingly common, and Part D enrollees increasingly need access to their services. As noted previously, in implementing the any willing pharmacy provision, we indicated that standard terms and conditions could vary to accommodate different types of pharmacies so long as all similarly situated pharmacies were offered the same terms and conditions. In the original rule to implement Part D (70 FR 4194, January 28, 2005), we defined certain types of pharmacies (that is, retail, mail order, Long Term Care (LTC)/institutional, and I/T/U [Indian Health Service, Indian tribe or tribal organization, or urban Indian organization]) at Sec.   423.100 to operationalize various statutory provisions that specifically mention these types of pharmacies (for example, section 1860D-4(b)(1)(C)(iv) of the Act). However, these definitions were never intended to limit the scope of the any willing pharmacy requirement. Nevertheless, we have anecdotal evidence that some Part D plan sponsors have declined to permit willing pharmacies to participate in their networks on the grounds that they do not meet the Part D plan sponsor's definition of a pharmacy type for which it has developed standard terms and conditions.     Section 1860D-4(b)(1)(A) of the Act requires Part D plan sponsors to permit the participation of ``any pharmacy'' that meets the standard terms and conditions. Accordingly, it is not appropriate for Part D plan sponsors to offer standard terms and conditions for network participation that are specific to only one particular type of pharmacy, and then decline to permit a willing pharmacy to participate on the grounds that it does not squarely fit into that pharmacy type. Therefore, we are clarifying in this preamble that although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. In particular, we consider ``similarly situated'' pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.     Thus, Part D plan sponsors must not exclude pharmacies from their retail pharmacy networks solely on the basis that they, for example, maintain a traditional retail business while also specializing in certain drugs or diseases or providing home delivery service by mail to surrounding areas. Or as another example, a Part D plan sponsor must not preclude a pharmacy from network participation as a retail pharmacy because that pharmacy also operates a home infusion book of business, or vice versa. Later in this section we are proposing to codify our requirements for when a Part D sponsor must provide a pharmacy with a copy of its standard terms and conditions. These requirements, if finalized, would apply to all pharmacies, regardless of whether they fit into traditional pharmacy classifications or have unique or innovative business or care delivery models. b. Revise the Definition of Retail Pharmacy and Add a Definition of Mail-Order Pharmacy     Since the inception of the Part D program, Part D statute, regulations, and sub-regulatory guidance have referred to ``mail- order'' pharmacy and services without defining the term ``mail order''. Unclear references to the term ``mail order'' have generated confusion in the marketplace over what constitutes ``mail-order'' pharmacy or services. This confusion has contributed to complaints from pharmacies and beneficiaries regarding how Part D plan sponsors classify pharmacies for network participation, the Plan Finder, and Part D enrollee cost-sharing expectations. Additionally, pharmacies that are not mail-order pharmacies, but that may offer home delivery services by mail (relative to that pharmacy's overall operation), have complained because Part D plan sponsors classified them as mail-order pharmacies for network participation and required them to be licensed in all United States, territories, and the District of Columbia, as would be required for traditional mail-order pharmacies providing a mail-order benefit.     In creating the Part D program, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added the convenient access provision of section 1860D-4(b)(1)(C) of the Act and the level playing field provision of section 1860D- 4(b)(1)(D) of the Act. The convenient access provisions, as codified at Sec.  423.120(a)(1)-(7), require Part D plan sponsors to secure the participation in their networks a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary) and includes special provisions for standards with respect to Long Term Care (LTC) and I/T/U pharmacies (as defined at Sec.   423.100). The level playing field provision, as codified at Sec.   423.120(a)(10), requires Part D plan sponsors to permit enrollees to receive the same benefits, including extended days' supplies, through a pharmacy (other than a mail-order pharmacy) (that is, a retail pharmacy), although the Part D plan sponsor may require the enrollee to pay a higher level of cost-sharing to do so.     We currently define ``retail pharmacy'' at Sec.  423.100 to mean ``any licensed pharmacy that is not a mail-order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.'' Although we did not define ``non- retail pharmacy,'' Sec.  423.120(a)(3) provides that ``a Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, ``including pharmacies offering home delivery via mail- order and institutional pharmacies,'' provided the convenient access requirements are met (emphasis added). In the preamble to our January 2005 final rule, we also stated, ``examples of non-retail pharmacies include I/T/U, FQHC, Rural Health Center (RHC) and hospital and other provider-based pharmacies, as well as Part D [plan]-owned and operated pharmacies that serve only plan members'' (see 70 FR 4249). We also stated ``home infusion pharmacies will not count toward Part D plans' pharmacy access requirements (at Sec.  423.120(a)(1)) because they are not retail pharmacies'' (see 70 FR 4250).     Since 2005, our regulation at Sec.  423.120(a) has included access requirements for retail, home infusion, LTC, and I/T/U pharmacies. While mail-order pharmacies could be considered

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one of several subsets of non-retail pharmacies, we never defined the term mail-order pharmacy in regulation, nor have we specified access or service-level requirements at Sec.  423.120(a) for mail-order pharmacies.     As discussed previously, our classifications of certain types of pharmacies were never intended to limit or exclude participation of pharmacies, such as pharmacies with multiple lines of business, that do not fit into one of these classifications. Additionally, we have recognized since our January 2005 final rule that pharmacies may have multiple lines of business, including retail pharmacies that may offer home delivery services (see 70 FR 4235 and 4255).     Nonetheless, despite this guidance and specific access requirements for LTC and HI pharmacies at Sec.  423.120(a), some Part D plan sponsors interpreted ``including pharmacies offering home delivery via mail-order and institutional pharmacies'' at Sec.  423.120(a)(3) to mean that any pharmacies, even retail pharmacies, that may offer home delivery services by mail are mail-order pharmacies. Although Sec.   423.120(a)(3) specifically allows for access to non-retail pharmacies, and we intended ``including pharmacies offering home delivery via mail- order and institutional pharmacies'' to mean home infusion pharmacies, mail-order pharmacies, long-term care pharmacies, or other non-retail pharmacies that offer home delivery services by mail, some Part D plan sponsors began to require any interested pharmacies, even retail pharmacies, that may offer home delivery services by mail to contract as mail-order pharmacies in order to participate in the plan's contracted pharmacy network. Because Part D plan sponsors frequently require contracted mail-order pharmacies to be licensed in all United States, territories, and the District of Columbia, the classification of any pharmacies that may offer home delivery services by mail as mail-order pharmacies for purposes of contracting with Part D plan sponsors as a network pharmacy, including licensure requirements, led to complaints from beneficiaries and pharmacies, including retail, specialty, and other pharmacies.     Although the language at Sec.  423.120(a)(3) is specific to non- retail pharmacies, there is a great deal of confusion regarding mail- order pharmacy in the Part D marketplace. We believe it is inappropriate to classify pharmacies as ``mail-order pharmacies'' solely on the basis that they offer home delivery by mail. Because the statute at section 1860D-4(b)(1)(D) of the Act discusses cost sharing in terms of mail order versus other non-retail pharmacies, mail-order cost sharing is unique to mail-order pharmacies, as we have proposed to define the term. For example, while a non-retail home infusion pharmacy may provide services by mail, cost-sharing is commensurate with retail cost-sharing. Therefore, to clarify what a mail-order pharmacy is, we propose to define mail-order pharmacy at Sec.  423.100 as a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.     Although we propose to add the definition of mail-order pharmacy, we also believe that our existing definition of retail pharmacy has contributed, in part, to the confusion in the Part D marketplace. As discussed previously, the existing definition of ``retail pharmacy'' at Sec.  423.100 means ``any licensed pharmacy that is not a mail-order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.'' This definition, given the rapidly evolving pharmacy practice landscape, may be a source of some confusion given that it expressly excludes mail-order pharmacies, but not other non-retail pharmacies such as home infusion or specialty pharmacies.     We note that Medicaid recently adopted a definition of ``retail community pharmacy.'' Pursuant to section 1927(k)(10) of the Act, as amended by section 2503 of the Affordable Care Act (ACA), for purposes of Medicaid prescription drug coverage, CMS defines ``retail community pharmacy'' at Sec.  447.504(a) as ``an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the walk-in general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not- for-profit pharmacies, government pharmacies, or pharmacy benefit managers.'' Although this definition adds greater clarity about the locations or practice settings where retail pharmacies may be found, we were concerned that, for the purposes of the Part D program, the mention of additional types of pharmacies in our regulation could contribute to more confusion instead of less.     However, two aspects of this definition are similar to Part D statutory language in section 1860D-4(b)(1)(C) and (D) of the Act. The first is the concept that a retail pharmacy is open to dispense prescription medications to the walk-in general public, which echoes the requirement at section 1860D-4(b)(1)(C) of the Act that Part D plan sponsors secure the participation in their networks a sufficient number of pharmacies that dispense (other than mail order) drugs directly to patients. The second is the concept that prescriptions are dispensed at retail prices, or for the Part D program, retail cost-sharing, which echoes the requirement at section 1860D-4(b)(1)(D) of the Act that Part D plan sponsors permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail-order pharmacy), with any differential in charge paid by such enrollees. Because these concepts are consistent with the Part D statute, we believe their inclusion in our definition of retail pharmacy at Sec.  423.100 would be appropriate.     Therefore, to clarify what a retail pharmacy is, we propose to revise the definition of retail pharmacy at Sec.  423.100 First, we note that the existing definition of ``retail pharmacy'' is not in alphabetical order, and we propose a technical change to move it such that it would appear in alphabetical order. Second, we propose to incorporate the concepts of being open to the walk-in general public and retail cost-sharing such that the definition of retail pharmacy would mean ``any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.''     Although we were originally unsure whether Part D enrollees would need routine access to specialty drugs and specialty pharmacies beyond our out-of-network requirements (see 70 FR 4250), as the Part D program has evolved, the use of specialty drugs in the Part D program has grown exponentially and will likely continue to do so. The June 2016 MedPAC report (available at [*http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf*](http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf)) notes growth in the use of specialty drugs in the Part D program is currently outpacing other drugs and health spending, generally. Such drugs are often high-cost and complex, for

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diseases including, but not limited to, cancer, Hepatitis C, HIV/AIDS, multiple sclerosis, and rheumatoid arthritis. The report also highlights that each year since 2009, more than half of the United States Food and Drug Administration (FDA) approvals have been for specialty drugs. Because many specialty drugs can be self-administered on an outpatient basis, even in the patient's home, and for chronic or long-term use, increasing numbers of Part D enrollees need routine access to specialty drugs and specialty pharmacies. Nonetheless, because the pharmacy landscape is changing so rapidly, we believe any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace, and we decline to propose a definition of specialty pharmacy at this time.     Similar to specialty pharmacy, we also decline to further define non-retail pharmacy. The pharmacy types that we define and propose to modify and define in regulation describe functional lines of business that an individual pharmacy may have, solely, or in combination. However, unlike mail order, home infusion, I/T/U, FQHC, LTC, hospital, other institutional, other provider-based, and ``members-only'' Part D plan-owned and operated pharmacy types or lines of business that comprise ``non-retail'', the term ``non-retail'' does not, itself, define a unique pharmacy functional line of business, and does not lend itself to a clear definition. Consistent with statutory any willing pharmacy and preferred pharmacy provisions, mail-order pharmacies may be preferred or non-preferred. Part D plan sponsors may establish unique non-preferred mail-order cost-sharing, or may establish such non-preferred mail-order cost sharing commensurate with those for retail pharmacies.     We solicit comment on our proposed definition of mail-order pharmacy and our proposed modification to the definition of retail pharmacy. Specifically, we solicit comment regarding whether stakeholders believe these definitions strike the right balance to resolve confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models. c. Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions     As noted previously, since the beginning of the Part D program, we have considered standard terms and conditions for network participation to set a ``floor'' of minimum requirements by which all similarly situated pharmacies must abide. We further believe it is reasonable for a Part D plan sponsor to require additional terms and conditions beyond those required in the standard contract for network participation for pharmacies to have preferred status. Therefore, we implemented the requirements of section 1860D-4(b)(1)(A) of the Act by requiring that standard terms and conditions be ``reasonable and relevant,'' but declined to further define ``reasonable and relevant'' in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.     We note that a pharmacy's ability to participate in a preferred or specially labeled subset of the Part D plan sponsor's larger contracted pharmacy network or to offer preferred cost sharing assumes that, at a minimum, the pharmacy is able to participate in the network. Where there are barriers to a pharmacy's ability to participate in the network at all, it raises the question of whether the standard (that is, entry-level) terms and conditions are reasonable and relevant.     It has been our longstanding policy that Part D plans cannot restrict access to certain Part D drugs to specialty pharmacies within their Part D network in such a manner that contravenes the convenient access protections of section 1860D-4(b)(1)(C) of the Act and Sec.   423.120(a) of our regulations. (See Q&A at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess\_051706.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf)). In 2006, we informed sponsors they cannot restrict access to drugs on the ``specialty/high cost'' tier to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (that is, a contracted network pharmacy that does not belong to the restricted subset). Since 2006, it has been our general policy that these types of special requirements for Part D plan sponsors to limit dispensing of specialty drugs be directly linked to patient safety or regulatory reasons.     As the specialty drug distribution market has grown, so has the number of organizations competing to distribute or dispense specialty drugs, such as pharmacy benefit managers (PBMs), health plans, wholesalers, health systems, physician practices, retail pharmacy chains, and small, independent pharmacies (see the URAC White Paper, ``Competing in the Specialty Pharmacy Market: Achieving Success in Value-Based Healthcare,'' available at   [*http://info.urac.org/specialtypharmacyreport*](http://info.urac.org/specialtypharmacyreport)). CMS is concerned that Part D plan sponsors might use their standard pharmacy network contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies. In fact, we have received complaints from pharmacies that Part D plan sponsors have begun to require accreditation of pharmacies, including accreditation by multiple accrediting organizations, or additional Part D plan-/PBM-specific credentialing criteria, for network participation. We agree that there is a role in the Part D program for pharmacy accreditation, to the extent pharmacy accreditation requirements in network agreements promote quality assurance. In particular, we support Part D plan sponsors that want to negotiate an accreditation requirement in exchange for, for example, designating a pharmacy as a specialty or preferred pharmacy in the Part D plan sponsor's contracted pharmacy network. However, we do not support the use of Part D plan sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (as discussed previously). Moreover, we are especially concerned about anecdotal reports that allege such standard terms and conditions for network participation are waived, for example, when a Part D plan sponsor needs a particular pharmacy in its network in order to meet convenient access requirements, or even for certain pharmacies that received preferred pharmacy status.     If the premise of accreditation or Part D plan sponsor- or PBM- specific credentialing requirements is to ensure more stringent quality standards, then there is no reasonable explanation for why a quality- related standard term or condition could be waived for situations when the Part D plan sponsor needs a particular pharmacy in its contracted

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pharmacy network in order to meet the convenient access standards or to designate a particular pharmacy with preferred pharmacy status. A term or condition which can be dropped in such situations is by definition not ``standard'' according to the plain meaning of the word. Waivers or inconsistent application of such standard terms and conditions is an explicit acknowledgement that such terms and conditions are not necessary for the ability of a pharmacy to perform its core functions, and are thus neither reasonable nor relevant for any willing pharmacy standard terms and conditions.     It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now. We continue to believe pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards, and Sec.  423.153(c)(1) requires representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states.     Additionally, because a pharmacy's ability to dispense certain medications is not dependent on it having the ability to dispense other medications, it is not relevant for sponsors to require pharmacies to dispense a particular roster of certain drugs or drugs for certain disease states in order to receive standard terms and conditions for network participation as a contracted network pharmacy for that Part D plan sponsor. Consequently, consistent with our longstanding policy, discussed previously, we would not expect Part D plan sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA- mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so. We solicit comment on this topic. d. Timing of Contracting Requirements     CMS has received complaints over the years from pharmacies that have sought to participate in a Part D plan sponsor's contracted network but have been told by the Part D plan sponsor that its standard terms are not available until the sponsor has completed all other network contracting. In other instances, pharmacies have told us that Part D plan sponsors delay sending them the requested terms and conditions for weeks or months or require pharmacies to complete extensive paperwork demonstrating their eligibility to participate in the sponsor's network before the sponsor will provide a document containing the standard terms and conditions. CMS believes such actions have the effect of frustrating the intent of the any willing pharmacy requirement, and as a result, we believe it is necessary to codify specific procedural requirements for the delivery of pharmacy network standard terms and conditions.     To this end, we propose to establish deadlines by which Part D plan sponsors must furnish their standard terms and conditions to requesting pharmacies. The first deadline we propose to establish is the date by which Part D plan sponsors must have standard terms and conditions available for pharmacies that request them. By mid-September of each year, Part D plan sponsors have signed a contract with CMS committing them to delivering the Part D benefit through an accessible pharmacy network during the upcoming year and have provided information about that network to CMS for posting on the Medicare Plan Finder Web site. At that point, Part D plan sponsors should have had ample opportunity to develop standard contract terms and conditions for the upcoming plan year. Therefore, we propose to require at Sec.  423.505(b)(18)(i) that Part D plan sponsors have standard terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year.     The second deadline we propose concerns the promptness of Part D plan sponsors' responses to pharmacy requests for standard terms and conditions. As discussed previously, we propose to require all Part D plan sponsors to have standard terms and conditions developed and ready for distribution by September 15. Therefore, we propose to require at Sec.  423.505(b)(18)(ii) that, after that date and throughout the following plan year, Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request. Part D plan sponsors would be required to clearly identify for interested pharmacies the avenue (for example, phone number, email address, Web site) through which they can make this request. In instances where the Part D plan sponsor requires a pharmacy to execute a confidentiality agreement with respect to the terms and conditions, the Part D plan sponsor would be required to provide the confidentiality agreement within two business days after receipt of the pharmacy's request and then provide the standard terms and conditions within 2 business days after receipt of the signed confidentiality agreement. While Part D plan sponsors may ask pharmacies to demonstrate that they are qualified to meet the Part D plan sponsors' standard terms and conditions before executing the contract, Part D plan sponsors would be required to provide the pharmacy with a copy of the contract terms for its review within the two-day timeframe. If finalized, this proposed requirement would permit pharmacies to do their due diligence with respect to whether a Part D plan sponsor's standard terms and conditions are acceptable at the same time Part D plan sponsors are conducting their own review of the qualifications of the requesting pharmacy. We specifically seek comment on whether these timeframes are the right length to address our goal but are operationally realistic. We also request examples of situations where a longer timeframe might be needed. 13. Changes to the Days' Supply Required by the Part D Transition Process     We promulgated regulations under the authority of section 1860D- 11(d)(2)(B) of the Act to require Part D sponsors to provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on the prescription drug plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). These regulations are codified at Sec.  423.120(b)(3). Specifically, these regulations require that a Part D sponsor ensure certain enrollees access to a temporary supply of drugs within the first 90 days under a new plan (including drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by ensuring a temporary fill when an enrollee requests a fill of a non-formulary drug during this time period. In the outpatient setting, the supply must be for at least 30 days of medication, unless the prescription is written for less. In the LTC setting, this supply must be for up to at least 91 days and may be up to 98 days, consistent with the dispensing increment, unless a less amount is prescribed.     We propose to make two changes to these regulations. First, we propose to shorten the required transition days'

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supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. Second, we propose a technical change to the current required days' transition supply in the outpatient setting to be a month's supply.     We provided our rationale for the transition fill days' supply requirement in the LTC setting in CMS final rule CMS-4085-F published on April 15, 2010 (75 FR 19678). In that final rule, we stated that for a new enrollee in a LTC facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. We further stated that, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens, we will require sponsors to honor multiple fills of non-formulary Part D drugs, as necessary during the entire length of the 90-day transition period. Thus, we required a Part D sponsor to provide a LTC resident enrolled in its Part D plan with at least a 31 day supply of a prescription with refills provided, if needed, up to a 93 days' supply (unless the prescription is written for less) (75 FR 19721). In a subsequent final rule published on April 15, 2011, we changed the 93 days' supply to 91 to 98 days' supply, as noted previously, to acknowledge variations in days' supplies that could result from the short-cycle dispensing of brand drugs in the LTC setting (76 FR 21460 and 21526).     We received and responded to a comment in the April 2010 final rule about transition and a longer timeframe in the LTC setting. We stated that a number of commenters supported our proposal of requiring an extended transition supply for enrollees residing in LTC facilities but that commenters requested that we provide the same protections to individuals requiring LTC in community-based settings. In our response to the comment, we indicated that residents of LTC institutions were more limited in access to prescribing physicians hired by LTC facilities due to a limited visitation schedule and more likely to require extended transition timeframes in order for the physician to work with the facility and LTC pharmacies on transitioning residents to formulary drugs. We further stated that we believed that community- based enrollees, in contrast, were less limited in their access to prescribing physicians and did not require an extended transition period to work with their physicians to successfully transition to a formulary drug. (75 FR 19721). Thus, the requirement to provide longer transition fill days' supply in the LTC setting was a result of our concerns that a longer timeframe would be needed in the LTC setting.     After more than 10 years of experience with Part D in LTC facilities, we have not seen the concerns that we expressed in the 2010 final rule materialize. We are not aware of any evidence that transition for a Part D beneficiary in the LTC setting necessarily takes any longer than it does for a beneficiary in the outpatient setting. We understand that it is common for Part D beneficiaries in the LTC setting to be cared for by on-staff or consultant physicians and other health professionals with prescriptive authority who are under contract with the LTC facility. Additionally, we also understand that Part D beneficiaries in the LTC setting are typically served by an on-site pharmacy or one under contract to service the LTC facility. Given this structure of the LTC setting, we understand that the LTC prescribers and pharmacies are readily available to address transition for Part D beneficiaries in the LTC setting. In addition, LTC facilities now have many years' experience with the Medicare Part D program generally and transition specifically.     While our concerns about the needed timeframe for transition in the LTC setting do not seem to have materialized, we have continuing concerns about drug waste and the costs associated with such waste in the LTC setting. Some of these concerns have been addressed by our rule requiring the short-cycle dispensing of brand drugs to Part D beneficiaries in LTC facilities in the April 2011 final rule. That rule, codified at 42 CFR 423.154, requires that all Part D sponsors require all network pharmacies servicing LTC facilities to dispense certain solid oral doses of covered Part D brand-name drugs to enrollees in such facilities in no greater than 14-day increments at a time to reduce drug waste. However, we now believe that CMS could eliminate additional drug waste and cost by no longer requiring a longer transition days' supply in the LTC setting. Therefore, we are proposing that the transition days' supply in the LTC setting be the same as it is in the outpatient setting.     Our second proposed change involves the current required 30 days' transition supply in the outpatient setting, which is codified at Sec.   423.120(b)(3)(iii)(A). We have received a number of inquiries from Part D sponsors regarding scenarios involving medications that do not easily add up to a 30 days' supply when dispensed (for example, drugs that typically are dispensed in 28-day packages). Historically, our response to those inquiries has been that the regulation requires plans to provide at least 30 days of medication, which requires plans to dispense more than one package to comply with the text of the regulation. However, the intent of the regulation was for the transition fill in the outpatient setting to be for at least a month's supply. For this reason, we are proposing a change to the regulation from ``30 days'' to ``a month's supply.'' If finalized, this change would mean that the regulation would require that a transition fill in the outpatient setting be for a supply of at least a month of medication, unless the prescription is written by the prescriber for less. Therefore, the supply would have to be for at least the days' supply that the applicable Part D prescription drug plans has approved as its retail month's supply in its Plan Benefit Package submitted to CMS for the relevant plan year, again, unless the prescription is written by the prescriber for less.     Together, our two proposals--if finalized--would mean that Sec.   423.120 (b)(3)(iii)(A) would be consolidated into Sec.  423.120 (b)(3)(iii) to read that the transition process must ``[e]nsure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least a month's supply of medication, unless the prescription is written by a prescriber for less than a month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of a month's supply of medication.'' Section 423.120(b)(3)(iii)(B) would be eliminated.     Please note that we also are proposing in II.A.15 Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes to revise Sec.  423.120(b)(3)(i)(B) to state that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as specified under paragraph Sec.  423.120(b)(3)(iv) or Sec.  423.120(b)(6) of this section.

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14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (Sec. Sec.  423.100, 423.120, and 423.128)     Section 1860D-4(b)(3)(E) of the Act requires Part D sponsors to provide ``appropriate notice'' to the Secretary, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its formulary, or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) implements that requirement by defining appropriate notice as that given at least 60 days prior to such change taking effect during a given contract year. We have recognized that both current and prospective enrollees of a prescription drug plan need to have the most current formulary information by the time of the annual election period described in Sec.  423.38(b) in order to enroll in the Part D plan that best suits their particular needs. To this end, Sec.  423.120(b)(6) prohibits Part D sponsors and MA organizations from removing a covered Part D drug from a formulary or changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual election period described in Sec.   423.38(b)(2) and 60 days subsequent to the beginning of the contract year associated with that annual election period. Our concern has been to prevent situations in which Part D sponsors change their formularies early in the contract year without providing appropriate notice as described in Sec.  423.120(b)(5) to new enrollees. Thus, Sec.   423.120(b)(6) has required that all materials distributed during the annual election period reflect the formulary the Part D sponsor will offer at the beginning of the contract year for which it is enrolling Part D eligible individuals. Lastly, under Sec.  423.128(d)(2)(iii), Part D sponsors must also provide current and prospective Part D enrollees with at least 60 days' notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. The general notice requirements and burden are currently approved by OMB under control number 0938-0964 (CMS-10141).     MedPAC observed that the continuity of a plan's formulary is very important to all beneficiaries in order to maintain access to the medications that were offered by the plan at the time the beneficiaries enrolled. While we agree with MedPAC's assertion, we acknowledge the need to balance formulary continuity with requests from Part D sponsors to provide greater flexibility to make midyear changes to formularies. Indeed, MedPAC made its observation in a report that suggested that CMS's rules regarding formulary changes warranted examination. There MedPAC pointed out, among other things, that CMS could provide Part D sponsors with greater flexibility to make changes such as adding a generic drug and removing its brand name version without first receiving agency approval. (MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, June 2016, page 192.)     This proposed rule would implement MedPAC's recommendation by permitting generic substitutions without advance approval as specified later in this section. We have also taken this opportunity to examine our regulations to determine how to otherwise facilitate the use of certain generics. Currently, Part D sponsors can add drugs to their formularies at any time; however, there is no guarantee that enrollees will switch from their brand name drugs to newly added generics. Therefore, Part D sponsors seeking to better manage the Part D benefit may choose to remove a brand name drug, or change its preferred or tiered cost-sharing, and substitute or add its therapeutic equivalent. But even this takes some time: Under current regulations, Part D sponsors must submit formulary change requests to CMS and provide specified notice before removing drugs or changing their cost-sharing (except for unsafe drugs or those withdrawn from the market). As noted earlier, the general notice requirements and burden are currently approved by OMB under control number 0938-0964 (CMS-10141). Also, as detailed previously, Sec.  423.120(b)(5)(i) requires 60 days' notice to specified entities prior to the effective date of changes and 60 days' direct notice to affected enrollees or a 60 day refill. The ability of Part D sponsors to make generic substitutions as approved by CMS is further limited by the fact that as detailed previously, under Sec.   423.120(b)(6), Part D sponsors generally cannot remove drugs or make cost-sharing changes from the start of the annual election period (AEP) until 2 months after the plan year begins.     We propose to provide Part D sponsors with more flexibility to implement generic substitutions as follows: The proposed provisions would permit Part D sponsors meeting all requirements to immediately remove brand name drugs (or to make changes in their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) therapeutically equivalent newly approved generics--rather than having to wait until the direct notice and formulary change request requirements have been met. The proposed provisions would also allow sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect 2 months after the start of the plan year. Related proposals would require advance general and retrospective direct notice to enrollees and notice to entities; clarify online notice requirements; except specified generic substitutions from our transition policy; and conform our definition of ``affected enrollees.'' Lastly, to address stakeholder requests for greater flexibility to make midyear formulary changes in general, we are also proposing to decrease the days of enrollee notice and refill required when (aside from generic substitution and drugs deemed unsafe or withdrawn from the market) drug removal or changes in cost-sharing will affect enrollees.     Specifically, we propose to add a new paragraph (b)(5)(iv) to Sec.   423.120 to permit Part D sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met. The generic drug would need to be offered at the same or a lower cost-sharing and with the same or less restrictive utilization management criteria originally applied to the brand name drug. The Part D sponsor could not have as a matter of timing been able to previously request CMS approval of the change because the generic drug had not yet been released to the market. Also, the Part D sponsor must have previously provided prospective and current enrollees general notice that certain generic substitutions could occur without additional advance notice. As proposed, we would permit Part D sponsors to substitute a generic drug for a brand name drug immediately rather than make that change effective, for instance, at the start of the next month. However, we solicit comment as to whether there would be a reason to require such a delay, especially given the fact that we are proposing not to require advance direct notice (rather, only advance general notice) or CMS approval. The proposed regulation would also require that, when generic drug substitutions occur, Part D sponsors must provide direct notice to affected enrollees and other specified notice to CMS and other entities. We also propose to specify in a revision to

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Sec.  423.120(b)(3)(i)(B) that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug under paragraph (b)(6) of this section.     A proposed exception to Sec.  423.120(b)(6) would permit Part D sponsors to make the above specified changes (removing covered Part D drugs from their formularies, or changing their cost-sharing, when substituting or adding their generic equivalents) during any time of the year. That section generally provides--with a current exception only for unsafe drugs and drugs removed from the market--that Part D sponsors generally cannot remove drugs or make cost-sharing changes between the beginning of the AEP and 60 days after the plan year begins. We believe that revising this provision would assist Part D sponsors by permitting substitutions to take place effect during a longer time period than is currently permitted. Given that the previous exception would permit generic substitutions prior to the start of the calendar year, we also propose to conform the definition of ``affected enrollees'' to clarify that applicable changes must affect their access to drugs during the current plan year.     We are aware that some may be concerned about not requiring advance CMS approval or advance direct notice to enrollees prior to making the permitted generic substitutions, or requiring a transition fill. But we would only permit immediate substitution when the generics are deemed therapeutically equivalent to the brand name drug being removed by the Federal Drug and Food Administration (FDA) and meet other requirements specified later in this section. This would not apply to follow-on biological products under current FDA guidance. The FDA has, in fact noted that, ``A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.'' (``Generic Drug Facts,'' see FDA Web site, [*https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm*](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm), accessed September 19, 2017, hereafter FDA, ``Abbreviated New Drug Application (ANDA): Generics''.) Additionally, immediate generic substitution has long been an established bedrock of commercial insurance, and we are not aware of any harm to the insured resulting from such policies.     Also, we do not believe a transition policy would be appropriate for these situations: The purpose of the transition process is to make sure that the medical needs of enrollees are safely accommodated in that they do not go without their medications or face an abrupt change in treatment. If the proposal to permit Part D sponsors to immediately substitute generics for brand name drugs upon market release were finalized, most enrollees in this situation would not have had an opportunity to try the drug prior to the drug substitution to see how it worked for them. In other words, an enrollee could not be certain that a generic substitution would not work, would constitute an abrupt change in treatment, or that the enrollee would be better served by taking no medication rather than the generic unless he or she had previously tried the generic drug.     Moreover, we have built beneficiary protections into the proposed provisions. First, proposed Sec.  423.120(b)(5)(iv)(A) addresses safety concerns by permitting Part D sponsors to add only therapeutically equivalent generic drugs. This means the FDA must have approved the generic drug in an abbreviated new drug application pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)), and it must be listed with the innovator drug in the publication ``Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) in which the FDA identifies drug products approved on the basis of safety and effectiveness by the FDA, and be considered by the FDA to be therapeutically equivalent to the brand name drug.     Second, we share the concern that prospective enrollees could be misled by Part D sponsors that deliberately offer brand name drugs during open enrollment periods only to remove them or change their cost-sharing as quickly as possible during the plan year. We believe that our proposed provision would address such problems: Under proposed Sec.  423.120(b)(5)(iv)(B), a Part D sponsor cannot substitute a generic for a brand name drug unless it could not have previously requested formulary approval for use of that drug. As a matter of operations, CMS permits Part D sponsors to submit formularies, and their respective change requests, only during certain windows. Under proposed Sec.  423.120(b)(5)(iv)(B), a Part D sponsor could not remove a brand name drug or change its preferred or tiered cost-sharing if that Part D sponsor could have included its generic equivalent with its initial formulary submission or during a later update window.     However, to be certain, that we have not missed practical or other complications that would hinder the ability of Part D sponsors to timely seek approval within the CMS timeframes, we solicit comment as to whether we should consider immediate substitution, potentially in limited circumstances, of specified generics for which Part D sponsors could have previously requested formulary approval. At the same time, we remain mindful of beneficiary protections and are hesitant to simply permit substitution of any generics regardless of how long they have been on the market. Accordingly, we welcome suggestions of any other practical cut-offs, as well as information on possible effects on beneficiaries that could result if we were to permit Part D sponsors to substitute specified generics that have been on the market for longer time periods.     Third, we believe the two-pronged approach of the proposed provision would provide appropriate notice for this type of formulary change. The general notice requirement of proposed Sec.   423.120(b)(iv)(C) would require that, before making any generic substitutions, a Part D sponsor provide all prospective and current enrollees with notice in the formulary and other applicable beneficiary communication materials stating that the Part D sponsor can remove, or change the preferred or tiered cost-sharing of, any brand name drug immediately without additional advance notice (beyond the general advance notice) when a new equivalent generic is added. This would, for instance, include the Evidence of Coverage (EOC). Proposed Sec.   423.120(b)(iv)(C) would also require that this general notice advise prospective and current enrollees that they will get direct notice about any specific drug substitutions made that would affect them and that the direct notice would advise them of the steps they could take to request coverage determinations and exceptions. Therefore, the general notice would advise enrollees about what might take place before any changes occur.     When the Part D sponsor substitutes a generic for a brand name drug, the proposed direct notice provision, Sec.  423.120(b)(5)(iv)(E), would require the Part D sponsor to provide affected enrollees with direct notice consistent with Sec.  423.120(b)(5)(ii). We currently require Part D sponsors to provide this information 60 days before such changes are made. Under the proposed changes, enrollees would receive the same information they receive under the current regulation--the only difference being that the notice could be provided

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after the effective date of the generic substitution. As discussed earlier, under the proposed provision Part D sponsors seeking to make immediate substitutions would be newly required to have previously provided general notice in beneficiary communication materials such as formularies and EOCs that certain generic substitutions could take place without additional advance notice.     We understand there may be concerns that the direct notice identifying the specific drug substitution would arrive after the formulary change has already taken place. As explained previously, we believe generic substitutions pose no threat to enrollee safety. Also, as noted earlier, we are proposing to revise Sec.  423.120(b)(6) to permit generic substitutions to take place throughout the entire year. This means that, under the proposed provision, a Part D sponsor meeting all the requirements would be able to substitute a generic drug for a brand name drug well before the actual start of the plan year (for instance, if a generic drug became available on the market days after the summer update). There is nothing in our regulation that would prohibit advance notice and, in fact, we would encourage Part D sponsors to provide direct notice as early as possible to any beneficiaries who have reenrolled in the same plan and are currently taking a brand name drug that will be replaced with a generic drug with the start of the next plan year. We would also anticipate that Part D sponsors will be promptly updating the formularies posted online and provided to potential beneficiaries to reflect any permitted generic substitutions--and at a minimum meeting any current timing requirements provided in applicable guidance. At this time we are not proposing to set a regulatory deadline by which Part D sponsors must update their formularies before the start of the new plan year. However, if we were to finalize this provision and thereafter find that Part D sponsors were not timely updating their formularies, we would reexamine this policy. And we would note, as regards timing, that Sec.   423.128(d)(2)(iii) requires that the current formulary posted online be updated at least monthly.     In cases in which the Part D sponsor would necessarily have to send notice after the fact, for example instances in which a drug is not released to the market until after the beginning of the plan year and the Part D sponsor then immediately makes a generic substitution, the proposed general notice would have already advised enrollees that they would receive information about any specific drug generic substitutions that affected them and that they would still be able to request coverage determinations and exceptions. While the timing would most likely mean most enrollees would only be able to make such requests after receiving a generic drug fill, in the vast majority of cases, an enrollee could not be certain that a generic substitution would not work unless he or she actually tried the generic drug. Additionally, we are strongly encouraging Part D sponsors to provide the retrospective direct notices of these generic substitutions (including direct notice to affected enrollees and notice to entities including CMS) no later than by the end of the month after which the change becomes effective. While sponsors are required to report this information to both enrollees and entities including CMS, we currently are not proposing to codify the end of month timing requirement; however, if we were to finalize this provision and thereafter find that Part D sponsors were not timely providing retrospective notice, we would reexamine this policy.     Fourth, enrollees would be protected from higher cost-sharing under proposed paragraph (b)(5)(iv)(A), which would require Part D sponsors to offer the generic with the same or lower cost-sharing and the same or less restrictive utilization management criteria as the brand name drug.     We also believe requirements and guidance regarding beneficiary communications will continue to provide beneficiary protections. Section 423.128(e)(5) currently requires Part D sponsors to furnish directly to enrollees an explanation of benefits (EOB) that includes any applicable formulary changes for which Part D plans are required to provide notice as described in Sec.  423.120(b)(5). As noted previously, Sec.  423.128(d)(2)(iii) currently requires Part D sponsors to post at least 60 days' notice of removals and cost-sharing changes online for current and prospective Part D enrollees. In light of our proposal for generic substitutions described previously, we propose to modify Sec.  423.128(d)(2)(iii) to require Part D sponsors to provide ``timely'' notice under 423.120(b)(5). This would mean that, under the proposed provision, a Part D sponsor would need to provide at least 30 days' online notice to affected enrollees before removing drugs or making cost-sharing changes except when adding a therapeutically equivalent generic as specified, and as has currently been the requirement, removing unsafe or withdrawn drugs. Part D sponsors could provide online notice after the effective date of changes only in those limited instances.     As regards content, Sec.  423.128(d)(2)(iii) requires--and would continue to do so under the proposed revisions--that Part D sponsors post online notice regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. Posting information online related to removing a specific drug or changing its cost-sharing solely to meet the content requirements of Sec.  423.128(d)(2)(iii) cannot replace general notice under proposed Sec.  423.120(b)(5)(iv)(C); direct notice to affected enrollees under Sec.  423.120(b)(5)(ii); or notice to CMS when required under Sec.  423.120(b)(5). For instance, as noted in the January, 28, 2005 final rule (70 FR 4265), we view online notification under Sec.   423.128(d)(2)(iii) on its own as an inadequate means of providing specific information to the enrollees who most need it, and we consider it an additional way that Part D sponsors provide notice of formulary changes to affected enrollees.     However, we do not mean to restrict or otherwise affect other rules governing the provisions of materials online. For instance, if Part D sponsors were able to fulfill CMS marketing and beneficiary communications requirements by posting a specific document online rather than providing it in paper, the fact the document was posted online would not preclude it from providing general notice required under our proposed provisions. In other words, if otherwise valid, provision of general notice in a document posted online could suffice as notice as regards that specified document under proposed Sec.   423.120(b)(5)(iv)(C). In contrast, we do not wish to suggest that posting one type of notice online would necessarily suffice to meet distinct notice requirements. For instance, providing the general advance notice that would be required under Sec.  423.120(b)(5)(iv)(C) in a document posted online could not meet the online content requirements of Sec.  423.128(d)(2)(iii) related to providing information about removing drugs or changing their cost-sharing. Nor, as noted previously, could the ***opposite*** apply: Posting the content required under Sec.  423.128(d)(2)(iii) online could not fulfill the advance general notice requirements that would be required under proposed Sec.  423.120(b)(5)(iv)(C) (or suffice to provide direct notice to affected enrollees under Sec.  423.120(b)(5)(ii) or notice to CMS under Sec.  423.120(b)(5)).     In addition to requiring the direct notice to affected enrollees discussed previously, proposed Sec.  423.120(b)(iv)(D) would also require Part D sponsors to provide the following entities with

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notice of the generic substitutions consistent with Sec.   423.120(b)(5)(ii): CMS, State Pharmaceutical Assistance Programs (as defined in Sec.  423.454), entities providing other prescription drug coverage (as described in Sec.  423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists. (To avoid repetition, we propose to revise the provision to refer to all of these entities as ``CMS and other specified entities'' for the purposes of Sec.  423.120(b).) Even though, as proposed, a Part D sponsor that met all of the requirements would be able to make the generic substitution immediately without submitting any formulary change requests to CMS, the Part D sponsor must include the generic substitution in the next available formulary submission to CMS. We note that Part D plans can determine the most effective means to communicate formulary change information to State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists and that, under our proposed provision, we would consider online posting sufficient for those purposes.     Lastly as part of our reexamination of the need to generally provide Part D sponsors greater flexibility in formulary changes, we plan to decrease the amount of direct notice required in cases where the removal of a drug or change in cost-sharing status will affect enrollees currently taking the drug. (This would contrast proposed notice requirements that would apply to immediate substitution of specified generics. There we would also require advance general notice that such changes can occur, and direct notice of the specific changes could be provided after their effective date.) Section 423.120(b)(5)(i) currently requires at least 60 days' notice to all entities prior to the effective date of changes and at least 60 days' direct notice to affected enrollees or a 60 day refill upon the request of an affected enrollee. We propose to reduce the notice requirement in both instances to at least 30 days and the refill requirement to a month. Beneficiaries would be affected, and therefore receive the 30 days' notice or a month refill, in cases in which, for instance, Part D sponsors planned to add prior authorization requirements as a result of new safety-related information or clinical guidelines. This proposal would permit Part D sponsors to institute formulary changes in half the time.     We are, again, aware that some may be concerned that we are reducing the number of days advance notice afforded to enrollees in these instances. But again, we believe current CMS requirements provide the necessary beneficiary protections, and that 30 (rather than 60) days' notice still will afford enrollees sufficient time to either change to a covered alternative drug or to obtain needed prior authorization or an exception for the drug affected by the formulary change. Existing CMS regulations establish robust beneficiary protections in the coverage and appeals process, including expedited adjudication timeframes for exigent circumstances (maximum timeframe of 24 hours for coverage determinations and 72 hours for level 1 and 2 appeals), and a requirement that Part D plan sponsors automatically forward all untimely coverage determinations and redeterminations to the IRE for independent review. Further, while 60 days' notice is currently required, we have no evidence to suggest that beneficiaries are currently utilizing the full 60 days. The reduction to 30 days would align these requirements with the timeframes for transition fills. And, with over 11 years of program experience, we have no evidence to suggest that 30 days has been an insufficient temporary days supply for transition fills.     (Note we are also proposing to amend the refill amount to months (namely a month) rather than days (it was 60 days previously) to conform to a proposed revision to the transition policy regulations at Sec.  423.120(b)(3).) For further discussion, see section III.A.15 of this proposed rule, Changes to the Transition.)     Summary: The following provides a high level summary of notice changes proposed in Sec.  423.120(b). Details on these requirements appear in the preamble and proposed provisions. This summary does not address other proposed changes (for instance, changes to transition requirements); notice provisions we do not propose to change (for instance, notice for safety edits); or other rules that may also apply (for instance, marketing and beneficiary communications rules regarding formulary updates).      Notice required for expedited substitutions of certain generics: Part D sponsors that would otherwise be permitted to make certain generic substitutions as specified under proposed Sec.   423.120(b)(5)(iv) would be required to provide the following types of notice:     ++ Advance general notice in the formulary and EOC and other applicable beneficiary communications stating that such changes may occur without notice.     ++ Notice that identifies the specific drug substitution made-- which may be provided after the effective date of the change--as follows:

--Direct notice to affected enrollees. --Notice posted online for current and prospective enrollees. --Notice to CMS. --Notice to other entities.

     Notice and refill required for certain other midyear formulary changes: Part D sponsors that would be otherwise permitted to remove or change the preferred or tiered cost-sharing status of drugs would be required to provide the below types of notice and refills under proposed Sec.  423.120(b)(5)(i) and (ii). However, these notice requirements do not apply when removing drugs deemed unsafe by the FDA or removed from the market by manufacturers (for applicable requirements see Sec.  423.120(b)(5)(iii).)      For affected enrollees--     ++ Advance direct written notice at least 30 days prior to the effective date; or     ++ Written notice of the change and a month supply of the brand name drug under the same terms as provided before the change; and      For entities and other enrollees:     ++ Advance notice identifying the specific drug changes to be made at least 30 days prior to the effective date of the change as follows:

--Notice posted online for current and prospective enrollees; --Notice to CMS; and --Notice to other entities. 15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing     Similar to the introduction of an abbreviated approval pathway for generic drugs provided by the Hatch-Waxman Act in 1984 to spur more competition through quicker approvals and introduction of lower cost therapeutic alternatives in the marketplace, Congress enacted the ``Biologics Price Competition and Innovation Act of 2009'' to balance innovation and consumer interests. Specifically, section 7002 of the ACA amended section 351 of the Public Health Service Act (PHS Act) (42 U.S.C 262), adding a subsection (k) to create an abbreviated licensure pathway for follow-on biological products that are demonstrated to be either ``biosimilar'' to or ``interchangeable'' with a United States Food and Drug Administration (FDA) licensed reference biological product. According to the FDA, ``a biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has

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no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.'' However, ``an interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.'' (See [*http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/*](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/)) Biosimilar biological products are, by definition, not interchangeable, and are not substitutable without a new prescription. Follow-on biological products are listed in the FDA's Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at   [*http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm*](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm) Part D plan sponsors are also encouraged to monitor the FDA's Web site for new biologic (BLA) approvals at   [*http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu*](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu)     Sections 1860D-2(b)(4) and 1860D-14(a)(1)(D)(ii-iii) of the Act specify lower Part D maximum copayments for low-income subsidy (LIS) eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act) than are available for all other Part D drugs. Currently the statutory cost sharing levels are set at the maximums. CMS does not interpret the statutory language to mean that each plan can establish lower LIS cost sharing on drugs, but rather, that CMS, through rulemaking, could establish lower cost sharing than the maximum amount, and it would therefore be the same for all Part D plans.     For the Part D program, CMS defines a ``generic drug'' at Sec.   423.4 as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)) is approved. Biosimilar and interchangeable biological products do not meet the section 1927(k)(7) definition of a multiple source drug or the CMS definition of a generic drug at Sec.  423.4 Consequently, follow-on biological products are subject to the higher Part D maximum copayments for LIS eligible individuals and non-LIS Part D enrollees in the catastrophic portion of the benefit applicable to all other Part D drugs. While the statutory maximum LIS copayment amounts apply to all phases of the Part D benefit, the statute only specifies non-LIS maximum copayments for the catastrophic phase. CMS clarified the applicable LIS and non-LIS catastrophic cost sharing in a March 30, 2015 Health Plan Management System (HPMS) memorandum. We advised that additional guidance may be issued for interchangeable biological products at a later date.     Nonetheless, treatment of follow-on biological products, which are generally high-cost, specialty drugs, as brands for the purposes of non-LIS catastrophic and LIS cost sharing generated a great deal confusion and concern for plans and advocates alike, and CMS received numerous requests to redefine generic drug at Sec.  423.4 Advocates expressed concerns that LIS enrollees were required to pay the higher brand copayment for biosimilar biological products. Stakeholders who contacted us asserted treatment of biosimilar biological products as brands for purposes of LIS cost-sharing creates a disincentive for LIS enrollees to choose lower cost alternatives. Some of these stakeholders also expressed similar concerns for non-LIS enrollees in the catastrophic portion of the benefit.     We agree and propose to revise the definition of generic drug at Sec.  423.4 to include follow-on biological products approved under section 351(k) of the PHS Act (42 U.S.C 262(k)) solely for purposes of cost-sharing under sections 1860D-2(b)(4) and 1860D-14(a)(1)(D)(ii-iii) of the Act. Lower cost sharing for lower cost alternatives will improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and will reduce costs to both Part D enrollees and the Part D program.     While CMS generally seeks to encourage the utilization of lower cost follow-on biological products, we propose to limit inclusion of follow-on biological products in the definition of generic drug to purposes of non-LIS catastrophic cost sharing and LIS cost sharing only because we want to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations. We do not believe that would be appropriate because the same FDA requirements for generic drug approval (for example, therapeutic equivalence) do not apply to biosimilar biological products, currently the only available follow-on biological products. Accordingly, CMS currently considers biosimilar biological products more like brand name drugs for purposes of transition or midyear formulary changes because they are not interchangeable. In these contexts, treating biosimilar biological products the same as generic drugs would incorrectly signal that CMS has deemed biosimilar biological products (as differentiated from interchangeable biological products) to be therapeutically equivalent. This could jeopardize Part D enrollee safety and may generate confusion in the marketplace through conflation with other provisions due to the many places in the Part D statute and regulation where generic drugs are mentioned. Therefore, we believe the proposed change to treat follow-on biological products as generics should be limited to purposes of non-LIS catastrophic and LIS cost sharing only.     We propose to modify the definition of generic drug at Sec.  423.4 as follows:      We propose to redesignate the existing definition as paragraph (i).      We propose to add a new paragraph (ii) to state ``for purposes of cost sharing under sections 1860D-2(b)(4) and 1860D- 14(a)(1)(D) of the Act only, a biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C 262(k)) is approved.''     We solicit comment on this proposed change to the definition of generic drug at Sec.  423.4 16. Eliminating the Requirement To Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (Sec.  423.265)     CMS has the authority under section 1857(e)(1) of the Act, incorporated for Part D by section 1860D-12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds ``necessary and appropriate,'' as well as authority under section 1860D-11(d)(2)(B) of the Act to propose regulations imposing ``reasonable minimum standards'' for Part D sponsors. Using this authority we previously issued regulations to ensure that multiple plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. At that time, separate meaningful difference rules were concurrently adopted for MA and stand- alone PDPs. This section addresses proposed changes to our regulations pertaining strictly to meaningful

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differences in PDP plan offerings. One of the underlying principles in the establishment of the Medicare Part D prescription drug benefit is that both market competition and the flexibility provided to Part D sponsors in the statute would result in the offering of a broad array of cost effective prescription drug coverage options for Medicare beneficiaries. We continue to support the concept of offering a variety of prescription drug coverage choices for Medicare beneficiaries consistent with our commitment to afford beneficiaries access to the prescription drugs they need.     PDP sponsors must offer throughout a PDP region a basic plan that consists of: Standard deductible and cost sharing amounts (or actuarial equivalents); an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year; a coverage gap phase; and finally, catastrophic coverage that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. Prior to our adopting regulations requiring meaningful differences between each PDP sponsor's plan offerings in a PDP Region, our guidance allowed sponsors that offered a basic plan to offer additional basic plans in the same region, as long as they were actuarially equivalent to the basic plan structure described in the statute. These sponsors could also offer enhanced alternative plans that provide additional value to beneficiaries in the form of reduced deductibles, reduced copays, coverage of some or all drugs while the beneficiary is in the gap portion of the benefit, coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under Sec.  423.100, or some combination of those features. As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plan benefit packages PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. To that end, CMS sets differential out-of-pocket cost (OOPC) targets each year, using an analysis performed on the previous year's bid submissions, to ensure contracting organizations submit bids that clearly offer differences in value to beneficiaries. Published annually in the Call Letter, the threshold differentials are defined for a basic and enhanced plan, as well as for two enhanced plans, when offered by a parent organization in the same region. For example, in CY 2018, a basic and enhanced plan are required at minimum to provide for a $20 out-of-pocket difference, while two enhanced plans are required to have at least a $30 differential. Over the years, the thresholds have ranged from $18 to $23 between basic and enhanced plans, and from $12 to $34 between two enhanced plans. We issued regulations in 2010, at Sec.   423.265(b)(2), that established our authority to deny bids that are not meaningfully different from other bids submitted by the same organization in the same service area. Our application of this authority has eliminated PDP sponsors' ability to offer more than one basic plan in a PDP region since all basic plan benefit packages must be actuarially equivalent to the standard benefit structure discussed in the statute, and in guidance we have also limited to two the number of enhanced alternative plans that we approve for a single PDP sponsor in a PDP region. As part of the same 2010 rulemaking, we also established at Sec.  423.507(b)(1)(iii) our authority to terminate existing plan benefit packages that do not attract a number of enrollees sufficient to demonstrate their value in the Medicare marketplace. Both of these authorities have been effective tools in encouraging the development of a variety of plan offerings that provide meaningful choices to beneficiaries.     We continue to be committed to maintaining benefit flexibility and efficiency throughout both the MA and Part D programs. We wish to continue the trend of using transparency, flexibility, program simplification, and innovation to transform the MA and Part D programs for Medicare enrollees to have options that fit their individual health needs. In our April 2017 Request for Information (RFI), we offered stakeholders the opportunity to submit their ideas on how to better accomplish these goals. In response to the RFI, we received two comments specific to the meaningful difference requirement for PDPs. One commenter urged us to eliminate meaningful difference requirements to allow market competition to determine the appropriate number and type of plan offerings. Alternatively, it was suggested that if the meaningful difference standard is retained, we should revise it to allow plans to be treated as meaningfully different based on differences in plan characteristics not previously considered by CMS. The commenter contends that the meaningful difference requirement, as currently applied, unfairly limits the number of plan offerings and beneficiary choices. Specifically, it was argued that the meaningful difference test does not recognize premiums as elements constituting meaningful differences, despite this being an extremely important factor for beneficiaries in making enrollment decisions. Another commenter recommended that we lower the OOPC differentials between basic and enhanced PDP offerings but at a minimum, we should lower the OOPC differential between enhanced PDP offerings.     While we received relatively few comments related to meaningful difference in response to the RFI, we did receive a number of comments both in support of and opposing the proposed increase in the meaningful difference threshold between enhanced PDP offerings we announced in the Draft CY 2018 Call Letter. Those in favor of our proposal believe that the increase would help to ensure that sponsors are offering meaningfully different plans and would minimize beneficiary confusion. Commenters opposed to the proposal argued that the increase would lead to more expensive plans and would effectively limit plan choice. They argued that expanding OOPC differentials would ultimately create more beneficiary disruption as sponsors would have to consolidate plans that do not meet the new threshold. This result would directly contradict our request that plan sponsors consider options to minimize beneficiary disruption. Commenters suggested that we should utilize OOPC estimates as they were originally intended, to ensure that beneficiaries receive a minimum additional value from enhanced plans. They added that steady and reasonable OOPC thresholds will give beneficiaries more consistent benefits and lower premiums.     We appreciate the importance of ensuring adequate plan choice for beneficiaries and the value of multiple plan offerings with a diversity of benefits, now and in the future. We agree with the argument that two enhanced plans offered by a plan sponsor could vary with respect to their plan characteristics and benefit design, such that they might appeal to different subsets of Medicare enrollees, but in the end have similar out-of-pocket beneficiary costs. We continue to believe however that a meaningful difference, that takes into account out-of-pocket costs, be maintained between basic and enhanced plans to ensure that there is a meaningful value for beneficiaries given the supplemental Part D premium associated with the enhanced plans. Therefore, effective for

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Contract Year (CY) 2019, we propose to revise the Part D regulations at Sec.  423.265 (b)(2) to eliminate the PDP EA to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in a service area. We believe these proposed revisions will help us accomplish the balance we wish to strike with respect to encouraging competition and plan flexibilities while still providing PDP choices to beneficiaries that represent meaningful choices in benefit packages. Anticipated impacts to this change include: (1) A modest increase in the number of plans that would be offered by PDP sponsors (if the EA to EA meaningful difference requirement was the sole barrier to a PDP sponsors offering a second EA plan in a region) and (2) a potential decrease in the average supplemental Part D premium.     We also announce our future intent to reexamine, with the benefit of additional information, how we define the meaningful difference requirement between basic and enhanced plans offered by a PDP sponsor within a service area. We recognize that the current OOPC methodology is only one method for evaluating whether the differences between plan offerings are meaningful, and will investigate whether the current OOPC model or an alternative methodology should be used to evaluate meaningful differences between PDP offerings. While we intend to conduct our own analyses, we also seek stakeholder input on how to define meaningful difference as it applies to basic and enhanced Part D plans. CMS will continue to provide guidance for basic and enhanced plan offering requirements in the annual Call Letter.     Beneficiaries can continue to rely on the many resources CMS makes available, such as the Medicare Plan Finder (MPF), 1-800-MEDICARE and the Medicare and You Handbook, to assist them and their caregivers in making the best plan choices that meet their individual health needs. To the extent that CMS finds its elimination results in potential beneficiary confusion or harm, CMS will consider reinstating the meaningful difference requirement through future rule making or consider taking other action. 17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale a. Introduction     Part D sponsors and their contracted PBMs have been increasingly successful in recent years at negotiating price concessions from pharmaceutical manufacturers, network pharmacies, and other such entities. Between 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes.     The data Part D sponsors submit to CMS as part of the annual required reporting of direct or indirect remuneration (DIR) show that manufacturer rebates, which comprise the largest share of all price concessions received, have accounted for much of this growth.\47\ The data also show that manufacturer rebates have grown dramatically relative to total Part D gross drug costs each year since 2010. Rebate amounts are negotiated between manufacturers and sponsors or their PBMs, independent of CMS, and are often tied to the sponsor driving utilization toward a manufacturer's product through, for instance, favorable formulary tier placement and cost-sharing requirements. ---------------------------------------------------------------------------

    \47\ Sponsors report all DIR to CMS annually by category at the plan level. DIR categories include: Manufacturer rebates, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug cost-related risk-sharing settlements, etc. ---------------------------------------------------------------------------

    The DIR data show similar trends for pharmacy price concessions. Pharmacy price concessions, net of all pharmacy incentive payments, have grown faster than any other category of DIR received by sponsors and PBMs and now buy down a larger share of total Part D gross drug costs than ever before. Such price concessions are negotiated between pharmacies and sponsors or their PBMs, again independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM.     When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent at the individual prescription level and less representative of the actual cost of the drug for the sponsor when it does not include such discounts. Finally, variation in the treatment of rebates and price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, as explained later in this section.     At the time the Part D program was established, we believed, as discussed in the Part D final rule that appeared in the January 28, 2005 Federal Register (70 FR 4244), that market competition would encourage Part D sponsors to pass through to beneficiaries at the point of sale a high percentage of the manufacturer rebates and other price concessions they received, and that establishing a minimum threshold for the rebates to be applied at the point of sale would only serve to undercut these market forces. However, actual Part D program experience has not matched expectations in this regard. In recent years, only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale. Instead, because of the advantages that accrue to sponsors in terms of premiums (also an advantage for beneficiaries), the shifting of costs, and plan revenues, from the way rebates and other price concessions applied as DIR at the end of the coverage year are treated under the Part D payment methodology, sponsors may have distorted incentives as compared to what we intended in 2005.     Therefore, in this request for information we discuss considerations related to and solicit comment on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. Feedback received will be used for consideration in future rulemaking on this topic. b. Background     Section 1860D-2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. Under our current regulations at Sec.  423.100, the negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point of sale by the Part D sponsor. This point of sale price is used to calculate beneficiary cost-sharing. More broadly, the negotiated price is the primary basis by which the Part D benefit is adjudicated, and is used to determine plan, beneficiary, manufacturer (in the

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coverage gap), and government liability during the course of the payment year, subject to final reconciliation following the end of the coverage year.     Under current law, when not explicitly required to do so for certain types of pharmacy price concessions, Part D sponsors can choose whether to reflect various price concessions, including manufacturer rebates, they or their intermediaries receive in the negotiated price. Specifically, section 1860D-2(d)(1)(B) of the Act merely requires that negotiated prices ``shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . . .'' In other words, Part D sponsors are allowed, but generally not currently required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. To date, sponsors have elected to include rebates and other price concessions in the negotiated price at the point-of-sale only very rarely. All rebates and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year and are used in our calculation of final plan payments, which, under the statute, are required to be based on costs actually incurred by Part D sponsors, net of all applicable DIR. (1) Premiums and Plan Revenues     The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point of sale) comes in the form of a lower plan premium. A sponsor must factor into its plan bid an estimate of the DIR expected to be generated--that is, it must lower its estimate of plan liability by a share of the projected DIR--which has the effect of reducing the price of coverage under the plan. Under the current Part D benefit design, price concessions that are applied post-point- of-sale, as DIR, reduce plan liability, and thus premiums, more than price concessions applied at the point of sale. When price concessions are applied to reduce the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost- sharing, as explained in this section, instead of plan and government liability; this is not the case when price concessions are applied post-point-of-sale, where the majority of the concession amount accrues to the plan, and the remainder accrues to the government. Therefore, to the extent that plan bids reflect accurate DIR estimates, the rebates and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point of sale, put downward pressure on plan premiums, as well as the government's subsidies of those premiums. The average Part D basic beneficiary premium has grown at an average rate of only about 1 percent per year between 2010 and 2015, and is projected to decline in 2018, due in part to sponsors' projecting DIR growth to outpace the growth in projected gross drug costs each year. The average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 8.1 percent per year between 2010 and 2015, partly for the same reason.     However, any DIR received that is above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums. The risk-sharing construct established under Part D by statute allows sponsors to retain as plan profit the majority of all DIR that is above the bid-projected amount.\48\ Our analysis of Part D plan payment and cost data indicates that in recent years, DIR amounts Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts. ---------------------------------------------------------------------------

    \48\ Medicare shares risk with Part D sponsors on the drug costs for which they are liable using symmetrical risk corridors and through the payment of 80 percent reinsurance in the catastrophic phase of the benefit. ---------------------------------------------------------------------------

    To capture the relative premium and other advantages that price concessions applied as DIR offer sponsors over lower point-of-sale prices, sponsors sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative. This may put upward pressure on Part D program costs and, as explained below, shift costs from the Part D sponsor to beneficiaries who utilize drugs in the form of higher cost- sharing and to the government through higher reinsurance and low-income cost-sharing subsidies. (2) Cost-Shifting     When manufacturer rebates and other price concessions are not reflected in the negotiated price at the point of sale (that is, applied instead as DIR at the end of the coverage year), beneficiary cost-sharing, which is generally calculated as a percentage of the negotiated price, becomes larger, covering a larger share of the actual cost of a drug. Although this is especially true when a Part D drug is subject to coinsurance, it is also true when a drug is subject to a copay because Part D rules require that the copay amount be at least actuarially equivalent to the coinsurance required under the defined standard benefit design. For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs, even after accounting for the premium savings tied to higher DIR. For the millions of low-income beneficiaries whose out-of-pocket costs are subsidized by Medicare through the low income cost-sharing subsidy, those higher costs are borne by the government. This potential for cost-shifting grows increasingly pronounced as manufacturer rebates and pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price. Numerous research studies further suggest that the higher cost-sharing that results can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.49 50 51 These effects of higher beneficiary cost-sharing under the current policies regarding the determination of negotiated prices must be weighed against the impact on beneficiary access to affordable drugs of the lower premiums that are currently charged for Part D coverage. ---------------------------------------------------------------------------

    \49\ Michele Heisler et al., ``The Health Effects of Restricting Prescription Medication Use Because of Cost,'' Medical Care, 626-634 (2004).     \50\ Peter Bach, ``Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs,'' The New England Journal of Medicine, 360, 626-633 (2009).     \51\ Sonya Blesser Streeter et al., ``Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions,'' Journal of Oncology Practice, 7, no. 3S, 46S-51S (2011). ---------------------------------------------------------------------------

    Moreover, beneficiaries progress through the four phases of the Part D benefit as their total gross drug costs and cost-sharing obligations increase. Because both of these values are calculated based on the negotiated prices reported at the point of sale, when manufacturer rebates and pharmacy price concessions are not applied at the point of sale, the higher negotiated prices that result move Part D beneficiaries more quickly through the Part D benefit. This, in turn, shifts more of the total drug spend into the catastrophic phase, where Medicare liability is highest (80 percent, paid as reinsurance) and plan liability, after the closing of the coverage gap, is lowest (15 percent). Part D program experience further suggests that sponsors are able to offset their already limited liability in the catastrophic phase by capturing additional rebates from manufacturers,

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the largest share of which, under current Part D rules, as explained previously, are allocated to reduce plan liability. Consistent with this benefit, we note that sponsors have negotiated more high price- high rebate arrangements, especially in recent years, which has caused the proportion of costs for which the plan sponsor is at risk to shrink when those higher rebates are not passed on at the point of sale. Under current rules, therefore, Part D sponsors may have weak incentives, and, in some cases even, no incentive, to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available. (3) Transparency and Differential Treatment     Given the significant growth in manufacturer rebates and pharmacy price concessions in recent years, when such amounts are not reflected in the negotiated price, at least to some degree, the true price of a drug to the plan is not available to consumers at the point of sale, nor is it reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Consequently, consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or the lowest-cost drug and pharmacy combination.     The quality of information available to consumers is even less conducive to producing efficient choices when rebates and other price concessions are treated differently by different Part D sponsors; that is, when they are applied to the point-of-sale price to differing degrees and/or estimated and factored into plan bids with varying degrees of accuracy. First, when some sponsors include price concessions in negotiated prices while others treat them as DIR, negotiated prices no longer have a consistent meaning across the Part D program, undermining meaningful price comparisons and efficient choices by consumers. Second, if a sponsor's bid is based on an estimate of net plan liability that is understated because the sponsor has been applying price concessions as DIR at the end of the coverage year rather than using them to reduce the negotiated price at the point of sale, it follows that the sponsor may be able to submit a lower bid than a competitor that applies price concessions at the point of sale or opts for lower net cost alternatives to high cost-highly rebated drugs when available. This lower bid results in a lower plan premium that must be paid by enrollees in the plan, which could allow the sponsor to capture additional market share. The resulting competitive advantage accruing to one sponsor over another in this scenario stems only from a technical difference in how plan costs are reported to CMS. Therefore, the opportunity for differential treatment of rebates and price concessions could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency. c. Manufacturer Rebates to the Point of Sale     We are soliciting comment from stakeholders on how we might most effectively design a policy requiring Part D sponsors to pass through at the point of sale a share of the manufacturer rebates they receive, in order to mitigate the effects of the DIR construct \52\ on costs to both beneficiaries and Medicare, competition, and efficiency under Part D. In this section, we put forth for consideration potential parameters for such a policy and seek detailed comments on their merits, as well as the merits of any alternatives that might better serve our goals of reducing beneficiary costs and better aligning incentives for Part D sponsors with the interests of beneficiaries and taxpayers. We specifically seek comment on how this issue could be addressed without increasing government costs and without reducing manufacturer payments under the coverage gap discount program. We encourage all commenters to provide quantitative analytical support for their ideas wherever possible. ---------------------------------------------------------------------------

    \52\ We use the term ``DIR construct'' to refer to how DIR is treated under current Part D payment rules and the advantages that accrue to Part D sponsors when they apply rebates and other price concessions as DIR at the end of the coverage year. ---------------------------------------------------------------------------

    Specifically, we are considering requiring, through future rulemaking, Part D sponsors to include in the negotiated price reported to CMS for a covered Part D drug a specified minimum percentage of the cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class. We will refer to the rebate amount that we would require be included in the negotiated price for a covered Part D drug as the ``point-of-sale rebate.'' Under such a policy, sponsors could apply as DIR at the end of the coverage year only those manufacturer rebates received in excess of the total point-of-sale rebates. In the unlikely event that total manufacturer rebate dollars received for a drug are less than the total point-of-sale rebates, the difference would be reported at the end of the coverage year as negative DIR. (1) Specified Minimum Percentage     We are considering setting the minimum percentage of manufacturer rebates that must be passed through at the point of sale at a point less than 100 percent of the applicable average rebate amount for drugs in the same drug category or class. For operational ease, we are considering setting the same minimum percentage, which we would specify in regulation, for all rebated drugs in all years--that is, the minimum percentage would not change by drug category or class or by year.     It is important to note that we are not considering requiring that 100 percent of rebates be applied at the point of sale. As explained earlier, the statutory definition of negotiated price in section 1860D- 2(d)(1)(B) of the Act requires that ``negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .'' (emphasis added). We believe this language, particularly when read in the context of the requirement in section 1860D-2(d)(2) of the Act that Part D sponsors report the aggregate price concessions made available ``by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers,'' contemplates that Part D sponsors have some flexibility in determining how to apply manufacturer rebates in order to reduce costs under the plan.     Furthermore, we are cognizant of the fact that while requiring that a higher share of rebates be included in the negotiated price would more meaningfully address the concerns highlighted earlier and lead to larger cost-sharing savings for many beneficiaries, doing so would also result in larger premium increases for all beneficiaries, as discussed in greater detail later in this section, and lower flexibility for Part D sponsors in regards to the treatment of manufacturer rebates, and thus, for some sponsors, weaker incentives to participate in the Part D program. We aim to set the minimum percentage of rebates that must be applied at the point of sale at a point that allows an appropriate balance between these outcomes and thus achieves the greatest possible increase in beneficiary access to affordable drugs.     We are soliciting comment on the minimum percentage of manufacturer rebates that should be reflected in the negotiated price in order to achieve this balance. We are also seeking comment on how and how often, if at all, that

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minimum percentage should be updated by CMS, and what factors should be considered in making any such change. We request that commenters provide analytical justification for their ideas wherever possible. We also are seeking comment on the effect that specifying a minimum percentage of rebates that must be reflected in the negotiated price would have on the competition for rebates under Part D and the total rebate dollars received by Part D sponsors and PBMs. (2) Applicable Average Rebate Amount     We are also particularly interested in stakeholder feedback regarding the following methodology to calculate the applicable average rebate amount, a specified minimum percentage of which would be required to be applied at the point of sale:      Rebate Year: We are considering requiring that point-of-sale rebate amounts be based on average manufacturer rebates expected to be received for each drug category or class under the manufacturer rebate agreements for the current payment year, not historical rebate experience. To the extent that rebate agreements are structured with contingencies that would be unclear at the point of sale, sponsors would be required to base the point-of-sale rebate amount on a good faith estimate of the rebates expected to be received. We solicit comments on whether this approach would ensure that the price available to beneficiaries at the point of sale reflects the actual price of a drug at that time, or if an alternative approach would do so more effectively.      Rebated Drugs: We are considering requiring that the average rebate amount be calculated using only drugs for which manufacturers provide rebates. We believe including non-rebated drugs in this calculation would serve only to drive down the average manufacturer rebates, which would dampen the intended effects of any change.     Additionally, we would likely consider each drug product with a unique 11-digit national drug code (NDC) separately for purposes of calculating the average rebate amount. PDE and rebate data submitted to CMS show that gross drug costs and rebate rates under a plan can vary even for the same drugs produced by the same manufacturer that are packaged differently and thus have different NDC-11 identifiers. Therefore, we believe that the average rebate amounts are more likely to be accurate when calculated based on the gross drug cost and rebate data at the 11-digit NDC level. We solicit comment on whether specifying such a requirement would also serve to ensure consistency in how average rebates are calculated across sponsors, which would make prices more comparable across Part D plans and enforcement easier.      Plan-Level Average: We are considering requiring that average rebate amounts be calculated separately for each plan (that is, calculated at the plan-benefit-package level). In other words, the same average rebate amount would not apply to the point-of- sale price for a covered drug across all plans under one contract, nor across all contracts under one sponsor. We believe this approach would result in the calculation of more accurate average rebates because the PDE and rebate data that are submitted by sponsors demonstrate that gross drug costs and rebate levels are not the same across all plans under one contract, nor across all contracts under one sponsor. This approach would also largely be consistent with how sponsors develop cost estimates for their Part D bids because benefit designs, including formulary structure, and assumptions about enrollee characteristics and utilization vary by plan, even for multiple plans under one contract. Similarly, final payments are calculated by CMS at the plan level, based on the data submitted by the sponsor. We solicit comment on whether the most appropriate approach for calculating the average rebate amount for point-of-sale application would be to do so at the plan level, using plan-specific information, given that moving a portion of manufacturer rebates to the point of sale would impact plan liability and payments, or if another approach would be more appropriate.      Drug Category or Class: We are considering requiring that the manufacturer rebate amount applied to the point-of- sale price for a covered drug be based on the plan's average rebate amount calculated for the rebated drugs in the same category or class. We are considering requiring sponsors to determine the average rebate amount at the therapeutic category or class level, rather than a drug- specific rebate amount, in order to maintain the confidentiality of any manufacturer-sponsor/PBM pricing relationship with respect to an individual drug. Given that rebate rates are typically negotiated at the individual drug level, we believe that the drug category/class- average approach we are considering would help maintain fair competition among drug manufacturers, as well as Part D sponsors, by preventing competitors from reverse engineering the particulars of any proprietary pricing arrangement. This approach would also increase price transparency over the status quo, especially at the drug category or class level, and improve market competition and efficiency under Part D as a result. In addition to feedback on this general approach and our rationale for it, we are seeking comment, in particular, on the drug classification system that Part D sponsors should be required to use to calculate their drug category/class-level average rebate amounts and why that system would be most appropriate for use in such a point- of-sale rebate policy. We also are seeking comment on the effect of calculating average rebates at the drug category/class level on competition and, in turn, on the total rebate dollars received.     We are also particularly interested in comments on how an average rebate amount should be calculated for a drug that is the only rebated drug in its drug category or class. An alternative approach would be necessary in this case because the average rebate amount calculated under the general approach we have described above would equal the drug-specific rebate amount, which, if included in the negotiated price, could result in the release of proprietary pricing information. We ask that commenters explain how any alternative they suggest for the only rebated drug scenario would address this concern and comment on the level of price transparency that would be achieved under the suggested alternative.      Weighting: We are considering requiring that when calculating the applicable average rebate amount for a particular drug category, the manufacturer rebate amount for each individual drug in that category be weighted by the total gross drug costs incurred for that drug, under the plan, over the most recent month, quarter, year, or another time period to be specified in future rulemaking for which cost data is available. We believe a weighted average is more accurate than a simple average because sponsors do not receive the same level of rebates for all drugs in a particular drug category or class, and thus, contrary to the assumption underlying a simple average, not all drugs contribute equally to the final average rebate percentage for a drug category or class received by the sponsor under a plan at the end of a payment year. A gross drug cost-weighted average ensures that drugs with higher utilization, higher costs, or both will be more important to the final average rebate rate realized for the drug category or class than lower utilization, lower cost, or lower cost-lower utilization drugs in the category or class.

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    In the case of a drug with less time on the market than the time period for which cost data would be required under this weighting approach or of a plan that has not been active in the Part D program for the time period required under the weighting approach, we are considering requiring that the drug's rebate amount be weighted by a sponsor's projection of total gross drug costs for the plan that takes into account any plan-specific cost experience already available. If no plan-specific cost experience is available when calculating average rebate amounts, such as at the beginning of a payment year for a new plan, are considering requiring sponsors to use the same drug cost projections on which they base their Part D bids. Further, for operational ease, it appears the manufacturer rebates used in the calculation of the average rebate amount would need to include all manufacturer rebates received for the drug, including all point-of-sale rebates. Then, in order not to double count the point-of-sale rebates, the total gross drug costs used to weight the average under this methodology would have to be based on the drug's price at the point of sale before it is lowered by any manufacturer rebates or other price concessions applied at the point of sale. We are interested in stakeholder feedback on these considerations.     For an illustration of how the weighted-average rebate amount for a particular drug category or class would be calculated, see the point- of-sale rebate example later in this section.      Timing: We are considering requiring Part D sponsors to recalculate the applicable average rebate amount every month, quarter, year, or another time period to be specified in future rulemaking, in order to ensure that the average reflects current cost experience and manufacturer rebate information. We believe that a requirement to recalculate the average rebate amount should balance the need to sustain a level of price transparency throughout the entire year with the additional burden on sponsors associated with more frequent updates. We are seeking comment on how often the applicable cost-weighted drug category/class-average rebate amount, and thus the point-of-sale rebate for any drug, should be recalculated. (3) Point-of-Sale Rebate Drugs     We are considering limiting the application of any point-of-sale rebate requirement to only rebated drugs. Under this approach, the calculated average rebate amount would only be required to be applied to the point-of-sale prices for drugs that are rebated, with each drug identified by its unique NDC-11 identifier. The alternative would result in a manufacturer that provides no rebates for a particular drug benefiting from a direct competitor's rebate, as the competitor's rebate would be used to lower the negotiated price and thereby potentially increasing sales of the non-rebated drug. However, to be clear, under this potential approach, sponsors would maintain their flexibility to include in the negotiated price for any drug, including a non-rebated drug, manufacturer rebates and other price concessions above those required to be included in the negotiated price for rebated drugs under a point-of-sale rebate policy such as the one we describe here.     Moreover, in order to limit the impact on premiums for all beneficiaries of adopting a requirement that sponsors include a portion of manufacturer rebates in the negotiated price at the point of sale, we are also seeking comment on the merits or limitations of, a more targeted version of the policy approach that would require sponsors to pass through a minimum percentage of rebates at the point of sale only for specific drugs or drug categories or classes. Under this alternative approach, the point-of-sale rebate policy would apply only for drugs or drug categories or classes that most directly contribute to increasing Part D drug costs in the catastrophic phase of coverage or drugs with high price-high rebate arrangements; such drugs or drug categories or classes are likely to have the most significant impact on beneficiary costs and serve to increase program costs overall, as discussed previously. We are interested in stakeholder feedback on whether targeting the rebate requirement in such a way would effectively address the misaligned sponsor incentives and market inefficiencies that exist under Part D today as a result of the DIR construct. In addition to general comments on the alternative, more targeted policy approach, we are particularly interested in recommendations for the criteria that we might use to determine which drugs or drug categories or classes to target under such an alternative approach. (4) Point-of-Sale Rebate Example     To illustrate how the weighted-average rebate amount for a particular drug class would be calculated under a point-of-sale rebate requirement that includes the features described earlier, we provide the following example: suppose drugs A, B, and C are the only three rebated drugs on the plan's formulary in a particular drug class. The negotiated prices, before application of the point-of-sale rebates, for the three drugs in the current time period are $200, $100, and $75, respectively. The manufacturer rebates expected by the plan in this payment year, given the information available in the current period, for drugs A, B, and C equal 20, 10, and 5 percent, respectively, of the drugs' pre-rebate negotiated prices. Over the previous time period, total gross drug costs incurred under the plan for drug A equaled $2 million, for drug B equaled $750,000, and for drug C equaled $150,000. Therefore, the gross drug cost-weighted average rebate rate for this drug class in the current time period is calculated as the following: [($2 million x 20 percent) + ($750,000 x 10 percent) + ($150,000 x 5 percent)]/($2 million + $750,000 + $150,000), or 16.64 percent. If we were to require that a minimum 50 percent of the average rebate be applied at the point of sale for all rebated drugs in this drug class (and the plan only applies the minimum required percentage), the final negotiated prices for drugs A, B, and C, now equal to $183.36, $91.68, and $68.76, respectively, would be 8.32 percent (50 percent of 16.64 percent) lower than the pre-rebated prices.     For each of the three drugs in this example, beneficiary out-of- pocket costs would be lower under the approach we are considering than under the status quo. Assuming, for instance, these drugs are subject to a 25 percent coinsurance, the enrollee's costs for the three drugs under this approach would be $45.84 (25 percent of $183.36) for drug A, $22.92 (25 percent of $91.68) for drug B, and $17.19 (25 percent of $68.76) for drug C. Under the status quo, the enrollee's costs would be $50 for drug A ($4.16 higher), $25 for drug B ($2.08 higher), and $18.75 for drug C ($1.56 higher).     Any difference between the rebates applied at the point of sale and those actually received would be captured as DIR through reporting at the end of the coverage year. Assume, for instance, that total gross drug costs for drugs A, B, and C equal $1.5 million, $1 million, and $200,000, respectively, in this period. The actual manufacturer rebates received, therefore, will equal $300,000, $100,000, and $10,000, respectively, for drugs A, B, and C in this period, based on the plan's expected rebate rates of 20, 10, and 5 percent, respectively, for the three drugs in this payment year. Based on the point-of-sale rebate rate calculated above for the applicable drug class and the total gross drug cost assumptions provided for the three drugs, we calculate the total point-of-

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sale rebates in this period to be $124,786.48 (8.32 percent of $1.5 million) for drug A, $83,189.66 (8.32 percent of $1 million) for drug B, and $16,637.93 (8.32 percent of $200,000) for drug C. Therefore, the manufacturer rebates applied by the plan as DIR at the end of the coverage year for the three drugs, respectively, would be $175,215.52, $16,810.34, and -$6,637.93 and total $185,387.93 across the drug class. (5) Additional Considerations     Under the policy approach that we are considering here for moving manufacturer rebates to the point of sale, the responsibility for calculating the appropriate point-of-sale rebate amount over the course of the year would fall on Part D sponsors given their role in administering the Medicare drug benefit. We would leverage existing reporting mechanisms to review the sponsors' calculations, as we do with other cost data required to be reported. Specifically, we would likely use the estimated rebates at point-of-sale field on the PDE record to collect point-of-sale rebate information, and the manufacturer rebates fields on the Summary and Detailed DIR Reports to collect final manufacturer rebate information at the plan and NDC levels. Differences between the manufacturer rebate amounts applied at the point of sale and rebates actually received would become apparent when comparing the data collected through those means at the end of the coverage year.     Additionally, we note that in accordance with Sec.  423.505(k) of the Part D regulations, a Part D sponsor is required to certify the accuracy, completeness, and truthfulness of all data related to payment, including the PDE data and information on allowable costs that it submits for purposes of risk corridor and reinsurance payment. A Part D sponsor certifies its Part D cost data by signing and submitting attestations to CMS. By signing the attestations, the Part D sponsor certifies (based on best knowledge, information, and belief) that the PDE data, DIR data, and any other information provided for the purposes of determining payment to the plan for the applicable contract year are accurate, complete, and truthful. If we were to move forward with a point-of-sale rebate policy, we would also consider amending Sec.   423.505(k) to add a new requirement that the CEO, CFO, or COO attest (based on best knowledge, information, and belief) to the accuracy, completeness, and truthfulness of the average rebate amount included in the negotiated price and reported on the PDE. The submission of accurate, complete, and truthful data regarding the average rebate amount included in the negotiated price would be necessary to ensure accurate reinsurance and risk corridor payments.     Under the approach we are considering, if a Part D sponsor discovers errors after the certification has been made (that is, after the attestation has been signed), the Part D sponsor would submit corrected PDE data, and, under most circumstances, CMS would reconcile the error through the reopening process described at Sec.  423.346 All reopenings are at the discretion of CMS. CMS performs a global reopening approximately 4 years after the initial reconciliation for that contract year. A Part D sponsor's reopening request resulting from errors in PDE data discovered after the global reopening for the contract year in which the error occurred would be evaluated by CMS on a case by case basis. Any errors in the calculation of the average rebate amount that result in overpayments would be required to be reported and returned consistent with Sec.  423.360 and the applicable subregulatory guidance on overpayments.     We note that prior to the submission of the attestation, and more specifically, prior to the PDE submission deadline for the initial reconciliation for a contract year, if a Part D sponsor discovers an issue with the average rebate amount included in the negotiated price and reported on the PDE, all affected PDEs would need to be adjusted or ***deleted*** in accordance with applicable CMS guidance. As of the publication of this request for information, the applicable guidance is October 6, 2011 CMS memorandum, Revision to Previous Guidance Titled ``Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.''     We encourage stakeholders to comment on what other enforcement and oversight mechanisms should be instituted to ensure compliance with any potential point-of-sale rebate requirement. We are particularly interested in stakeholder feedback on how we might ensure accurate rebate amounts are applied at the point of sale when rebate agreements are structured with contingencies that would be unclear at the point of sale.     We also seek stakeholder comment on what, if any, special considerations should be taken into account in the design of a point- of-sale rebate policy, for Part D employer group waiver plans (EGWPs). We are also interested in feedback on what particular effects requiring Part D sponsors to apply some manufacturer rebates at the point of sale would have on the EGWP market, as well as on how such a requirement might impact the retiree drug subsidy program.     Finally, we note that the negotiated price is also the basis by which manufacturer liability for discounts in the coverage gap is determined. Under section 1860D-14A(g)(6) of the Act, the negotiated price used for coverage gap discounts is based on the definition of negotiated price in the version of Sec.  423.100 that was in effect as of the passage of the Patient Protection and Affordable Care Act (PPACA). Under this definition, the negotiated price is ``reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale'' (emphasis added). Because this definition of negotiated price only references the price concessions that the Part D sponsor has elected to pass through at the point of sale, we are uncertain as to whether we would have the authority to require sponsors include in the negotiated price the weighted-average rebate amounts that would be required to be passed through under any potential point-of-sale rebate policy, for purposes of determining manufacturer coverage gap discounts. We intend to consider this issue further and will address it in any future rulemaking regarding the requirements for determining the negotiated price that is available at the point of sale. (6) Impacts of Applying Manufacturer Rebates at the Point of Sale     Under a point-of-sale rebate policy designed as we have described in this comment solicitation, beneficiaries would see lower prices at the pharmacy point-of-sale, and on Plan Finder, beginning immediately in the year the policy takes effect. Lower point-of-sale prices would result directly in lower cost-sharing costs for non-low income beneficiaries, especially for those who use drugs in highly competitive, highly-rebated categories or classes. For low income beneficiaries whose out-of-pocket costs are subsidized through Medicare's low-income cost-sharing subsidy, cost-sharing savings resulting from lower point-of-sale prices would accrue to the government. Plan premiums would likely increase as a result of such a point-of-sale rebate policy--if some rebates are required to be passed through to beneficiaries at the point of sale, fewer such concessions could be apportioned to reduce plan liability, which would have the effect of

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increasing the cost of coverage under the plan. At the same time, the reduction in cost-sharing obligations for the average beneficiary would likely be large enough to lower their overall out-of-pocket costs. The increasing cost of coverage under Part D plans as a result of rebates being applied at the point of sale likely would have a more significant impact on government costs, which would increase overall due to the significant growth in Medicare's direct subsidies of plan premiums and low income premium subsidies.     Partially offsetting the increase in direct subsidy and low income premium subsidy costs for the government would be decreases in Medicare's reinsurance and low income cost-sharing subsidies. Decreases in Medicare's reinsurance subsidy result when lower negotiated prices slow down the progression of beneficiaries through the Part D benefit and into the catastrophic phase, and when the government's 80 percent reinsurance payments for allowable drug costs incurred in the catastrophic phase are based on lower negotiated prices. Similarly, low income cost-sharing subsidies would decrease if beneficiary cost- sharing obligations decline due to the reduction in prices at the point of sale. Finally, the slower progression of beneficiaries through the Part D benefit would also have the effect of reducing manufacturer gap discount payments as fewer beneficiaries would enter the coverage gap phase or progress entirely through it.     The following tables summarize the 10-year impacts we have modeled for when 33, 66, 90, and 100 percent of all manufacturer rebates are applied at the point of sale: \53\ ---------------------------------------------------------------------------

    \53\ Assumptions: (1) For purposes of calculating impacts only, we assume that total rebates will equal about 20 percent of allowable Part D drug costs projected for each year modeled, and that rebates are perfectly substituted with the point-of-sale discount in all phases of the Part D benefit, including the coverage gap phase.     (2) Used 2016 distribution of costs by benefit phase to form assumptions.     (3) Assumed no other behavioral changes by sponsors, beneficiaries, or others.

                                 Table 10A--Total Impacts for 2019 Through 2028                                                  [In $billions] ----------------------------------------------------------------------------------------------------------------                                                         33%             66%             90%            100% ---------------------------------------------------------------------------------------------------------------- Beneficiary Costs...............................          -$19.6          -$39.1          -$53.2          -$56.9     Cost-Sharing................................           -28.8           -57.8           -78.9           -85.2     Premium.....................................             9.2            18.7            25.7            28.3 Government Costs................................            27.3            55.1            75.5            82.1     Direct Subsidy..............................            62.8           128.1           177.4           200.0     Reinsurance.................................           -21.7           -44.7           -62.2           -73.1     LI Cost-Sharing Subsidy.....................           -16.6           -34.2           -47.7           -53.7     LI Premium Subsidy..........................             2.9             5.9             8.1             8.9 Manufacturer Gap Discount.......................            -9.7           -19.4           -26.4           -29.4 ----------------------------------------------------------------------------------------------------------------

                                Table 10B--2019-2028 Per Member-Per Month Impacts ----------------------------------------------------------------------------------------------------------------                                                         33%             66%             90%            100% ---------------------------------------------------------------------------------------------------------------- Beneficiary Costs...............................         -$30.33         -$60.58         -$82.42         -$88.13     Cost-Sharing................................          -44.61          -89.50         -122.26         -131.97     Premium.....................................           14.29           28.92           39.83           43.84 Government Costs................................           42.38           85.40          117.01          127.22     Direct Subsidy..............................           97.45          198.93          275.43          310.58     Reinsurance.................................          -33.76          -69.57          -96.84         -113.75     LI Cost-Sharing Subsidy.....................          -25.80          -53.06          -74.11          -83.42     LI Premium Subsidy..........................            4.49            9.10           12.53           13.81 Manufacturer Gap Discount.......................          -15.01          -30.02          -40.93          -45.48 ----------------------------------------------------------------------------------------------------------------

                                  Table 10C--2019-2028 Impacts--Percent Change ----------------------------------------------------------------------------------------------------------------                                                         33%             66%             90%            100% ---------------------------------------------------------------------------------------------------------------- Beneficiary Costs...............................              -3              -5              -7              -8     Cost-Sharing................................              -6             -12             -16             -17     Premium.....................................               4               7              10              11 Government Costs................................               2               4               5               6     Direct Subsidy..............................              24              49              67              76     Reinsurance.................................              -3              -7              -9             -11     LI Cost-Sharing Subsidy.....................              -4              -9             -12             -14     LI Premium Subsidy..........................               4               8              11              12 Manufacturer Gap Discount.......................              -7             -13             -18             -20 ----------------------------------------------------------------------------------------------------------------

    While we did not account for behavioral changes when modeling these impacts, requiring rebates to be applied at the point of sale might induce changes in sponsor behavior related to drug pricing that would further reduce the cost of the Part D program for beneficiaries and taxpayers. Specifically, requiring that at least a minimum percentage of manufacturer rebates be used to lower the price at the point of sale could limit the potential for sponsors to leverage the benefits that accrue to them when price concessions are applied as DIR at the end of the

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coverage year rather than as discounts at the point of sale, and thus potentially better align sponsors' incentives with those of beneficiaries and taxpayers. For example, we believe such an approach could reduce the incentive for sponsors to favor high cost-highly rebated drugs to lower net cost alternatives, when such alternatives are available, and also potentially increase the incentive for sponsors and PBMs to negotiate lower prices at the point of sale instead of higher DIR. We seek comment on the extent to which a point-of-sale rebate policy might be expected to further align the incentives for beneficiaries, sponsors, and taxpayers.     Finally, we believe requiring that some manufacturer rebates be applied at the point of sale as we are considering doing would improve price transparency and limit the opportunity for differential reporting of costs and price concessions, which may have a positive effect on market competition and efficiency. We solicit comment on whether basing the rebate applied at the point of sale on average rebates at the drug category/class level, as described previously, would meaningfully increase price transparency over the status quo by ensuring a consistent percentage of the rebates received are reflected in the price at the point of sale, while also protecting the details of any manufacturer-sponsor pricing relationship. d. Pharmacy Price Concessions to Point of Sale     In recent years, a growing proportion of Part D sponsors and their contracted PBMs have entered into payment arrangements with Part D network pharmacies in which a pharmacy's reimbursement for a covered Part D drug is adjusted after the point of sale based on the pharmacy's performance on various measures defined by the sponsor or its PBM. Furthermore, we understand that the share of pharmacies' reimbursements that is contingent upon their performance under such arrangements has also grown steadily each year. As a result, sponsors and PBMs have been recouping increasing sums from network pharmacies after the point of sale (pharmacy price concessions) for ``poor performance'' relative to standards defined by the sponsor or PBM. These sums are far greater than those paid to network pharmacies after the point of sale (pharmacy incentive payments) for ``high performance.'' We refer to pharmacy price concessions and incentive payments collectively as pharmacy payment adjustments. These findings are largely based on the aggregate pharmacy payment adjustment data submitted to CMS by Part D sponsors as part of the annual required reporting of DIR, which show that performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased most dramatically after 2012.     In order to address the effects of the DIR construct, as it relates to pharmacy payment adjustments, on cost, competition, and efficiency under Part D, in the Part C and Part D final rule that appeared in the May 23, 2014 Federal Register (79 FR 29844), we amended the definition of ``negotiated prices'' at Sec.  423.100 to require Part D sponsors to include in the negotiated price at the point of sale all pharmacy price concessions and incentive payments to pharmacies, with an exception, which was intended to be narrow, allowed for contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale (the reasonably determined exception). However, when we formulated these requirements in 2014, the most recent year for which DIR data was available was 2012 and we did not anticipate the growth of performance-based pharmacy payment arrangements that we have observed in subsequent years. We now understand that the reasonably determined exception we currently allow applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements, and, as a result, this exception prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs.     Specifically, we have heard from several stakeholders that have suggested that the reasonably determined exception applies to all performance-based pharmacy payment adjustments. The amount of these adjustments, by definition, is contingent upon performance measured over a period that extends beyond the point of sale and, thus, cannot be known in full at the point of sale. Therefore, performance-based pharmacy payment adjustments cannot ``reasonably be determined'' at the point of sale as they cannot be known in full at the point of sale. We initially proposed, in a September 29, 2014 memorandum entitled Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, that if the amount of the post-point of sale pharmacy payment adjustment could be reasonably approximated at the point of sale, the adjustment should be reflected in the negotiated price, even if the actual amount of the payment adjustment was subject to later reconciliation and thus not known in full at the point of sale. However, we did not finalize that interpretation because we determined that it was inconsistent with the existing regulation given that it would have effectively eliminated the reasonably determined exception from inclusion in the negotiated price for all pharmacy price concessions, as we stated in our follow-up memorandum of the same name released on November 5, 2014.     Given the predominance of performance-contingent pharmacy payment arrangements, we do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that achieves meaningful price transparency, ensures that all pharmacy payment adjustments are taken into account consistently by all Part D sponsors, and prevents the shifting of costs onto beneficiaries and taxpayers. Therefore, we are soliciting comment from stakeholders on how we might update the requirements governing the determination of negotiated prices, to better reflect current pharmacy payment arrangements, so as to ensure that the reported price at the point of sale includes all pharmacy price concessions. In this section, we put forth for consideration one potential approach for doing so and seek comments on its merits, as well as the merits of any alternatives that might better serve our goals of reducing beneficiary costs and better aligning incentives for Part D sponsors with the interests of beneficiaries and taxpayers. We encourage all commenters to provide quantitative analytical support for their ideas wherever possible. (1) All Pharmacy Price Concessions     We are considering revising the definition of negotiated price at Sec.  423.100 to remove the reasonably determined exception and to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy. We believe we have the discretion to require that all pharmacy price concessions be applied at the point of sale, and not just a share of the amounts as we discussed earlier for manufacturer rebates. Such a requirement would preserve the flexibilities provided under section 1860D-2(d)(1)(B) of the Act with respect to the treatment of manufacturer rebates, while also allowing for greater

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transparency and consistency in the reporting of pharmacy price concessions. First, section 1860D-2(d)(2) of the Act, which provides the context critical to our interpretation that sponsors are granted flexibility in how to apply manufacturer rebates, does not contemplate price concessions from sources other than manufacturers, such as pharmacies, being passed through in various ways. Second, even when all price concessions from pharmacies are required to be applied at the point of sale, sponsors would retain the flexibility to determine how to apply manufacturer rebates and other price concessions received from sources other than pharmacies in order to reduce costs under the plan. Finally, we believe that requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices ``take into account'' at least some price concessions and, therefore, would be consistent with the plain language of section 1860D-2(d)(1)(B) of the Act. We are considering requiring all, and not only a share of, pharmacy price concessions be included in the negotiated price in order to maximize the level of price transparency and consistency in the determination of negotiated prices and bids and meaningfully reduce the shifting of costs from sponsors to beneficiaries and taxpayers. (2) Lowest Possible Reimbursement     In order to effectively capture all pharmacy price concessions at the point of sale consistently across sponsors, we are considering requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point of sale would need to include all price concessions that could potentially flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow to network pharmacies and increase prices over the lowest reimbursement level, such as incentive fees. That is, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that prescription under the arrangement if the pharmacy's performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible contingent incentive reimbursement (such as in situations where a pharmacy's performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR. For an illustration of how negotiated prices would be reported under such an approach, see the example provided later in this section.     We are interested in public comment on whether requiring the negotiated price at the point of sale to reflect the lowest possible pharmacy reimbursement would effectively address recent developments in industry practices, that is, the growing prevalence of performance- based pharmacy payment arrangements, and ensure that all pharmacy price concessions are included in the negotiated price, and thus shared with beneficiaries, in a consistent manner by all Part D sponsors. By requiring that sponsors assume the lowest possible pharmacy performance when reporting the negotiated price, we would be prescribing a standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point of sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point of sale. We are also interested in public comment on whether requiring the negotiated price to be the lowest possible pharmacy reimbursement would serve to maximize the cost- sharing savings accruing to beneficiaries by passing through all potential pharmacy price concessions at the point of sale.     Further, we are interested in public comment on whether this approach would be clearer for Part D sponsors to follow than the requirements in place today, which require Part D sponsors to assess which types of pharmacy payment adjustments fall under the reasonably determined exception. We are interested in public comment on whether providing such additional clarity and thus limiting the need for interpretation of the requirements by Part D sponsors would improve consistency in the application of the requirements regarding pharmacy price concessions across sponsors, as well as reducing sponsor burden in terms of the resources necessary to ensure compliance in the absence of clear guidance. In addition, we welcome feedback on whether the change we describe here would improve the quality of pricing information available across Part D plans and thus improve market competition and cost-efficiency under Part D.     Requiring the negotiated price to reflect the lowest possible pharmacy reimbursement, would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements and thus closer to the actual cost of the drug for the Part D sponsor. We are interested in public comment on whether such an outcome would help us to achieve meaningful price transparency. We have learned from the DIR data reported to CMS and feedback from numerous stakeholders that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties. Therefore, we seek comment on whether a requirement that the negotiated price reflect the lowest possible reimbursement to a network pharmacy, including all potential pharmacy price concessions, is likely to capture the actual price of the drug at a network pharmacy, or at least move closer to it.     Finally, we are considering requiring that all contingent incentive payments be excluded from the negotiated price because including the actual amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a ``high performing'' pharmacy, which receives an incentive payment, than at a ``poor performing'' pharmacy, which is assessed a penalty. This pricing differential could potentially create a perverse incentive for beneficiaries to choose a lower performing pharmacy for the advantage of a lower price. We seek comment on whether such an approach would prevent this unintended consequence and thus avoid reducing the competitiveness of high performing pharmacies by increasing the negotiated price charged to the beneficiary at those pharmacies. (3) Lowest Possible Reimbursement Example     To illustrate how Part D sponsors and their intermediaries would report costs under the approach we are considering, we provide the following example: Suppose that under a performance-based payment arrangement between a

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Part D sponsor and its network pharmacy, the sponsor will: (1) Recoup 5 percent of its total Part D-related payments to the pharmacy at the end of the contract year for the pharmacy's failure to meet performance standards; (2) recoup no payments for average performance; or (3) provide a bonus equal to 1 percent of total payments to the pharmacy for high performance. For a drug that the sponsor has agreed to pay the pharmacy $100 at the point of sale, the pharmacy's final reimbursement under this arrangement would be: (1) $95 for poor performance; (2) $100 for average performance; or (3) $101 for high performance. However, under all performance scenarios, the negotiated price reported to CMS on the PDE at the point of sale for this drug would be $95, or the lowest reimbursement possible under the arrangement. Thus, if a plan enrollee were required to pay 25 percent coinsurance for this drug, then the enrollee's costs under all scenarios would be 25 percent of $95, or $23.75, which is less than the $25 the enrollee would pay today (when the negotiated price is likely to be reported as $100). Any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR at the end of the coverage year. The sponsor would report $0 as DIR under the poor performance scenario ($95 minus $95), - $5 as DIR under the average performance scenario ($95 minus $100), and - $6 as DIR under the high performance scenario ($95 minus $101), for every covered claim for this drug purchased at this pharmacy. (4) Additional Considerations     As with the policy approach that we described previously for moving manufacturer rebates to the point of sale, we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at the point of sale, as we do with other cost data required to be reported. Specifically, we would likely use the estimated rebates at point-of-sale field on the PDE record to also collect point-of-sale pharmacy price concessions information, and fields on the Summary and Detailed DIR Reports to collect final pharmacy price concession information at the plan and NDC levels. Differences between the amounts applied at the point of sale and amounts actually received, therefore, would become apparent when comparing the data collected through those means at the end of the coverage year.     Finally, as noted previously, the negotiated price is also the basis by which manufacturer liability for discounts in the coverage gap determined. Under section 1860D-14A(g)(6) of the Act, the definition of negotiated price used for coverage gap discounts is based on the regulatory definition of the negotiated price in the version of Sec.   423.100 that was in effect as of the passage of the PPACA. As discussed previously, this definition of negotiated price only references the price concessions that the Part D sponsor has elected to pass through at the point of sale. As such, we are uncertain as to whether we would have the authority to require sponsors include pharmacy price concessions in the negotiated price for purposes of determining manufacturer coverage gap discounts. We intend to consider this issue further and will address it in any future rulemaking regarding the requirements for determining the negotiated price that is available at the point of sale. (5) Impacts for Applying Pharmacy Price Concessions at the Point of Sale     Requiring that all pharmacy price concessions that sponsors and PBMs receive be used to lower the price at the point of sale, as we described earlier, would affect beneficiary, government, and manufacturer costs largely in the same manner as discussed previously in regards to moving manufacturer rebates to the point of sale. The difference is in the magnitude of the impacts given that sponsors and PBMs receive significantly higher sums of manufacturer rebates than of pharmacy price concessions. The following table summarizes the 10-year impacts we have modeled for moving all pharmacy price concessions to the point of sale: \54\ ---------------------------------------------------------------------------

    \54\ Assumptions: (1) For purposes of calculating impacts only, we assume that pharmacy price concession will equal about 3 percent of allowable Part D costs projected for each year modeled, and that the concession amounts are perfectly substituted with the point-of- sale discount in all phases of the Part D benefit, including the coverage gap phase.     (2) Used 2016 distribution of costs by benefit phase to form assumptions.     (3) Assumed no other behavioral changes by sponsors, beneficiaries, or others.

                      Table 11--2019-2028 Point-of-Sale Pharmacy Price Concessions Impacts ----------------------------------------------------------------------------------------------------------------                                                                        Total      Per member-per                                                                     (billions)         month      Percent change ---------------------------------------------------------------------------------------------------------------- Beneficiary Costs...............................................          -$10.4         -$16.09              -1     Cost-Sharing................................................           -16.1          -24.89              -3     Premium.....................................................             5.7            8.79               2 Government Costs................................................            16.6           25.65               1     Direct Subsidy..............................................            33.5           51.89              13     Reinsurance.................................................            -8.8          -13.74              -1     LI Cost-Sharing Subsidy.....................................            -9.9          -15.23              -3     LI Premium Subsidy..........................................             1.8            2.73               2 Manufacturer Gap Discount.......................................            -5.0           -7.69              -3 ----------------------------------------------------------------------------------------------------------------

    Moreover, while not accounted for when modeling these impacts, we seek comment on whether requiring that all pharmacy price concessions be included in the negotiated price, as we have described, would also lead to prices and Part D bids and premiums being more accurately comparable and reflective of relative plan efficiencies, with no unfair competitive advantage accruing to one sponsor over another based on a technical difference in how costs are reported. We are further interested in comments on whether this outcome could make the Part D market more competitive and efficient.

B. Improving the CMS Customer Experience

1. Restoration of the Medicare Advantage Open Enrollment Period (Sec. Sec.  422.60, 422.62, 422.68, 423.38 and 423.40)     Section 4001 of the Balanced Budget Act of 1997 (BBA), added section

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1851(e) of the Act establishing specific parameters in which elections can be made and/or changed during open enrollment and disenrollment periods under the Medicare Advantage (MA) program. In addition, section 1851(e)(6) of the Act permits MA organizations, at their discretion, to choose not to accept enrollment requests during the open enrollment period (that is, choose to be closed to accept enrollments for all or a portion of the enrollment period). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1851(e)(2) of the Act to further establish open enrollment periods during which MA-eligible individuals were limited to a single election to (that is, enroll, disenroll, or change MA plans) during such period.     From 2007 to 2010, the Act outlined an Open Enrollment Period (OEP)--referred to hereafter as the ``old OEP''--which provided MA- eligible individuals one opportunity to make an enrollment change between January 1 and March 31. It permitted new enrollment into an MA plan from Original Medicare, switches between MA plans, and disenrollment from a MA plan to Original Medicare. During this old OEP, individuals were not allowed to make changes to their Part D coverage. Hence, an individual who had Part D coverage through a Medicare Advantage Prescription Drug plan (MA-PD plan) could only use the old OEP to switch to (1) another MA-PD plan; or (2) Original Medicare with a Prescription Drug Plan (PDP). This old OEP did not permit someone enrolled in either an MA-only plan or Original Medicare without a PDP to enroll in Part D coverage through this enrollment opportunity. The old OEP was codified at Sec.  422.62(a)(5) in 2005 (see 70 FR 4587).     In 2010, section 3204 of the Patient Protection and Affordable Care Act modified section 1851(e)(2)(C) of the Act to no longer offer the old OEP and instead provide a different enrollment period for MA enrollees to leave the MA program and return to Original Medicare in the first 45 days of the calendar year. The statute further permitted individuals who utilized this disenrollment opportunity to enroll in a Part D plan upon their return to Original Medicare. On April 15, 2011, we amended Sec.  422.62(a)(5) and codified Sec. Sec.  422.62(a)(7) and 423.38(d) to conform with this statutory change and to establish the current Medicare Advantage Disenrollment Period (MADP) with its coordinating Part D enrollment period. These changes were effective for the 2011 plan year (76 FR 21442 and43).     Section 17005 of the 21st Century Cures Act (the Cures Act) modified section 1851(e)(2) of the Act to eliminate the MADP and to establish, beginning in 2019, a new OEP--hereafter referred to as the ``new OEP''--to be held from January 1 to March 31 each year. Subject to the MA plan being open to enrollees as provided under Sec.   422.60(a)(2), this new OEP allows individuals enrolled in an MA plan to make a one-time election during the first 3 months of the calendar year to switch MA plans or to disenroll from an MA plan and obtain coverage through Original Medicare. In addition, this provision affords newly MA-eligible individuals (those with Part A and Part B) who enroll in a MA plan, the opportunity to also make a one-time election to change MA plans or drop MA coverage and obtain Original Medicare. Newly eligible MA individuals can only use this new OEP during the first 3 months in which they have both Part A and Part B. Similar to the old OEP, enrollments made using the new OEP are effective the first of the month following the month in which the enrollment is made, as outlined in Sec.  422.68(c). In addition, an MA organization has the option under section 1851(e)(6) of the Act to voluntarily close one or more of its MA plans to OEP enrollment requests. If an MA plan is closed for OEP enrollments, then it is closed to all individuals in the entire plan service area who are making OEP enrollment requests. All MA plans must accept OEP disenrollment requests, regardless of whether or not it is open for enrollment.     There are a few key differences between the old OEP and the new OEP as authorized by the Cures Act. Unlike the old OEP, this new OEP permits changes to Part D coverage for individuals who, prior to the change in election during the new OEP, were enrolled in an MA plan. As eligibility to use the new OEP is available only for MA enrollees, the ability to make changes to Part D coverage is limited to any individual who uses the OEP; however, the new OEP does not provide enrollment rights to any individual who is not enrolled in an MA plan during the applicable 3-month period. Individuals who use the new OEP to make changes to their MA coverage may also enroll in or disenroll from Part D coverage. For example, an individual enrolled in an MA-PD plan may use the new OEP to switch to: (1) Another MA-PD plan; (2) an MA-only plan; or (3) Original Medicare with or without a PDP. The new OEP would also allow an individual enrolled in an MA-only plan to switch to--(1) another MA-only plan; (2) an MA-PD plan; or (3) Original Medicare with or without a PDP. However, this enrollment period does not allow for Part D changes for individuals enrolled in Original Medicare, including those with enrollment in stand-alone PDPs.     In addition, individuals with enrollment in Original Medicare or other Medicare health plan types, such as cost plans, are not able use the new OEP to enroll in an MA plan, regardless of whether or not they have Part D. We note that the inability for an individual enrolled in Original Medicare to use the new OEP is a significant difference from the old OEP. Furthermore, and significantly different from the old OEP, unsolicited marketing is prohibited by statute during this period.     To implement the changes required by the Cures Act, we propose the following revisions:      Amend current Sec.  422.62(a)(5) and add Sec. Sec.   423.38(e) and 423.40(e) to establish the new OEP starting 2019 and the corresponding limited Part D enrollment period.      Amend Sec. Sec.  422.62(a)(7), 422.68(f), 423.38(d) and 423.40(d) to end the MADP at the end of 2018.      Remove current regulations in Sec.  422.62(a)(3) and (a)(4) that outline historical OEPs which have not been in existence for more than a decade. As these past enrollment periods are no longer relevant to the current enrollment periods available to MA-eligible individuals, we are proposing to ***delete*** these paragraphs and renumber the enrollment periods which follow them. As such, we propose that Sec.  422.62 (a)(5) become Sec.  422.62 (a)(3), and both Sec. Sec.   422.62 (a)(6) and (a)(7) be renumbered as Sec. Sec.  422.62(a)(4) and (a)(5), respectively.      Amend new redesignated paragraph (a)(4) (proposed to be redesignated from (a)(6)) to make two technical changes to replace the phrase ``as defined by CMS'' with ``as defined in Sec.  422.2'' and to capitalize ``original Medicare.''      As noted previously, and discussed in section III.C.7, Sec. Sec.  422.2268 and 423.2268 would be revised to prohibit marketing to MA enrollees during the OEP.      Conforming technical edits to update cross references in Sec. Sec.  422.60(a)(2), 422.62(a)(5)(iii), and 422.68(c). 2. Reducing the Burden of the Compliance Program Training Requirements (Sec. Sec.  422.503 and 423.504)     Sections 1857(e) and 1860D-12(b)(3)(D) of the Act specify that contracts with MA organizations and

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Part D sponsors shall contain other terms and conditions that the Secretary may find necessary and appropriate. We have previously established that all Part C and Part D contracting organizations must have the necessary administrative and management arrangements to have an effective compliance program, as reflected in Sec.   422.503(b)(4)(vi) and Sec.  423.504(b)(4)(vi). Effective compliance programs are those designed and implemented to prevent, detect and correct Medicare non-compliance, fraud waste and abuse and address improper conduct in a timely and well-documented manner. Medicare non- compliance may include inaccurate and untimely payment or delivery of items or medical services, complaints from providers and enrollees, illegal activities and unethical behavior. While there is no ``one-size fits all'' program for every contracting organization, there are seven core elements that must exist to have an effective compliance program that is tailored to the organization's unique operations, compliance risks, resources and circumstances. These 7 core elements are codified in current regulations at Sec. Sec.  422.503(b)(4)(vi)(A) through (G) and 423.504(b)(4)(vi)(A) through (G). One of the 7 core elements is training and education. Compliance programs for Part C and Part D organizations must include training and education between the compliance officer and the sponsoring organization's employees, senior administrators, governing body members as well as their first-tier, downstream and related entities (FDRs).     FDRs have long complained of the burden of having to complete multiple sponsoring organizations' compliance trainings and the amount of time it can take away from providing care to beneficiaries. We attempted to resolve this burden by developing our own web-based standardized compliance program training modules and establishing, in a May 23, 2014 final rule (79 FR 29853 and 29855), which was effective January 1, 2016, that FDRs were required to complete the CMS training to satisfy the compliance training requirement. The mandatory use of the CMS training by FDRs was a means to ensure that FDRs would only have to complete the compliance training once on an annual basis. The FDRs could then provide the certificate of completion to all Part C and Part D contracting organizations they served, hence, eliminating the prior duplication of effort that so many FDRs stated was creating a huge burden on their operation.     However, CMS continues to receive hundreds of inquiries and concerns from sponsors and FDRs regarding their difficulties with adopting CMS' compliance training to satisfy the compliance program training requirement. While CMS' previous market research indicated that this provision would mitigate the problems raised by FDRs who held contracts with multiple sponsors and who completed repetitive trainings for each sponsor with which they contract, in practice, we learned that the problems persisted. Many sponsors are unwilling to accept completion of the CMS training as fulfillment of the training requirement and identify which critical positions within the FDR are subject to the training requirement. As a result, FDRs are still being subjected to multiple sponsors' specific training programs. FDRs have the additional burden of taking CMS training and reporting completion back to the sponsor or sponsors with which they contract. Furthermore, the industry has indicated that the requirement has increased the burden for various Part C and Part D program stakeholders, including hospitals, suppliers, health care providers, pharmacists and physicians, all of which may be considered FDRs. Since the implementation of the mandatory CMS-developed training has not achieved the intended efficiencies in the administration of the Part C and Part D programs, we propose to ***delete*** the provisions from the Part C and Part D regulations that require use of the CMS-developed training. Additionally we propose to restructure Sec.  422.503(b)(4)(vi)(C)(1) (with the proposed revisions) into two paragraphs (that is, paragraph (C)(1) and (C)(2)) to separate the scope of the compliance training from the frequency with which the training must occur, as these are two distinct requirements. With this proposed revision, the organization of Sec.  422.503(b)(4)(vi)(C) will mirror that of Sec.   423.504(b)(4)(vi)(C). Further, we propose to revise the text in Sec.   423.504(b)(4)(vi)(C)(2) to track the phrasing in Sec.   422.503(b)(4)(vi)(C)(2), as reorganized. The technical changes in the text eliminate any potential ambiguity created by different phrasing in what we intend to be identical requirements as to the timing requirements for the training. We believe these technical changes make the requirements easier to understand.     Furthermore, we believe that the broader requirement that plan sponsors provide compliance training to their FDRs no longer promotes the effective and efficient administration of the Medicare Advantage and Prescription Drug programs. Part C and Part D sponsoring organizations have evolved greatly and their compliance program operations and systems are well established. Many of these organizations have developed effective training and learning models to communicate compliance expectations and ensure that employees and FDRs are aware of the Medicare program requirements. Also, the attention focused on compliance program effectiveness by CMS' Part C and Part D program audits has further encouraged sponsors to continually improve their compliance operations.     CMS does not generally interfere in private contractual matters between sponsoring organizations and their FDRs. Our contract is with the sponsoring organization, and sponsoring organizations are ultimately responsible for compliance with all applicable statutes, regulations and sub-regulatory guidance, regardless who is performing the work. Additionally, delegated entities range in size, structure, risks, staffing, functions, and contractual arrangements which necessitates the sponsoring organization have discretion in its method of oversight to ensure compliance with program requirements. This may be accomplished through routine monitoring and implementing corrective action, which may include training or retraining as appropriate, when non-compliance or misconduct is identified.     We will continue to hold MA organizations and Part D sponsors accountable for the failures of their FDRs to comply with Medicare program requirements, even with these proposed changes. Existing regulations at Sec.  422.503(b)(4)(vi) and Sec.  423.504(b)(4)(vi) require that every sponsor's contract must specify that FDRs must comply with all applicable federal laws, regulations and CMS instructions. Additionally, we audit sponsors' compliance programs when we conduct routine program audits, and our audit process includes evaluations of sponsoring organizations' monitoring and auditing of their FDRs as well as FDR oversight. Our audits also evaluate formulary administration and processing of coverage and appeal requests in the Part C and Part D programs. FDRs often perform some or all of these functions for sponsors, so if they are non-compliant, it will come to light during the program audit and the sponsoring organization is ultimately held responsible for the FDRs' failure to comply with program requirements.     Given that compliance programs are very well established and have grown more sophisticated since their inception, coupled with the industry's desire to perform well on audit, the

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CMS training requirement is not the driver of performance improvement or FDR compliance with key CMS requirements. Given this accumulated program experience and the growing sophistication of the industry's compliance operations, as well as our continuing requirements on sponsors for oversight and monitoring of FDRs, we are proposing to ***delete*** not just the regulatory provision requiring acceptance of CMS' training as meeting the compliance training requirements, but also the reference to FDRs in the compliance training requirements codified at Sec. Sec.  422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). Specifically, we propose to remove the phrases in paragraphs (C)(1) and (C)(2) that refer to first tier, downstream and related entities and remove the paragraphs specific to FDR training at Sec. Sec.   422.503(b)(4)(vi)(C)(2) and (3) and 423.504(b)(4)(vi)(C)(3) and (4); we are also proposing technical revisions to restructure Sec.   422.503(b)(4)(vi)(C)(1) into two paragraphs and ensure that the remaining text is grammatically correct and consistent with Office of the Federal Register style. Compliance training would still be required of MA and Part D sponsors, their employees, chief executives or senior administrators, managers, and governing body members. This change will allow sponsoring organizations, and the FDRs with which they contract, the maximum flexibility in developing and meeting training requirements associated with effective compliance programs. We invite comments concerning this proposal and suggestions on other options we can implement to accomplish the desired outcome. 3. Medicare Advantage Plan Minimum Enrollment Waiver (Sec.  422.514(b))     Under section 1857(b) of the Act, CMS may not enter into a contract with a MA organization unless the organization complies with the minimum enrollment requirement. Under the basic rule at Sec.   422.514(a), to provide health care benefits under the MA program, MA organizations must demonstrate that they have the capability to enroll at least 5,000 individuals, and provider sponsored organizations (PSOs) must demonstrate that they have the capability to enroll at least 1,500 individuals. If an MA organization intends to offer health care benefits outside urbanized areas as defined in Sec.  422.62(f), then the minimum enrollment level is reduced to 1,500 for MA organizations and to 500 for PSOs. The statute permits CMS to waive this requirement in the first 3 years of the contract for an MA contract applicant. We have codified this authority at Sec.  422.514(b) and limited it to circumstances where the MA contract applicant is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. We are proposing to revise Sec.  422.514 regarding the minimum enrollment requirements to improve program efficiencies.     Currently, MA organizations, including PSOs, with an approved minimum enrollment waiver for their first contract year have the option to resubmit the waiver request for CMS in the second and third year of the contract. In conjunction with the waiver request, the MA organization must continue to demonstrate the organization's ability to operate and demonstrate that it has and uses an effective marketing and enrollment system, despite continued failure to meet the minimum enrollment requirement. In addition, the current regulation limits our authority to grant the waiver in the third year to situations where the MA organization has at least attained a projected number of enrollees in the second year. Since 2012, we have not received any waiver to the minimum enrollment requirement during the second and third year of the contract. Rather, we only received minimum enrollment waiver requests through the initial application process.     We believe the current requirement to resubmit the waiver in the second and third year of the contract is unnecessary. The statute does not require a reevaluation of the minimum enrollment standard each year and plainly authorizes a waiver ``during the first 3 contract years with respect to an organization.'' The current minimum enrollment waiver review in the initial MA contract application provides CMS the confidence to determine whether an MA organization may operate for the first 3 years of the contract without meeting the minimum enrollment requirement. CMS currently monitors low enrollment at the plan benefit package (PBP) level. We note that a similar provision in current Sec.   422.506(b)(1)(iv) permits CMS to terminate an MA contract (or terminate a specific plan benefit package) if the MA plan fails to maintain a sufficient number of enrollees to establish that it is a viable independent plan option for existing or new enrollees. In addition, compliance with Sec.  422.514 is required under Sec.  422.503(a)(13). If an organization's PBP does not achieve and maintain enrollment levels in accordance with the applicable low and minimum enrollment policies in existing regulations, CMS may move to terminate the PBP absent an approved waiver from CMS during the first 3 years of the contract pursuant to Sec.  422.510(a).     Under our proposal, we would only review and approve waivers through the MA application process as opposed to the current practice of reviewing annual requests and, potentially, requests from existing MA organizations that fail to maintain enrollment in the second or third year of operation.     We are proposing to revise the text in Sec.  422.514(b) to provide that the waiver of the minimum enrollment requirement may be in effect for the first 3 years of the contract. Further, we are proposing to ***delete*** all references to ``MA organizations'' in paragraph (b) to reflect our proposal that we would only review and approve waiver requests during the contract application process. We also propose to ***delete*** current paragraphs (b)(2) and (b)(3) in their entirety to remove the requirement for MA organizations to submit an additional minimum enrollment waiver annually for the second and third years of the contract. Finally, the proposed text also includes technical changes to redesignate paragraphs (b)(1)(i) through (iii) as (b)(1) through (3), consistent with regulation style requirements of the Office of the Federal Register. 4. Revisions to Timing and Method of Disclosure Requirements (Sec. Sec.  422.111 and 423.128)     As provided in sections 1852(c)(1) and 1860D-4(a)(1)(A) of the Act, Medicare Advantage (MA) organizations and Part D sponsors must disclose detailed information about the plans they offer to their enrollees ``at the time of enrollment and at least annually thereafter.'' This detailed information is specified in section 1852(c)(1) of the Act, with additional information specific to the Part D benefit also required under section 1860D-4(a)(1)(B) of the Act. Under Sec.   422.111(a)(3), CMS requires MA plans to disclose this information to each enrollee ``at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.'' A similar rule for Part D sponsors is found at Sec.  423.128(a)(3). Additionally, Sec.  417.427 directs 1876 cost plans to follow the disclosure requirements in Sec.  422.111 and Sec.  423.128 In making the changes proposed here, we will also affect 1876 cost plans, though it is not necessary to change the regulatory text at Sec.  417.427     Sections 422.111(b) and 423.128(b) of the Part C and Part D program regulations, respectively, describe the information plans must disclose. The content listed in Sec.  422.111(b) is found in

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an MA plan's Evidence of Coverage (EOC) and provider directory. The content listed in Sec.  423.128(b) is found in a Part D Sponsor's EOC, formulary, and pharmacy directory. Section 422.111(h)(2)(i) requires that plans must maintain an internet Web site that contains the information listed in Sec.  422.111(b) and also states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site ``does not relieve the MA organization of its responsibility under Sec.  422.111(a) to provide hard copies to enrollees.''     We propose two changes to the disclosure requirements. First, we propose to revise Sec. Sec.  422.111(a)(3) and 423.128(a)(3) to require MA plans and Part D Sponsors to provide the information in paragraph (b) of the respective regulations by the first day of the annual enrollment period, rather than 15 days before. In addition, we propose to modify the sentence in Sec.  422.111(h)(2)(ii) which states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site does not relieve the plan of responsibility to provide hard copies to enrollees. We propose to revise the sentence slightly and add ``upon request'' to the existing regulatory language to make it clear when any document that is required to be delivered under paragraph (a) in a manner that includes provision of a hard copy upon request, posting the document on the Web site (whether that document is the EOC, SB, directory information or other materials) does not relieve the MA organizations of a responsibility to deliver hard copies upon request. We intend these proposals to provide CMS with the flexibility to permit delivery other than through mailing hard copies (which is the requirement today for all materials and information covered by Sec.  422.111(a)), including through electronic delivery or posting on the Web site in conjunction with delivery of a hard copy notice describing how the information and materials are available. We believe this proposal will ultimately provide additional flexibility to plans to take advantage of technological developments and reduce the amount of mail enrollees receive from plans.     Prior to the 2009 contract year, Sec. Sec.  422.111(a) and 423.128(a) required the provision of the materials in their respective paragraphs (b) at the time of enrollment and at least annually thereafter, but did not specify a deadline. In the September 18, 2008, final rule, CMS required MA organizations to send this material to current enrollees 15 days before the annual coordinated election period (AEP) (73 FR 54216). The rationale for this requirement was to provide beneficiaries with comprehensive information prior to the AEP so that they could make informed enrollment decisions.     However, we have found through consumer testing that the large size of these mailings overwhelmed enrollees. In particular, the EOC is a long document that enrollees found difficult to navigate. Enrollees were more likely to review the Annual Notice of Change (ANOC), a shorter document summarizing any changes to plan benefits beginning on January 1 of the upcoming year, if it was separate from the EOC. Sections 422.111(d) and 423.128(g)(2) require MA organizations and Part D sponsors to provide the ANOC to all enrollees at least 15 days before the AEP.     The ANOC is intended to convey all of the information essential to an enrollee's decision to remain enrolled in the same plan for the following year or choose another plan during the AEP. CMS's research and experience have indicated that the ANOC is particularly useful to and used by enrollees. Therefore, we are not proposing to change the Sec. Sec.  422.111(d) and 423.128(g) requirements that the ANOC be received 15 days prior to AEP.     Unlike the ANOC, the EOC is a document akin to a contract that provides enrollees with exhaustive information about their medical coverage and rights and responsibilities as members of a plan. The provider directory, pharmacy directory, and formulary also contain information necessary to access care and benefits. As such, CMS requires MA organizations and Part D sponsors to make these documents available at the start of the AEP, so CMS proposes to amend Sec. Sec.   422.111(a)(3) and 423.128(a)(3) to remove the current deadline and insert ``by the first day of the annual coordinated election period.'' To the extent that enrollees find the EOC, provider directory, pharmacy directory, and formulary useful in making informed enrollment decisions, CMS believes that receipt of these documents by the first day of the AEP is sufficient. Any changes in the plan rules reflected in these documents for the next year should be adequately described in the ANOC, which will be provided earlier.     This change would also provide an additional 2 weeks for MA organizations and Part D plan sponsors to prepare, review, and ensure the accuracy of the EOC, provider directory, pharmacy directory, and formulary documents. CMS considers the additional time for the EOC important due to the high number errors plans self-identify in the document through errata sheets they submit to CMS and mail to beneficiaries. In 2017, plans submitted 166 ANOC/EOC errata, which identified 221 ANOC errors and 553 EOC errors. Additional time to produce the EOC will give plans more time to conduct quality assurance and improve accuracy and result in fewer errata sheets in the future.     In addition to the proposed changes in Sec. Sec.  422.111(a)(3) and 423.128(a)(3), we also propose to give plans more flexibility to provide the materials specified in Sec.  422.111(b) electronically. The language in Sec.  422.111(h)(2)(ii) requiring hard copies of the specified documents first appeared in the January 28, 2005, final rule (70 FR 4587) in Sec.  422.111(f)(12). At that time, MA plans were not required to maintain a Web site, but if they chose to they were required to include the EOC, Summary of Benefits, and provider network information on the Web site. However, plans were prohibited from posting these documents online as a substitute for providing hard copies to enrollees. A subsequent final rule, published April 15, 2011, established that MA plans are required to maintain an internet Web site at Sec.  422.111(h)(2) and moved the requirement that posting documents on the plan Web site did not substitute for hard copies from Sec.   422.111(f)(12) to Sec.  422.111(h)(2)(ii) (76 FR 21502).     There is no parallel to Sec.  422.111(h)(2)(ii) in Sec.  423.128 Instead, Sec.  423.128(a) states that Part D sponsors must disclose the information in paragraph (b) in the manner specified by CMS. Section 423.128(d)(2)(i) requires Part D sponsors to maintain an internet Web site that includes information listed in Sec.  423.128(b). CMS sub- regulatory guidance has instructed plans to provide the EOC in hard copy, but we believe that the regulatory text would permit delivery by notifying enrollees of the internet posting of the documents, subject to the right to request hard copies.\55\ As explained previously regarding the changes to Sec.  422.111, we intend for plans to have the flexibility to provide documents such as the Summary of Benefits, the EOC, and the provider network information in electronic format. We intend to change the relevant sub-regulatory guidance to coincide with this as well. ---------------------------------------------------------------------------

    \55\ Medicare Marketing Guidelines, section 60.6, issued July 20, 2017, [*https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY-2018-Medicare-Marketing-Guidelines\_Final072017.pdf*](https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY-2018-Medicare-Marketing-Guidelines_Final072017.pdf) ---------------------------------------------------------------------------

    In the preamble to the 2005 final rule, we noted that the prohibition on

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substituting electronic posting on the MA plan's internet site for delivery of hardcopy documents was in response to comments recommending this change (70 FR 4623). At the time, we did not think enough Medicare beneficiaries used the internet to permit posting the documents online in place of mailing them.     In the 12 years since the rule was finalized, research indicates that internet use has increased significantly among Medicare beneficiaries. Drawing on nationally representative surveys, the Pew Research Center found that 67 percent of American adults age 65 and older use the internet. Half of seniors have broadband available at home. Internet use increases even more among seniors age 65-69, of which 82 percent use the internet and 66 percent have broadband at home.\56\ Electronic documents include advantages such as word search tools, the ability to magnify text, screen reader capabilities, and bookmarks or embedded links, all of which make documents easier to navigate. Given that the younger range of Medicare beneficiaries have a higher rate of internet access, we believe the number of beneficiaries who ``use the internet'' will only continue to grow with time. Posted electronic documents can also be accessed from anywhere the internet is available. ---------------------------------------------------------------------------

    \56\ Pew Research Center, May 2017, ``Tech Adoption Climbs Among Older Adults'', [*http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/*](http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/). ---------------------------------------------------------------------------

    As mentioned previously, the EOC sometimes contains errors. To correct these, MA and Part D plans currently have to mail errata sheets and post an updated version online. The hardcopy version of the EOC is then out-of-date. Beneficiaries either have to refer to errata sheets in addition to the hardcopy EOC or go online to access a corrected EOC. Increasing beneficiary use of the electronic EOC ensures that beneficiaries are using the most accurate information. Under this proposal to permit flexibility for us to approve non-hard-copy delivery in some cases, we intend to continue requiring hardcopy mailings of any ANOC or EOC errata.     Plans have also continued to request CMS give plans the flexibility to provide the EOC electronically. They have frequently cited the expense of printing and mailing large documents. Medicaid managed care plans already have the flexibility to provide directories, formularies, and member handbooks (similar to the EOC) electronically, per Sec. Sec.  438.10(h)(1), 438.10(h)4)(i), and 438.10(g)(3) respectively.     To begin addressing this, in the Medicare Marketing Guidelines released July 2, 2015, CMS notified plans that they could mail either a hardcopy provider and/or pharmacy directory or a hardcopy notice to enrollees instructing them where to find the directories online and how to request a hard copy. That guidance has been moved to Chapter 4, section 110.2.3, of the Medicare Managed Care Manual. If plans choose to mail a notice with the location of the online directory rather than a hard copy, the notice must include: A direct link to the online directory, the customer service number to call and request a hard copy, and if available the email address to request a hard copy. The notice must be distinct, separate, and mailed with the ANOC/EOC.\57\ Section 60.4 of the Medicare Marketing Guidelines released July 20, 2017, extends the same flexibility to formularies, with the same required content in the notice identifying the location of the online formulary. As CMS has received few complaints from any source about this new process, allowing plans the option to use a similar strategy for additional materials is appropriate. ---------------------------------------------------------------------------

    \57\ Medicare Managed Care Manual Chapter 4--Benefits and Beneficiary Protections, Rev. 121, issued April 22, 2016, [*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf*](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf) ---------------------------------------------------------------------------

    Upon finalizing this rule, we would issue sub-regulatory guidance to identify permissible manners of disclosure; we expect that guidance would be similar to the current guidance for the provider directory, pharmacy directory, and formulary regarding dissemination of the EOC. Importantly, this provision does not eliminate the requirement for plans to provide accessible formats of required documents. As recipients of federal funding, plans are obligated to provide materials in accessible formats upon request, at no cost to the individual, to individuals with disabilities, under Section 504 of the Rehabilitation Act of 1973 and to take reasonable steps to provide meaningful access, including translation services, to individuals who have limited English proficiency under Title VI of the Civil Rights Act of 1964.     To create this flexibility, CMS proposes modifying the sentence, ``Such posting does not relieve the MA organization of its responsibility under Sec.  422.111(a) to provide hard copies to enrollees,'' to include ``upon request'' in Sec.  422.111(h)(2)(ii) and to revise Sec.  422.111(a) by inserting ``in the manner specified by CMS.'' These changes will align Sec. Sec.  422.111(a) and 423.128(a) to authorize CMS to provide flexibility to MA plans and Part D sponsors to use technology to provide beneficiaries with information. CMS intends to use this flexibility to provide sponsoring organizations with the ability to electronically deliver plan documents (for example, the Summary of Benefits) to enrollees while maintaining the protection of a hard copy for any enrollee who requests such hard copy. As the current version of Sec.  422.111(a) and (h)(2) require hard copies, we believe this proposal will ultimately result in reducing burden and providing more flexibility for sponsoring organizations. 5. Revisions to Sec. Sec.  422 and 423 Subpart V, Communication/ Marketing Materials and Activities     Section 1851(h) of the Act prohibits Medicare Advantage (MA) organizations from distributing marketing materials and application forms to (or for the use of) MA eligible individuals unless the document has been submitted to the Secretary at least 45 days (10 days for certain materials) prior to use and the document has not been disapproved. Further, in section 1851(j), the Secretary is authorized to adopt standards regarding marketing activities, and the statute identifies certain prohibited activities. While the Act requires the submission and review of the marketing materials and applications, it does not provide a definition of what materials fall under the umbrella term ``marketing.'' Sections 1806D-1(d)(3)(B)(iv) and 1860D-4(l) of the Act provide similar restrictions on use of marketing and enrollment materials and activities to promote enrollment in Part D plans.     Section 1876(c)(3)(C) of the Act states that no brochures, application forms, or other promotional or informational material may be distributed by cost plan to (or for the use of individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review, and (ii) the Secretary has not disapproved the distribution of the material. As delegated this authority by the Secretary, CMS reviews all such material submitted and disapproves such material upon determination that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation. Similar to 1851(h) of the Act, section 1876(c)(3)(C) of the Act focuses more on the review and approval of materials as opposed to providing an exhaustive list of materials that would qualify as marketing or promotional information and materials.

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As part of the implementation of section 1876(c)(3)(C) of the Act, the regulation governing cost plans at Sec.  417.428(a) refers to Subpart V of part 422 for marketing guidance. Throughout this proposal, the changes discussed for MA organizations/MA plans and prescription drug plan (PDP) sponsors/Part D plans applies as well to cost plans subject to the same requirements as a result of this cross-reference.     Section 422.2260(1)-(4) of the Part C program regulations currently identifies marketing materials as any materials that: (1) Promote the MA organization, or any MA plan offered by the MA organization; (2) inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization; (3) explain the benefits of enrollment in an MA plan, or rules that apply to enrollees; and (4) explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage. Section 423.2260(1)-(4) applies identical regulatory provisions to the Part D program.     Sections 422.2260(5) and 423.2260(5) provide specific examples of materials under the ``marketing materials'' definition, which include: General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet; marketing representative materials such as scripts or outlines for telemarketing or other presentations; presentation materials such as slides and charts; promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers); membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees; letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.; and membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or no claim specific notification information). Finally, Sec. Sec.  422.2260(6) and 423.2260(6) provide a list of materials that are not considered marketing materials, including materials that are targeted to current enrollees; are customized or limited to a subset of enrollees or apply to a specific situation; do not include information about the plan's benefit structure; and apply to a specific situation or cover claims processing or other operational issues.     We are proposing several changes to Subpart V of the part 422 and 423 regulations. To better outline these proposed changes, they are addressed in four areas of focus: (1) Including ``communication requirements'' in the scope of Subpart V or parts 422 and 423, which will include new definitions for ``communications'' and ``communication materials;'' (2) amending Sec. Sec.  422.2260 and 423.2260 to add (at a new paragraph (b)) a definition of ``marketing'' in place of the current definition of ``marketing materials'' and to provide lists identifying marketing materials and non-marketing materials; (3) adding new regulation text to prohibit marketing during the Open Enrollment Period proposed in section III.B.1 of this proposed rule; (4) technical changes to other regulatory provisions as a result of the changes to Subpart V. To the extent necessary, CMS relies on its authority to add regulatory and contract requirements to the cost plan, MA, and Part D programs to propose and (ultimately) adopt these changes. We note as well that sections 1851(h) and (j) of the Act (cross-referenced in sections 1860D-1 and 1860D-4(l)) of the Act address activities and direct that the Secretary adopt standards limiting marketing activities, which CMS interprets as permitting regulation of communications about the plan that do not rise to the level of activities and materials that specifically promote enrollment. a. Revising the Scope of Subpart V To Include Communications and Communications Materials     The current version of Subpart V of parts 422 and 423 regulation focuses on marketing materials, as opposed to other materials currently referred to as ``non-marketing'' in the sub-regulatory Medicare Marketing Guidelines. This leaves a regulatory void for the requirements that pertain to those materials that are not considered marketing. Historically, the impact of not having regulatory guidance for materials other than marketing has been muted because the current regulatory definition of marketing is so broad, resulting in most materials falling under the definition. The overall effect of this combination--no definition of materials other than marketing and a broad marketing definition--is that marketing and communications with enrollees became synonymous.     With this CMS proposal to narrow the marketing definition, we believe there is a need to continue to apply the current standards to and develop guidance for those materials that fall outside of the proposed definition. We propose changing the title of each Subpart V by replacing the term ``Marketing'' with ``Communication.'' We propose to define in Sec. Sec.  422.2260(a) and 423.2260(a) definitions of ``communications'' (activities and use of materials to provide information to current and prospective enrollees) and ``communications materials'' (materials that include all information provided to current members and prospective beneficiaries). We propose that marketing materials (discussed later in this section) would be a subset of communications materials. In many ways, the proposed definition of communications materials is similar to the current definition of marketing materials; the proposed definition has a broad scope and would include both mandatory disclosures that are primarily informative and materials that are primarily geared to encourage enrollment.     CMS also proposes, through revisions to Sec. Sec.  422.2268 and 423.2268, to apply some of the current standards and prohibitions related to marketing to all communications and to apply others only to marketing. Marketing and marketing materials would be subject to the more stringent requirements, including the need for submission to and review by CMS. Under this proposal, those materials that are not considered marketing, per the proposed definition of marketing, would fall under the less stringent communication requirements.     In addition to these proposals related to defined terms and revising the scope of Subparts V in parts 422 and 423, we are proposing changes to the current regulations at Sec. Sec.  422.2264 and 423.2264 and Sec. Sec.  422.2268 and 423.2268 that are related to our proposal to distinguish between marketing and communications.     With regard to Sec. Sec.  422.2264 and 423.2264, we are proposing the following changes:      ***Deletion*** of paragraph (a)(3), which currently provides for an adequate written explanation of the grievance and appeals process to be provided as part of marketing materials. In our view grievance and appeals communications would not be within the scope of marketing as proposed in this rule.      ***Deletion*** of paragraph (a)(4), which provides for CMS to determine that marketing materials include any other information necessary to enable beneficiaries to make an informed decision about enrollment. The intent of this section was to ensure that materials which include measuring or ranking mechanisms such as Star Ratings were a part of CMS's marketing review. We

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propose ***deleting*** this section as the exclusion list to be codified at Sec.  422.2260(c)(2)(ii) ensures materials that include measuring or ranking standards will be considered marketing, thus making Sec. Sec.   422.2264(a)(4) and Sec.  423.2264(a)(4) duplicative.      ***Deletion*** of paragraph (e), which requires sponsoring organizations to provide translated materials in certain areas where there is a significant non-English speaking population. We propose to recodify these requirement as a general communication standard in Sec. Sec.  422.2268 and 423.2268, at new paragraph (a)(7). As part of the redesignation of this requirement as a standard applicable to all communications and communication materials, we are also proposing revisions. First, we are proposing to revise the text so that it is stated as a prohibition on sponsoring organizations: For markets with a significant non-English speaking population, provide materials, as defined by CMS, unless in the language of these individuals. We propose adding the statement of ``as defined by CMS'' to the first sentence to allow the agency the ability to define the significant materials that would require translation. We propose ***deleting*** the word ``marketing'' so the second sentence now reads as ``materials'', to make it clear that the updated section applies to the broader term of communications rather than the more narrow term of marketing.     In addition, we are proposing to revise Sec. Sec.  422.2262(d) and 423.2262(d) to ***delete*** the term ``ad hoc'' from the heading and regulation text in favor of referring to ``communication materials'' to conform to the addition of communication materials under Subpart V.     Current regulations at Sec. Sec.  422.2268 and 423.2268 list prohibited marketing activities. These activities include items such as providing meals to potential enrollees, soliciting door to door, and marketing in provider settings. With the proposal to distinguish between overall communications and marketing activities, we are proposing to break out the prohibitions into categories: those applicable to all communications (activities and materials) and those that are specific to marketing and marketing materials. In reviewing the various standards under the current regulations to determine if they would apply to communications or marketing, we looked at the each standard as it applied to the new definitions under Subpart V. Prohibitions that offer broader beneficiary protections and are currently applicable to a wide variety of materials are proposed here to apply to communications activities and communication materials; this list of prohibitions is proposed as paragraph (a) Conversely, prohibitions that are currently targeted to activities and materials that are within the narrower scope of marketing and marketing materials are proposed at paragraph (b) as prohibitions on marketing. We are not proposing to expand the list of prohibitions but are proposing to notate which prohibitions are applicable to which category. The only substantive change is in connection with paragraph (a)(7), which we discuss earlier in this section. We welcome comment on our proposed distinctions between these types of prohibitions and whether certain standards or prohibitions from current Sec. Sec.  422.2268 and 423.2268 should apply more narrowly or broadly than we have proposed. b. Amending the Regulatory Definition of Marketing and Marketing Materials     In conjunction with adding new proposed communication requirements, we also propose a definition of ``marketing'' be codified in Sec. Sec.   422.2260(b) and 423.2260(b). Under this proposal, we would ***delete*** the current text in that section defining only ``marketing materials'' to add a new definition of ``marketing'' and lists of materials that are ``marketing materials'' and that are not. Specifically, the term ``marketing'' would be defined as the use of materials or activities by the sponsoring organization (that is, the MA organization, Part D Sponsor, or cost plan, depending on the specific part) or downstream entities that are intended to draw a beneficiary's attention to the plan or plans and influence a beneficiary's decision making process when making a plan selection; this last criterion would also be met when the intent is to influence an enrollee's decision to remain in a plan (that is, retention-based marketing).     The current regulations address both prohibited marketing activities and marketing materials. The prohibited activities are directly related to marketing activities, but the current definition of ``marketing materials'' is overly broad and has resulted in a significant number of documents being classified as marketing materials, such as materials promoting the sponsoring organization as a whole (that is, brand awareness) rather than materials that promote enrollment in a specific Medicare plan. We believe that Congress' intent was to target those materials that could mislead or confuse beneficiaries into making an adverse enrollment decision. Since the original adoption of Sec. Sec.  422.2260 and 423.2260, CMS has reviewed thousands of marketing materials, tracked and resolved thousands of beneficiary complaints through the complaints tracking module (CTM), conducted secret shopping programs of MA plan sales events, and investigated numerous marketing complaints. These efforts have provided CMS insight into the types of plan materials that present the greatest risk of misleading or confusing beneficiaries. Based on this experience, we believe that the current regulatory definition of marketing materials is overly broad. As a result, materials that pose little to no threat of a detrimental enrollment decision fall under the current broad marketing definition. As such, the materials are also required to follow the associated marketing requirements, including submission to CMS for potential review under limited statutory timeframes. CMS believes that the level of scrutiny required on numerous documents that are not intended to influence an enrollment decision, combined with associated burden to sponsoring organizations and CMS, is not justified. By narrowing the materials that fall under the scope of marketing, this proposal will allow us to better focus its review on those materials that present the greatest likelihood for a negative beneficiary experience.     We propose to more appropriately implement the statute by narrowing the definition of marketing to focus on materials and activities that aim to influence enrollment decisions. We believe this is consistent with Congress's intent. Moreover, the new definition differentiates between factually providing information about the plan or benefits (that is, the Evidence of Coverage (EOC)) versus persuasively conveying information in a manner designed to prompt the beneficiary to make a new plan decision or to stay with their current plan (for example, a flyer that touts a low monthly premium). As discussed later, the majority of member materials would no longer fall within the definition of marketing under this proposal. The EOC, subscriber agreements, and wallet card instructions are not developed nor intended to influence enrollment decisions. Rather, they are utilized for current enrollees to understand the full scope of and the rules associated with their plan. We believe the proposed new marketing definition appropriately safeguards potential and current enrollees while not placing an undue burden on sponsoring organizations. Moreover, those materials that would be

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excluded from the marketing definition would fall under the proposed definition of communication materials, with what we believe are more appropriate requirements. CMS notes that enrollment and mandatory disclosure materials continue to be subject to requirements in Sec. Sec.  422.60(c), 422.111, 423.32(b), and 423.128     Second, we propose to revise the list of marketing materials, currently codified at Sec. Sec.  422.2260(5) and 423.2260(5), and to include it in the proposed new Sec. Sec.  422.2260(c)(1) and 423.2260(c)(1). The current list of examples includes: brochures; advertisements in newspapers and magazines, and on television, billboards, radio, or the internet, and billboards; social media content; marketing representative materials, such as scripts or outlines for telemarketing or other presentations; and presentation materials such as slides and charts. In conjunction with the proposed new definition of marketing, we are proposing to remove from the list of examples items such as membership communication materials, subscriber agreements, member handbooks, and wallet card instructions to enrollees, as they would no longer fall under the proposed regulatory definition of marketing. The proposed text complements the new definition by providing a concise non-exhaustive list of example material types that would be considered marketing.     Third, we propose to revise the list of exclusions from marketing materials, currently codified at Sec. Sec.  422.2260(6) and 423.2260(6), and to include it in the proposed new Sec. Sec.   422.2260(c)(2) and 423.2260(c)(2) to identify the types of materials that would not be considered marketing. Materials that do not include information about the plan's benefit structure or cost sharing or do not include information about measuring or ranking standards (for example, star ratings) will be excluded from marketing. In addition, materials that do mention benefits or cost sharing, but do not meet the definition of marketing as proposed here, would also be excluded from marketing. We also propose that required materials in Sec.  422.111 and Sec.  423.128 not be considered marketing, unless otherwise specified. Lastly, we are proposing to exclude materials specifically designated by us as not meeting the definition of the proposed marketing definition based on their use or purpose. The purpose of this proposed revision of the list of exclusions from marketing materials, as with the proposed marketing definition and proposed non-exhaustive list of marketing materials, is to maintain the current beneficiary protections that apply to marketing materials but to narrow the scope to exclude materials that are unlikely to lead to or influence an enrollment decision.     In the proposed changes to the exclusions from marketing materials, we intend to exclude materials that do not include information about the plan's benefit structure or cost-sharing. We believe that materials that do not mention benefit structure or cost sharing would not be used to make an enrollment decision in a specific Medicare plan, rather they would be used to drive beneficiaries to request additional information that would fall under the new definition of marketing. Similarly, we want to be sure it is clear that the use of measuring or ranking standards, such as the CMS Star Ratings, even when not accompanied by other plan benefit structure or cost sharing information, could lead a beneficiary to make an enrollment decision. It should be noted that our authority for similar requirements can be found under the current Sec. Sec.  422.2264(a)(4) and 423.2264(a)(4). We believe this is clearer and more appropriately housed under the regulatory definition of marketing. As such, together with the proposed update to excluded materials, we will make the technical change to remove (a)(4) from Sec. Sec.  422.2264 and 423.2264 In addition, we propose to exclude materials that mention benefits or cost sharing but do not meet the proposed definition of marketing. The goal of this proposal is to exclude member communications that convey important factual information that is not intended to influence the enrollee's decision to make a plan selection or to stay enrolled in their current plan. An example is a monthly newsletter to current enrollees reminding them of preventive services at $0 cost sharing.     In addition, we note the proposal excludes those materials required under Sec.  422.111 (for MA plans) and Sec.  423.128 (for Part D sponsors), unless otherwise specified by CMS because of their use or purpose. This proposal is intended to exclude post-enrollment materials that we require be disclosed and distributed to enrollees, such as the EOC. Such materials convey important plan information in a factual manner rather than to entice a prospective enrollee to choose a specific plan or an existing enrollee to stay in a specific plan. In addition, either these materials use model formats and text developed by us or are developed by plans based on detailed instructions on the required content from us; this high level of standardization by us on the front-end provides the necessary beneficiary protections and negates the need for our review of these materials before distribution to enrollees.     The proposed changes do not release cost plans, MA organizations, or Part D sponsors from the requirements in sections 1876(c)(3)(C), 1851(h), and 1860D-1(b)(1)(B)(vi) of the Act to have application forms reviewed by CMS as well. To clarify this requirement, we are proposing to revise Sec.  417.430(a)(1) and Sec.  423.32(b), which pertain to application and enrollment processes, to add a cross reference to Sec. Sec.  422.2262 and 423.2262, respectively. The cross references directly link enrollment applications back to requirements related to review and distribution of marketing materials. These proposed changes update an old cross-reference, codify existing practices, and are consistent with language already in Sec.  422.60(c). c. Prohibition of Marketing During the Open Enrollment Period     The 21st Century Cures Act (the Cures Act) amended section 1851(e)(2) of the Act by adding a new continuous open enrollment and disenrollment period (OEP) for MA and certain PDP members. See section III.A.X for CMS's other proposal related to that provision. As part of establishing this OEP, the Cures Act prohibits unsolicited marketing and mailing marketing materials to individuals who are eligible for the new OEP. We are proposing to add a new paragraph (b)(9) to both proposed Sec. Sec.  422.2268 and 423.2268 to apply this prohibition on marketing. However, we request comment on how the agency could implement this statutory requirement. The new OEP is not available for enrollees in Medicare cost plans; therefore, these limitations would apply to MA enrollees and to any PDP enrollee who was enrolled in an MA plan the prior year. CMS is concerned that it may be difficult for a sponsoring organization to limit marketing to only those individuals who have not yet enrolled in a plan during the OEP. One mechanism could be to limit marketing entirely during that period, but we are concerned that such a prohibition would be too broad We believe that using a ``knowing'' standard will both effectuate the statutory provision and avoid against overly broad implementation. We welcome comment on how a sponsoring organization could appropriately control who would or should be marketed to during the new OEP, such as through as mailing campaigns aimed at a more general audience.

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d. Technical Changes to Other Regulatory Provisions as a Result of the Changes to Subpart V     As previously stated, because of the broad regulatory definition of marketing, the term marketing and communication became synonymous. With the proposed updates to Subpart V in both part 422 and part 423, a definition of the broader term communication would be added and the definition of marketing, as well as the materials that fall within the scope of that definition, would be narrowed. As a result, a number of technical changes will be needed to update certain sections of the regulation that use the term marketing. Accordingly, we propose the following technical changes in Part C:      In Sec.  422.54, we propose to update paragraphs (c)(1)(i) and (d)(4)(ii) to replace ``marketing materials'' with ``communication materials.''      In Sec.  422.62, we propose to update paragraph (b)(3)(B)(ii) by replacing ``in marketing the plans to the individual'' with ``in communication materials.''      In Sec.  422.102(d), we propose to use ``supplemental benefits packaging'' instead of ``marketing of supplemental benefits.''      In Sec.  422.206(b)(2)(i), we propose to replace ``Sec.   422.80 (concerning approval of marketing materials and election forms)'' with ``all applicable requirements under subpart V''.      In Sec.  422.503(b)(4)(ii), we propose to replace the term ``marketing'' with the term ``communication.''      In Sec.  422.510(a)(4)(iii), we propose to remove the word ``marketing'' so that the reference is to the broader Subpart V.     CMS has had longstanding authority to initiate ``marketing sanctions'' in conjunction with enrollment sanctions as a means of protecting beneficiaries from the confusion that stems from receiving information provided by a plan that is--as a result of enrollment sanctions--unable to accept enrollments. In this rulemaking, CMS is proposing to replace the term ``marketing'' with ``communications'' in Sec.  422.750 and 422.752 to reflect its proposal for Subpart V. The intent of this proposal to change the terminology is not to expand the scope of CMS's authority with respect to sanction regulations. Rather, CMS intends to preserve the existing reach of its sanction authority it currently has--to prohibit any communications under the current broad definition of ``marketing materials'' from being issued by a sponsoring organization while that entity is under sanction. For this reason, CMS is proposing the following changes to Sec. Sec.  422.750 and 422.752:      In Sec.  422.750, we propose to revise paragraph (a)(3) to refer to suspension of ``communication activities.''      In Sec.  422.752, we propose to replace the term ``marketing'' in paragraph (a)(11) and the heading for paragraph (b) with the term ``communications.''     We are not proposing any changes to the use of the term ``marketing'' in Sec. Sec.  422.384, 422.504(a)(17), 422.504(d)(2)(vi), or 422.514, as those regulations use the term in a way that is consistent with the proposed definition of the term ``marketing,'' and the underlying requirements and standards do not need to be extended to all communications from an MA organization.     We also propose the following technical changes in Part D:      In Sec.  423.38(c)(8)(i)(C), we propose to revise the paragraph to read: ``The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communication materials.''      In Sec.  423.504(b)(4)(ii), we propose to replace ``marketing'' with ``communications'' to reflect the change to Subpart V.     For the reasons explained in connection with our proposal to revise the Part C sanction regulations, we also propose the following changes:      In Sec.  423.505(b)(25), we propose to replace ``marketing'' with ``communications'' to reflect the change to Subpart V.      In Sec.  423.509(a)(4)(V)(A), we propose to ***delete*** the word ``marketing'' and instead simply refer to Subpart V.     We are not proposing any changes to the use of the term ``marketing'' in Sec. Sec.  423.505(d)(2)(vi), 423.871(c), or 423.756(c)(3)(ii), as those regulations use the term in a way that is consistent with the proposed definition of the term ``marketing,'' and the underlying requirements and standards do not need to be extended to all communications from a PDP sponsor.     We solicit comment on the proposed technical changes, particularly whether a proposed revision here would be more expansive than anticipated or have unintended consequences for sponsoring organizations or for CMS's oversight and monitoring of the MA and Part D programs.     In conclusion, we believe that our proposal here--the proposed definitions of ``communications,'' ``communications materials,'' ``marketing,'' and ``marketing materials;'' and the various proposed changes to Subpart V; to distinguish between prohibitions applicable to communications and those applicable to marketing; and to conform Sec.   417.430(a)(1) and Sec.  423.32(b) to Sec.  422.60(c) and reflect the statutory direction regarding enrollment materials; all maintain the appropriate level of beneficiary protection. These proposals will facilitate and focus our oversight of marketing materials, while appropriately narrowing the scope of what is considered marketing. We believe beneficiary protections are further enhanced by adding communication materials and associated standards under Subpart V. These changes allow us to focus its oversight efforts on plan marketing materials that have the highest potential for influencing a beneficiary to make an enrollment decision that is not in the beneficiary's best interest. We solicit comment on these proposals and whether the appropriate balance is achieved with the proposed regulation text. 6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (Sec. Sec.  423.590 and 423.636)     Sections 1860D-4(g) and (h) of the Act require the Secretary to establish processes for initial coverage determinations and appeals similar to those used in the Medicare Advantage program. In accordance with section 1860D-4(g) of the Act, Sec.  423.590 establishes Part D plan sponsors' responsibilities for processing redeterminations, including adjudication timeframes. Pursuant to section 1860D-4(h) of the Act, Sec.  423.600 sets forth the requirements for an independent review entity (IRE) for processing reconsiderations.     We are proposing changes to the adjudication timeframe for Part D standard redetermination requests for payment at Sec.  423.590(b) and the related effectuation provision Sec.  423.636(a)(2). Specifically, we are proposing to change the timeframe for issuing decisions on payment redeterminations from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request. This proposed 14-day timeframe for issuing a decision related to a payment request would also apply to the IRE reconsideration pursuant to Sec.  423.600(d). We are not proposing to make changes to the existing requirements for making payment. When applicable, the Part D plan sponsor must make payment no later than 30 days from receipt of the request

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for redetermination, or the IRE reconsideration notice, respectively.     Some of the feedback received from the RFI published in the 2018 Call Letter related to simplifying and establishing greater consistency in Part D coverage and appeals processes. The proposed change to a 14 calendar day adjudication timeframe for payment redeterminations, which would also apply to payment requests at the IRE reconsideration level of appeal, will establish consistency in the adjudication timeframes for payment requests throughout the plan level and IRE processes, as Sec.  423.568(c) requires a plan sponsor to notify the enrollee of its determination no later than 14 calendar days after receipt of the request for payment. We believe affording more time to adjudicate payment redetermination requests (including obtaining necessary documentation to support the request) will ease burden on plan sponsors because it could reduce the need to deny payment redeterminations due to missing information. We also expect the proposed change to the payment redetermination timeframe would reduce the volume of untimely payment redeterminations that must be auto-forwarded to the IRE.     In addition, having more time to gather information and process these requests could be beneficial to enrollees because decisions will be more fully informed, potentially resulting in fewer decisions having to undergo further appeal. While we acknowledge that some enrollees would have to wait longer for a decision, we note that the proposed changes are limited to payment requests where the enrollee has already received the drug, ensuring any delay would not adversely affect the enrollee's health. As noted previously, when coverage is approved, the plan would remain obligated to remit payment to affected enrollees within 30 days. Allowing plan sponsors and the IRE additional time to process payment appeal requests may assist these adjudicators in allocating resources in a manner that is most efficient and enrollee friendly, for example, ensuring adequate resources are directed to processing more time-sensitive pre-service requests where the enrollee has not yet obtained the drug, particularly during periods of increased case volume. 7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (Sec.  422.590)     Section 1852(g) of Act requires MA organizations to have a procedure for making timely determinations regarding whether an enrollee is entitled to receive a health service and any amount the enrollee is required to pay for such service. Under this statutory provision, the MA plan also is required to provide for reconsideration of that determination upon enrollee request.     In accordance with section 1852(g) of the Act, our current regulations at Sec. Sec.  422.578, 422.582, and 422.584 provide MA enrollees with the right to request reconsideration of a health plan's initial decision to deny Medicare coverage. Pursuant to Sec.  422.590, when the MA plan upholds initial payment or service denials, in whole or in part, it must forward member case files to an independent review entity (IRE) that contracts with CMS to review plan-level appeals decisions; that is, plans are required to automatically forward to the IRE any reconsidered decisions that are adverse or partially adverse for an enrollee without the enrollee taking any action.     Currently, MA plans are required to notify enrollees upon forwarding cases to the IRE, as set forth at Sec.  422.590(f). CMS sub- regulatory guidance, set forth in Chapter 13 of the Medicare Managed Care Manual, specifically directs plans to mail a notice to the enrollee informing the individual that the plan has upheld its decision to deny coverage, in whole or in part, and thus is forwarding the enrollee's case file to the IRE for review. We have made a model notice available for plans to use for this purpose. (See Medicare Managed Care Manual, Chapter 13, Sec.  10.3.3, 80.3, and Appendix 10.) In addition, the Part C IRE is required, under its contract with CMS, to notify the enrollee when the IRE receives the reconsidered decision for review. We are proposing to revise Sec.  422.590 to remove paragraph (f) and redesignate the existing paragraphs (g) and (h) as (f) and (g), respectively. The Part C IRE is contractually responsible for notifying an enrollee that the IRE has received and will be reviewing the enrollee's case; thus, we believe the plan notice is duplicative and nonessential. Under this proposal, the IRE would be responsible for notifying enrollees upon forwarding all cases--including both standard and expedited cases. We will continue to closely monitor the performance of the IRE and beneficiary complaints related to timely and appropriate notification that the IRE has received and will be reviewing the enrollee's case.     We received feedback in response to the Request for Information included in the 2018 Call Letter related to simplifying and streamlining appeals processes. To that end, we believe this proposed change will help further these goals by easing burden on MA plans without compromising informing the beneficiary of the progress of his or her appeal. If this proposal is finalized, and plans are no longer required to notify an enrollee that his or her case has been sent to the IRE, we would expect plans to redirect resources previously allocated to issuing this notice to more time-sensitive activities such as review of pre-service and post-service coverage requests, improved efficiency in appeals processing, and provision of health benefits in an optimal, effective, and efficient manner. 8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards a. Legislative Background     Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D-4(e) of the Act. Among other things, these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA-PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e- prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.     For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D-4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256). b. Regulatory History     Transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced

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over time to ensure that the standards did not hold back progress in the industry. We discussed these processes in the November 7, 2005 final rule (70 FR 67579).     The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified ``updating process'' when a non-HIPAA standard could be updated with a newer ``backward-compatible'' version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted non-HIPAA standard without modification, however, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the Federal Register. We utilized this streamlined process when we published an interim final rule with comment on June 23, 2006 (71 FR 36020). That rule recognized NCPDP SCRIPT 8.1 as a backward compatible update to the NCPDP SCRIPT 5.0 for the specified transactions, thereby allowing for use of either of the two versions in the Part D program. Then, on April 7, 2008, we used notice and comment rulemaking (73 FR 18918) to finalize the identification of the NCPDP SCRIPT 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0, and, effective April 1, 2009, retire NCPDP SCRIPT 5.0 and adopt NCPDP SCRIPT 8.1 as the official Part D e-prescribing standard for the specified transactions. On July 1, 2010, CMS utilized the streamlined process to recognize NCPDP SCRIPT 10.6 as a backward compatible update of NCPDP SCRIPT 8.1 in an interim final rule (75 FR 38026).     We finalized the NCPDP SCRIPT 10.6 as a Backward Compatible Version of NCPDP SCRIPT 8.1, and retired NCPDP SCRIPT 8.1 and adopted the NCPDP SCRIPT 10.6 as the official Part D e-Prescribing Standard for the specified transactions in the CY 2013 Physician Fee Schedule, effective November 1, 2013. For a more detailed discussion, see the CY 2013 PFS final rule (77 FR 69329 through 69333).     c. Proposed adoption of NCPDP SCRIPT version 2017071 as the official Part D E-Prescribing Standard for certain specified transactions, retirement of NCPDP SCRIPT 10.6, proposed conforming changes elsewhere in 423.160, and correction of a historic typographical error in the regulatory text which occurred when NCPDP SCRIPT 10.6 was initially adopted.     The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,600 members who are interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.     NCPDP has developed the NCPDP SCRIPT standard for use by prescribers, dispensers, pharmacy benefit managers (PBMs), payers and other entities who wish to electronically transmit information about prescriptions and prescription-related information. NCPDP has periodically updated its SCRIPT standard over time, and three separate versions of the NCPDP SCRIPT standard, versions 5.0, 8.1 and most recently 10.6 have been adopted by CMS for the part D e-prescribing program through the notice and comment rulemaking process. We believe that our current proposal to adopt the NCPDP SCRIPT 2017071 as the official part D e-prescribing standard for certain specified transactions, and to retire the current standard for those transactions would, among other things, improve communications between the prescriber and dispensers, and we welcome public comment on these proposals.     Our actions were, in part, precipitated by a May 24, 2017, letter from the NCPDP that requested our adoption of NCPDP SCRIPT Standard Version 2017071. This version was balloted and approved July 28, 2017. The letter noted the considerable amount of time that had passed since the last update to the current adopted standard (NCPDP SCRIPT 10.6), and that there were many changes to the NCPDP SCRIPT Standard version 2017071 that would benefit its users.     CMS reviewed the specifications for NCPDP SCRIPT Standard Version 2017071 and found that this version would allow users substantial improvements in efficiency. Version 2017071 supports communications regarding multi-ingredient compounds, thereby allowing compounded medication to be prescribed electronically. Previously prescriptions for compounds were handwritten and sent via fax to the dispenser, which often required follow up communications between the prescriber and pharmacy. The ability to process prescriptions for compounds electronically in lieu of relying on more time intensive interpersonal interactions would be expected to improve efficiency.     While we do not propose mandating its use at this time, one transaction supported by the proposed version of NCPDP SCRIPT would also provide interested users with a Census transaction functionality which is designed to service beneficiaries residing in long term care. The Census feature would trigger timely notification of a beneficiary's absence from a long term care facility, which would enable discontinuation of daily medication dispensing when a leave of absence occurs, thereby preventing the dispensing of unneeded medications. Version 2017071 also contains an enhanced Prescription Fill Status Notification that allows the prescriber to specify if/when they want to receive the notifications from the dispenser. It now supports data elements for diabetic supply prescriptions and includes elements which could be required for the pharmacy during the dispensing process which may be of value to prescribers who need to closely monitor medication adherence.     We therefore believe that the functionalities offered by NCPDP SCRPT 2017071 could offer efficiencies to the industry, and believe that it would be an appropriate e-prescribing standard for the transactions currently covered by the Medicare Part D program. Furthermore, NCPDP SCRIPT 2017071 supports transactions new to the part D e-prescribing program that we believe would prove beneficial to the industry. Therefore, in addition to the transactions for which prior versions of NCPDP SCRIPT were adopted (as reflected in the current regulations at 423.160(b)), we propose to require use of NCPDP SCRPT 2017071 for the following transactions:      Prescription drug administration message,      New prescription requests,      New prescription response denials,      Prescription transfer message,      Prescription fill indicator change,      Prescription recertification,      Risk Evaluation and Mitigation Strategy (REMS) initiation request,      REMS initiation response, REMS request, and      REMS response.     We believe that transitioning to the new 2017071 versions of the transactions already covered by the current part D e-prescribing standard (version 10.6 of the NCPDP SCRIPT) will impose deminimus cost on the

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industry as the burden in using the updated standards is anticipated to be the same as using the old standards for the transactions currently covered by the program. We are also proposing adoption of version 2017071 of the NCPDP SCRIPT standards for the nine new transactions to replace manual processes that currently occur. Reducing the manual processes currently used to support these transactions will improve efficiency, accuracy, and user satisfaction with the system. While system implementation may result in minimal expenses, we believe that these minimal expenses will be more than offset by rendering these manual transactions obsolete. That is, we believe that prescribers and dispensers that are now e-prescribing largely invested in the hardware, software, and connectivity necessary to e-prescribe. We do not anticipate that the retirement of NCPDP SCRIPT 10.6 in favor of NCPDP SCRIPT 2017071 will result in significant costs.     As such, we are proposing to revise Sec.  423.160(b)(1)(iv) so as to limit its application to transactions before January 1, 2019 and add a new Sec.  423.160(b)(1)(v). The requirement at Sec.  423.160(b)(1)(v) would identify the standards that will be in effect on or after January 1, 2019, for those that conduct e-prescribing for part D covered drugs for part D eligible beneficiaries. If finalized, those individuals and entities would be required to use NCPDP SCRIPT 2017071 to convey prescriptions and prescription-related information for the following transactions:      Get message transaction.      Status response transaction.      Error response transaction.      New prescription request transaction.      Prescription change request transaction.      Prescription change response transaction.      Refill/Resupply prescription request transaction.      Refill/Resupply prescription response transaction.      Verification transaction.      Password change transaction.      Cancel prescription request transaction.      Cancel prescription response transaction.      Fill status notification.      Prescription drug administration message.      New prescription requests.      New prescription response denials.      Prescription transfer message.      Prescription fill indicator change.      Prescription recertification.      Risk Evaluation and Mitigation Strategy (REMS) initiation request.      REMS initiation response, REMS request      REMS initiation response.      REMS request.      REMS response.     We are also proposing to adopt NCPDP SCRIPT 2017071 as the official part D e-prescribing standard for the medication history transaction at Sec.  423.160(b)(4). As a result, we are also proposing to retire NCPDP SCRIPT versions 8.1 and 10.6 for medication history transactions transmitted on or after January 1, 2019.     Furthermore, we propose to amend Sec.  423.160(b)(1) by modifying Sec.  423.160(b)(1)(iv) to limit usage of NCPDP SCRIPT version 10.6 to transactions before January 1, 2019.     In addition, we propose to add Sec.  423.160(b)(1)(v) to provide that NCPDP Version 2017071 must be used to conduct the covered transactions on or after January 1, 2019. Furthermore, we are proposing to amend Sec.  423.160(b)(2) by adding Sec.  423.160(b)(2)(iv) to name NCPDP SCRIPT Version 2017071 for the applicable transactions. Finally, we propose to incorporate NCPDP SCRIPT version 2017071 by reference in our regulations. We seek comment regarding our proposed retirement of NCPDP SCRIPT version 10.6 on December 31, 2018 and adoption of NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e- prescribing standard for the e-prescribing functions outlined in our proposed Sec.  423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in our proposed Sec.  423.160(b)(4), effective January 1, 2019. We are also soliciting comments regarding the impact of these proposed effective dates on industry and other interested stakeholders.     We are also proposing a technical correction of a prior regulation. On July 30, 2012, we published regulation (CMS-1590-P), which established version 10.6 as the Part D e-prescribing standard effective March 1, 2015 for certain electronic transactions that convey prescription or prescription related information, as listed in Sec.   423.160(b)(2)(iii). However, despite the regulation clearly noting adoption of NCPDP SCRIPT 10.6 as the part D e-prescribing standard for the listed transactions, due to a typographical error, Sec.   423.160(b)(1)(iv) references (b)(2)(ii) (NCPDP SCRIPT 8.1), rather than (b)(2)(iii) (NCPDP SCRIPT 10.6). We propose a correction of this typographical error by changing the reference at Sec.  423.160 (b)(1)(iv) to reference (b)(2)(iii) instead of (b)(2)(ii).     In proposing updates to the Part D E-Prescribing Standards CMS has reviewed specification documents developed by the National Council for Prescription Drug Programs (NCPDP). The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble to the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons or how the agency worked to make the materials reasonably available. In addition, the preamble to the proposed rule must summarize the materials.     Consistent with those requirements CMS has established procedures to ensure that interested parties can review and inspect relevant materials. The proposed update to the Part D prescribing standards has relied on the NCPDP SCRIPT Implementation Guide Version 2017071 approved July 28, 2017. Members of the NCPDP may access these materials through the member portal at [*www.ncpdp.org*](http://www.ncpdp.org); non- NCPDP members may obtain these materials for information purposes by contacting the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Mailstop C1-26-05, or by calling (410) 786- 3694. 9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (Sec. Sec.   422.502 and 423.503)     In April 2010, we clarified our authority to deny contract qualification applications from organizations that have failed to comply with the requirements of a Medicare Advantage or Part D plan sponsor contract they currently hold, even if the submitted application otherwise demonstrates that the organization meets the relevant program requirements. As part of that rulemaking, we established, at Sec.   422.502(b)(1) and Sec.  423.503(b)(1), that we would review an applicant's prior contract performance for the 14-month period preceding the application submission deadline (see 75 FR 19684 through 19686). We conduct that review in accordance with a methodology we publish each year \58\ and use to score each applicant's performance by assigning weights based on the severity of its non-compliance in several

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performance categories. Under the annual contract qualification application submission and review process we conduct, organizations must submit their application by a date, usually in mid-February, announced by us. We now propose to reduce the past performance review period from 14 months to 12 months. ---------------------------------------------------------------------------

    \58\ [*https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Final\_2018\_Application\_Cycle\_Past\_Performance\_Methodology.pdf*](https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Final_2018_Application_Cycle_Past_Performance_Methodology.pdf) ---------------------------------------------------------------------------

    We originally established the 14-month review period because it covered the time period from the start of the preceding contract year through the date on which CMS receives contract applications for the upcoming contract year. We believed at the time that the combination of the most recent complete contract year and the 2 months preceding the application submission provided us with the most complete picture of the most relevant information about an applicant's past contract performance. Our application of this authority since its publication has prompted comments from contracting organizations that the 14-month period is too long and is unfair as it is applied. In particular, organizations have noted that non-compliance that occurs during January and February of a given year is counted against an organization in 2 consecutive past performance review cycles while non-compliance occurring in all other months is counted in only one review cycle. The result is that some non-compliance is ``double counted'' based solely on the timing of the non-compliance and can, depending on the severity of the non-compliance, prevent an organization from receiving CMS approval of their application for 2 consecutive years.     Rather than creating a gap in the look-back period, as we were concerned in 2010, 75 FR 19685, we now believe a 12-month look-back period provides a more accurate period to consider. We believe it is still important to capture in each review cycle an applicant's most recent contract performance. Therefore, we propose to revise Sec.   422.502(b)(1) and Sec.  423.503(b)(1) to reduce the review period from 14 to 12 months. This would effectively establish a new review period for every application review cycle of March 1 of the year preceding the application submission deadline through February 28 (February 29 in leap years) of the year in which the application is submitted and would eliminate the counting of instances of non-compliance in January and February of each year in 2 separate application cycles. We also propose to have this review period change reflected consistently in the Part C and D regulation by revising the provisions of Sec.  422.502(b)(2) and Sec.  423.503(b)(2) to state that CMS may deny an application from an existing Medicare Advantage or Part D plan sponsor in the absence of a record of at least 12, rather than 14, months of Medicare contract performance by the applicant. We do not intend to change any other aspect of our consideration of past performance in the application process. 10. Preclusion List--Part D Provisions a. Background (1) 2014 Final Rule     On May 23, 2014, we published a final rule in the Federal Register titled ``Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29844). Among other things, this final rule implemented section 6405(c) of the Affordable Care Act, which provides the Secretary with the authority to require that prescriptions for covered Part D drugs be prescribed by a physician enrolled in Medicare under section 1866(j) of the Act (42 U.S.C 1395cc(j)) or an eligible professional as defined at section 1848(k)(3)(B) of the Act (42 U.S.C 1395w-4(k)(3)(B)). More specifically, the final rule revised Sec.   423.120(c)(5) and added new Sec.  423.120(c)(6), the latter of which stated that for a prescription to be eligible for coverage under the Part D program, the prescriber must have (1) an approved enrollment record in the Medicare fee for service program (that is, original Medicare); or (2) a valid opt out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC).     The purpose of this change was to help ensure that Part D drugs are prescribed only by qualified prescribers. In a June 2013 report titled ``Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI-02-09-00608), the Office of Inspector General (OIG) found that the Part D program improperly paid for drugs prescribed by persons who did not appear to have the authority to prescribe. We also noted in the final rule the reports we received of prescriptions written by physicians with suspended licenses having been covered by the Part D program. These reports raised concerns within CMS about the propriety of Part D payments and the potential for Part D beneficiaries to be prescribed dangerous or unnecessary drugs by individuals who lack the authority or qualifications to prescribe medications. Given that the Medicare FFS provider enrollment process, as outlined in 42 CFR part 424, subpart P, collects identifying information about providers and suppliers who wish to enroll in Medicare, we believed that forging a closer link between Medicare's coverage of Part D drugs and the provider enrollment process would enable CMS to confirm the qualifications of the prescribers of such drugs. That is, requiring Part D prescribers to enroll in Medicare would provide CMS with sufficient information to determine whether a physician or eligible professional is qualified to prescribe Part D drugs.     We stated in the May 23, 2014 final rule that the compliance date for our revisions to new Sec.  423.120(c)(6) would be June 1, 2015. We believed that this delayed date would give physicians and eligible professionals who would be affected by these provisions adequate time to enroll in or opt-out of Medicare. It would also allow CMS, A/B MACs, Medicare beneficiaries, and other impacted stakeholders sufficient opportunity to prepare for these requirements. (2) 2015 Interim Final Rule     On May 6, 2015, we published in the Federal Register an interim final rule with comment period (IFC) titled ``Medicare Program; Changes to the Requirements for Part D Prescribers'' (80 FR 25958). This IFC made changes to certain requirements outlined in the May 23, 2014 final rule related to beneficiary access to covered Part D drugs.     First, we changed the compliance date of Sec.  423.120(c)(6) from June 1, 2015 to January 1, 2016. This was designed to give all affected parties more time to prepare for the additional provisions included in the IFC before Part D drugs prescribed by individuals who are neither enrolled in nor opted-out of Medicare are no longer covered.     Second, we revised paragraph Sec.  423.120(c)(6)(ii) to address a gap in Sec.  423.120(c)(6) regarding certain types of prescribers; such prescribers included pharmacists who may be authorized under state law to prescribe medications but are ineligible to enroll in Medicare and thus, under Sec.  423.120(c)(6), would not have their prescriptions covered. Revised paragraph (c)(6)(ii) stated that pharmacy claims and beneficiary requests for reimbursement for Part D prescriptions written by prescribers other than physicians and eligible professionals who are nonetheless permitted by state or other applicable law to prescribe medications (defined in Sec.  423.100 as ``other authorized prescribers'') will not be rejected or denied, as applicable, by the pharmacy benefit manager (PBM) if all other requirements are met. This meant that

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the enrollment requirement specified in Sec.  423.120(c)(6) would not apply to other authorized prescribers--that is, to individuals who are ineligible to enroll in or opt out of Medicare because they do not meet the statutory definition of ``physician'' or ``eligible professional'' yet who are otherwise legally authorized to prescribe drugs.     Third, and to help ensure that beneficiaries would not experience a sudden lapse in Part D prescription coverage upon the January 1, 2016 effective date, we added a new paragraph Sec.  423.120(c)(6)(v). This provision stated that a Part D sponsor or its PBM must, beginning on January 1, 2016 and upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor or PBM would otherwise be required to reject or deny, as applicable, under Sec.  423.120(c)(6):      Provide the beneficiary with:     ++ A 3-month provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law); and     ++ Written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS; and      Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent the notice referred to in the previous paragraph.     The 3-month provisional supply and written notice were intended to (1) notify beneficiaries that a future prescription written by the same prescriber would not be covered unless the prescriber enrolled in or opted-out of Medicare, and (2) give beneficiaries time to make arrangements to continue receiving the prescription if the prescriber of the medication did not intend to enroll in or opt-out of Medicare. (3) Preparations for Enforcement of Part D Prescriber Enrollment Requirement     Immediately after the publication of the previously mentioned May 23, 2014 final rule, we undertook major efforts to educate affected stakeholders about the forthcoming enrollment requirement. Particular focus was placed on reaching out to Part D prescribers with information regarding (1) the overall purpose of the enrollment process; (2) the important program integrity objectives behind Sec.  423.120(c)(6); (3) the mechanisms by which prescribers may enroll in Medicare (for example, via the Internet based Provider Enrollment, Chain and Ownership System (PECOS); and (4) how to complete an enrollment application. Numerous prescribers have, in preparation for the enforcement of Sec.  423.120(c)(6), enrolled in or opted out of Medicare, and we are appreciative of their cooperation in this effort. However, based on internal CMS data, as of July 2016 approximately 420,000 prescribers--or 35 percent of the total 1.2 million prescribers of Part D drugs--whose prescriptions for Part D drugs would be affected by the requirements of Sec.  423.120(c)(6) have yet to enroll or opt out. Of these prescribers, 32 percent are dentists, 11 percent are student trainees, 7 percent are nurse practitioners, 6 percent are pediatric physicians, and 5 percent are internal medicine physicians.     Several provider organizations, moreover, have expressed concerns about the enrollment requirements. They have contended that (1) most prescribers pose no risk to the Medicare program; and (2) certain types of physicians and eligible professionals prescribe Part D drugs only very infrequently. Their general position, in short, is that the burden to the prescriber community would outweigh the payment safeguard benefits of Sec.  423.120(c)(6). After the publication of the IFC, and based on our desire to give prescribers and other stakeholders more time to prepare for the enrollment requirements, we announced a phased- in enforcement of the enrollment requirements and stated that full enforcement would be delayed until January 1, 2019. (Information was posted at the following link: [*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Prescriber-Enrollment-Information.html*](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Prescriber-Enrollment-Information.html) ) However, the concerns of these provider organizations remain.     We do recognize these concerns. We wish to reduce as much burden as possible for providers without compromising our program integrity objectives. In addition, over 400,000 prescribers remain unenrolled and, as a consequence, approximately 4.2 million Part D beneficiaries (based on analysis performed on 2015 and 2016 PDE data) could lose access to needed prescriptions when full enforcement of the enrollment requirement begins on January 1, 2019 unless their prescriber enrolls or opt outs or they change prescribers. We believe that an appropriate balance is possible between burden reduction and the need to protect Medicare beneficiaries and the Trust Funds. To this end, we propose several changes to Sec.  423.120(c)(6). b. Proposed Provisions     In accordance with section 1871 of the Act, within 3 years of the publication of the May 6, 2015 IFC, we must either publish a final rule or publish a notice of a different timeline. If we finalize the proposals described in this notice of proposed rulemaking, we would not finalize the provisions of the IFC. Instead, the proposals described in this publication would supersede our earlier rulemaking.     The effective date of our proposed provisions in Sec.   423.120(c)(5) would be 60 days after the publication of a final rule. The effective date of our proposed revisions to Sec.  423.120(c)(6) would be January 1, 2019. (1) Prescriber NPI Validation on Part D Claims (a) Provisions of Sec.  423.120(c)(5)     Section 423.120(c)(5) states that before January 1, 2016, the following are applicable:      In paragraph (c)(5)(i), we state that a Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.      In paragraph (c)(5)(ii), we state that a Part D sponsor must ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug, by taking the steps described in paragraph (c)(5)(iii) of this section.      In paragraph (c)(5)(iii), we state that the sponsor must communicate at point-of-sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(iii).     ++ In paragraph (c)(5)(iii)(A), we state that if the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to (1) confirm that the NPI is active and valid; or (2) correct the NPI.     ++ In paragraph (c)(5)(iii)(B), we state that if the pharmacy:     ++ Confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable; or     ++ Cannot or does not correct or confirm that the NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).      In paragraph (c)(5)(iv), we state that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor--     ++ Has complied with paragraphs (c)(5)(ii) and (iii) of this section;

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    ++ Has verified that a submitted NPI was not in fact active and valid; and     ++ The agreement between the parties explicitly permits such recoupment.      In paragraph (c)(5)(v), we state that with respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.     These provisions, which focus on NPI submission and validation, are no longer effective because the January 1, 2016 end-date for their applicability has passed. Since that time, however, and as explained in detail in section (b)(1)(b) below, congressional legislation requires us to revisit some of the provisions in former paragraph (c)(5) and, as warranted, to re-propose them in what would constitute a new paragraph (c)(5). We believe that these new provisions would not only effectively implement the legislation in question but also enhance Part D program integrity by streamlining and strengthening procedures for ensuring the identity of prescribers of Part D drugs. This would be particularly important in light of our preclusion list proposals. (b) Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)     MACRA was signed into law on April 16, 2015, just before the IFC was finalized. Section 507 of MACRA amends section 1860D-4(c) of the Act (42 U.S.C 1395w-104(6)) by requiring that pharmacy claims for covered Part D drugs include prescriber NPIs that are determined to be valid under procedures established by the Secretary in consultation with appropriate stakeholders, beginning with plan year 2016.     In light of the enactment of MACRA, on June 1, 2015, we issued a guidance memo, ``Medicare Prescriber Enrollment Requirement Update'' (memo). The memo noted that Sec.  423.120(c)(5) would no longer be applicable beginning January 1, 2016 due to the IFC we had just published, but that its provisions reflected certain existing Part D claims procedures established by the Secretary in consultation with stakeholders through the National Council for Prescription Drug Programs (NCPDP) that would comply with section 507 of MACRA, except one.     The provisions in Sec.  423.120(c)(5) that reflected the procedures that would comply with section 507 of MACRA are the following:      Paragraph (c)(5)(iii).      Paragraph (c)(5)(iii)(A).      Paragraph (c)(5)(iii)(B)(1). (Note that paragraph (c)(5)(iii)(B)(2) would not comply with section 507 because the sponsor has no evidence that the NPI is active or valid.)      Paragraph (c)(5)(iv).      Paragraph (c)(5)(v).     Given this, we are proposing to include these provisions in new paragraph (c)(5). They would be enumerated as, respectively, new paragraphs (c)(5)(ii), (c)(5)(ii)(A), (c)(5)(ii)(B), (c)(5)(iii), and (c)(5)(iv). Current paragraphs (c)(5)(i), (c)(5)(ii), and (c)(5)(iii)(B)(2) would not be included in new paragraph (c)(5).     We also note that in the May 6, 2015 IFC, we revised Sec.   423.120(c)(6)(i) to require a Part D plan sponsor to reject, or require its pharmaceutical benefit manager (PBM) to reject, a pharmacy claim for a Part D drug, unless the claim contains the NPI of the prescriber who prescribed the drug. This provision, too, reflects existing Part D claims procedures and policies that comply with section 507 of MACRA. We thus propose to retain this provision and seek comment on associated burdens or unintended consequences and alternative approaches. However, we wish to move it from paragraph (c)(6) to paragraph (c)(5) so that most of the NPI provisions in Sec.  423.120 are included in one subsection. We believe this would improve clarity. (2) Targeted Approach to Part D Prescribers     We believe that the most effective means of reducing the burden of the Part D enrollment requirement on prescribers, Part D plan sponsors, and beneficiaries without compromising our payment safeguard aims would be to concentrate our efforts on preventing Part D coverage of prescriptions written by prescribers who pose an elevated risk to Medicare beneficiaries and the Trust Funds. In other words, rather than require the enrollment of Part D prescribers regardless of the possible level of risk posed, we propose to focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers.     There is precedent for such a risk based approach. For instance, consistent with Sec.  424.518, A/B MACs are required to screen applications for enrollment in accordance with a CMS assessment of risk and assignment to a level of ``limited,'' ``moderate,'' or ``high.'' Applications submitted by provider and supplier types that have historically posed higher risks to the Medicare program are subjected to a more rigorous screening and review process than those that present limited risks. Moreover, Sec.  424.518 states that providers and suppliers that have had certain adverse actions imposed against them, such as felony convictions or revocations of enrollment, are placed into the highest and most rigorous screening level. We recognize that the risk based approach in Sec.  424.518 applies to enrollment application screening rather than payment denials. However, we believe that using a risk-based approach would enable CMS to focus on prescribers who pose threats to the Medicare program and its beneficiaries, while minimizing the burden on those who do not. The process we envision and propose, which would replace the prescriber enrollment requirement outlined in Sec.  423.120(c)(6) with a claims payment-oriented approach, would consist of the following components:      Step 1: We would research our internal systems and other relevant data for prescribers who have engaged in behavior for which CMS:     ++ Has revoked the prescriber's enrollment and the prescriber is under a reenrollment bar; or     ++ Could have revoked the prescriber (to the extent applicable) if he or she had been enrolled in Medicare.     Concerning revocations, we have the authority to revoke a provider's or supplier's Medicare enrollment for any of the applicable reasons listed in Sec.  424.535(a). There are currently 14 such reasons. When revoked, the provider or supplier is barred under Sec.   424.535(c) from reenrolling in Medicare for a period of 1 to 3 years, depending upon the severity of the underlying behavior. We have an obligation to protect the Trust Funds from providers and suppliers that engage in activities that could threaten the Medicare program, its beneficiaries, and the taxpayers. In light of the significance of behavior that could serve as grounds for revocation, we believe that prescribers who have engaged in inappropriate activities should be the focus of our Part D program integrity efforts under Sec.   423.120(c)(6).      Step 2--We would review, on a case-by-case basis, each prescriber who--     ++ Is currently revoked from Medicare and is under a reenrollment bar. We would examine the reason for the prescriber's revocation.     ++ Has engaged in behavior for which CMS could have revoked the

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prescriber to the extent applicable if he or she had been enrolled in Medicare.     The prescribers to be reviewed would be those who, according to PDE data and CMS' internal systems, are eligible to prescribe drugs covered under the Part D program. That is, our review would not be limited to those persons who are actually prescribing Part D drug, but would include those that potentially could prescribe drugs. We believe that the inclusion of these individuals in our review would help further protect the integrity of the Part D program.     We are also seeking comment on an alternative by which we would first identify, through PDE data, those providers who are prescribing drugs to Medicare beneficiaries. This would significantly reduce the universe of prescribers who are on the preclusion list and reduce the government's surveillance of prescribers. We anticipate that this could create delays in our ability to screen providers due to data lags and may introduce some program integrity risks. We are particularly interested in hearing from the public on the potential risks this could pose to beneficiaries, especially in light of our efforts to address the opioids epidemic.      Step 3--Based on the results of Steps 1 and 2, we would compile a ``preclusion list'' of prescribers who fall within either of the following categories:     ++ Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.     ++ Have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.     We propose to adopt this preclusion list approach as an alternative to enrollment in part to reflect the more indirect connection of prescribers in the Medicare Part D program. We seek comment on whether some of the bases for revocation should not apply to the preclusion list in whole or in part and whether the final regulation (or future guidance) should specify which bases are or are not applicable and under what circumstances. (i) Preclusion List     Considering the program integrity risk that the two previously mentioned sets of prescribers present, we must be able to accordingly protect Medicare beneficiaries and the Trust Funds. We thus propose to revise Sec.  423.120(c)(6), as further specified in this proposed rule, to require that a Part D plan sponsor must reject, or must require its PBM to reject, a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug prescribed by an individual on the preclusion list. We believe we have the legal authority for such a provision because sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program; also, section 1860D-12(b)(3)(D) of the Act authorizes the Secretary to add additional Part D contract terms as necessary and appropriate, so long as they are not inconsistent with the Part D statute. We note also that our proposal is of particular importance when considering the current nationwide opioid crisis. We believe that the inclusion of problematic prescribers on the preclusion list could reduce the amount of opioids that are improperly or unnecessarily prescribed by persons who pose a heightened risk to the Part D program and Medicare beneficiaries.     All grounds for revocation under Sec.  424.535(a) reflect behavior or circumstances that are of concern to us. However, considering the variety of factual scenarios that CMS may come across, we believe it is necessary for CMS to have the flexibility to take into account the specific circumstances involved when determining whether the underlying conduct is detrimental to the best interests of the Medicare program. Accordingly, CMS would consider the following factors in making this determination:      The seriousness of the conduct involved;      The degree to which the prescriber's conduct could affect the integrity of the Part D program; and      Any other evidence that CMS deems relevant to its determination.     We emphasize that in situations where the prescriber was enrolled and then revoked, CMS' determination would not negate the revocation itself. The prescriber would remain revoked from Medicare.     We also recognize that unique circumstances behind the potential or actual inclusion of a particular prescriber on the preclusion list could exist. Of foremost importance would be situations pertaining to beneficiary access to Part D drugs. We believe that we should have the discretion not to include (or, if warranted, to remove) a particular individual on the preclusion list (who otherwise meets the standards for said inclusion) should exceptional circumstances exist pertaining to beneficiary access to prescriptions. This could include circumstances similar to those described in section 1128(c)(3)(B) of the Act, whereby the Secretary may waive an OIG exclusion under section 1128(a)(1), (a)(3), or (a)(4) of the in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. In making a determination as to whether such circumstances exist, we would take into account-- (1) the degree to which beneficiary access to Part D drugs would be impaired; and (2) any other evidence that CMS deems relevant to its determination.     With respect to the foregoing, we solicit comment on the following issues:     ++ Whether the actions referenced in Sec.  424.535(a) are appropriate grounds for inclusion on the preclusion list.     ++ Whether actions other than those referenced in Sec.  424.535(a) should constitute grounds for inclusion on the preclusion and, if so, what those specific grounds are.     ++ Suggestions for means of monitoring abusive prescribing practices and appropriate processes for including such prescribers on the preclusion list. (b) Replacement of Enrollment Requirement With Preclusion List Requirement     We are proposing to ***delete*** the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim (or beneficiary request for reimbursement) for a Part D drug prescribed by a physician or eligible professional to be covered. We also propose to generally streamline the existing regulations because, given that we would no longer be requiring certain prescribers to enroll or opt out, we would no longer need an exception for ``other authorized providers,'' as defined in Sec.  423.100, for there would be no enrollment requirement from which to exempt them. Instead, we would require plan sponsors to reject claims for Part D drugs prescribed by prescribers on the preclusion list. We believe this latter approach would better facilitate our dual goals of reducing prescriber burden and protecting the Medicare program and its beneficiaries from prescribers who could present risks. (ii) Updates to Preclusion List     The preclusion list would be updated on a monthly basis. Prescribers would be added or removed from the list based on CMS' internal data that indicate, for instance: (1) Prescribers who have recently been convicted of a felony that,

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consistent with Sec.  424.535(a)(33), CMS determines to be detrimental to the best interests of the Medicare program, and (2) prescribers whose reenrollment bars have expired. As a particular prescriber's status with respect to the preclusion list changes, the applicable provisions of Sec.  423.120(c)(6) would control. To illustrate, suppose a prescriber in March 2020 is convicted of a felony that CMS deems detrimental to Medicare's best interests. Pharmacy claims for prescriptions written by the individual would thus be rejected by Part D sponsors or their PBMs upon the prescriber being added to the preclusion list. Conversely, a prescriber who was revoked under Sec.   424.535(a)(4) but whose reenrollment bar has expired would be removed from the preclusion list; claims for prescriptions written by the individual would therefore no longer be rejected based solely on his or her inclusion on the preclusion list. CMS would regularly review the preclusion list to determine whether certain individuals should be added to or removed therefrom based on changes to their status.     Consistent with our application of a reenrollment bar to providers and suppliers that are enrolled in and then revoked from Medicare, we propose to keep an unenrolled prescriber on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber had he or she been enrolled and then revoked. For example, suppose an unenrolled prescriber engaged in behavior that, had he or she been enrolled, would have warranted a 2-year reenrollment bar. The prescriber would remain on the preclusion list for that same period of time. We note that in establishing such a time period, we would use the same criteria that we do in establishing reenrollment bars.     Prescribers who were revoked from Medicare or, for unenrolled prescribers, engaged in behavior that could serve as a basis for an applicable revocation prior to the effective date of this rule (if finalized) could, if the requirements of Sec.  423.120(c)(6) are met, be added to the preclusion list upon said effective date even though the underlying action (for instance, felony conviction) occurred prior to that date. However, the Part D claim rejections by Part D sponsors and their PBMs under Sec.  423.120(c)(6) would only apply to claims for Part D prescriptions filled or refilled on or after the date he or she was added to the preclusion list; that is, sponsors and PBMs would not be required to retroactively reject claims based on the effective date of the revocation or, for unenrolled prescribers, the date of the behavior that could serve as a basis for an applicable revocation regardless of whether that date occurred before or after the effective date of this rule.     We do seek comment on a reasonable time period for Part D sponsors/ PBMs to incorporate the preclusion list into their claims adjudication systems, and whether and how our proposed regulatory text needs to be modified to accommodate such a time period. We wish to avoid a situation where a Part D sponsor/PBM pays for prescriptions written by individuals on the preclusion list before the sponsors/PBMs have incorporated the list but later are unable to submit their PDEs, which CMS typically edits based on date of service. (3) Provisional Coverage     The current text of Sec.  423.120(c)(6)(v) states that a Part D sponsor or its PBM must, upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to deny in accordance with Sec.   423.120(c)(6), furnish the beneficiary with (a) a provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law); and (b) written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS. The purpose of this provisional supply requirement is to give beneficiaries notice that there is an issue with respect to future Part D coverage of a prescription written by a particular prescriber.     Although CMS' proposed changes to Sec.  423.120(c)(6) would significantly reduce the number of affected prescribers and, by extension, the number of impacted beneficiaries, we remain concerned that beneficiaries who receive prescriptions written by individuals on the preclusion list might suddenly no longer have access to these medications without provisional coverage and without notice, which gives beneficiaries time to find a new prescriber. Therefore, we propose to maintain the provisional coverage requirement consistent with what was finalized in the IFC, but with a modification. Additionally, many commercial plans are pursuing policies to address the opioid epidemic, such as limiting the amount of initial opioid prescriptions. Given the opioid epidemic, we are considering other solutions for when a beneficiary tries to fill an opioid prescription from a provider on the preclusion list. We seek comment as to what limits or other guardrails CMS should set with respect to number of doses, initial dosing, and type of product for opioid prescriptions for particular clinical presentations (including acute pain, chronic pain, hospice setting and so forth).     An alternative method of ensuring beneficiaries have access to opioids as necessary would be to require the sponsor immediately provide a transfer to a new provider when the first provider is on the preclusion list. The new provider should be able to make an assessment and either provide appropriate SUD treatment or continue the opioid or pain management regimen, as medically appropriate. We are interested to hear from commenters how to operationalize this and whether there is a better method to ensure appropriate medication is provided without transferring the beneficiary to a new provider. We are proposing a 90- day provisional coverage period in lieu of a 3-month drug supply/90-day time period established in existing Sec.  423.120(c)(6), which was described on page 6 in the Technical Guidance on Implementation of the Part D Prescriber Enrollment Requirement (Technical Guidance) issued on December 29, 2015.\59\ Under the existing regulation (which, as noted above, we have not enforced), a sponsor or MA-PD must track a separate 90-day consecutive time period for each drug covered as a provisional supply from the initial date-of-service; the sponsor or MA-PD must not reject a claim or deny a beneficiary's request for reimbursement until the 90-day time period has passed or a 3-month supply has been dispensed, whichever comes first. Under our proposal, however, a beneficiary would have one 90-day provisional coverage period with respect to an individual on the preclusion list. Accordingly, a sponsor/PBM would track one 90-day time period from the date the first drug is dispensed to the beneficiary pursuant to a prescription written by the individual on the preclusion list. This dispensing event would trigger a written notice and a 90-day time period for the beneficiary to fill any prescriptions from that particular precluded prescriber and to find another prescriber during that 90-day time period. ---------------------------------------------------------------------------

    \59\ See [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Technical-Guidance-on-Implementation-of-the-Part-D-Prescriber-Enrollment-Requirement.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Technical-Guidance-on-Implementation-of-the-Part-D-Prescriber-Enrollment-Requirement.pdf) ---------------------------------------------------------------------------

    Our rationale for this change is that individuals on the preclusion list are demonstrably problematic. This has negative implications not only for the Trust Funds but also for beneficiary safety. Thus, it is imperative that a beneficiary switch to a new prescriber who is not on the preclusion list as soon as practicable. Under the current

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prescriber enrollment requirement, the vast majority of prescribers who are not enrolled in or opted-out of Medicare likely do not pose a risk to the beneficiary or the Trust Funds, and therefore we can allow a 3- month provisional supply/90-day time period for each prescription written by such a prescriber. In addition, our proposed policy would eliminate the difficulty sponsors and PBMs have under the current ``per drug'' provisional supply policy in determining whether the beneficiary already received a provisional supply of a drug. We seek specific comment on the modifications we are proposing as to the provisional coverage and time period.     With respect to beneficiaries who would also be entitled to a transition, we are not proposing any change to the current policy. If a Part D sponsor determines when adjudicating a pharmacy claim that a beneficiary is entitled to provisional coverage because the prescriber is on the preclusion list, but the drug is off-formulary and the transition requirements set forth in Sec.  423.120(b)(3) are also triggered, the beneficiary would not receive more than the applicable transition supply of the drug, unless a formulary exception is approved. We note that we considered proposing that the transition requirements would not apply during the provisional supply period in order to simplify the policy for situations when both apply to reduce beneficiary confusion. We seek comment on this or other alternatives for these situations.     We intend to allow the normal Part D rules (for example, edits, prior authorization, quantity limits) to apply during the 90-day provisional coverage period, but solicit comment on whether different limits should apply when opioids are involved, particularly when the reason for precluding the provider/prescriber relates to opioid prescribing. (4) Appeals     In our revisions to Sec.  423.120(c)(6), we propose to permit prescribers who are on the preclusion list to appeal their inclusion on this list in accordance with 42 CFR part 498. We believe that given the aforementioned pharmacy claim rejections that would be associated with a prescriber's appearance on the preclusion list, due process warrants that the prescriber have the ability to challenge this via appeal. Any appeal under this proposed provision, however, would be limited strictly to the individual's inclusion on the preclusion list. The proposed appeals process would neither include nor affect appeals of payment denials or enrollment revocations, for there are separate appeals processes for these actions. In addition, wewould send written notice to the prescriber of his or her inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the prescriber of his or her appeal rights. This is to ensure that the prescriber is duly notified of the action, why it was taken, and his or her ability to challenge our determination.     Consistent with our proposed provision in Sec.  423.120(c)(6) regarding appeal rights, we propose to update several other regulatory provisions regarding appeals:      We propose to revise Sec.  498.3(b) to add a new paragraph (20) stating that a CMS determination to include a prescriber on the preclusion list constitutes an initial determination. This revision would help enable prescribers to utilize the appeals processes described in Sec.  498.5      In Sec.  498.5, we propose to add a new paragraph (n) that would state as follows:     ++ In paragraph (n)(1), we propose that any prescriber dissatisfied with an initial determination or revised initial determination that he or she is to be included on the preclusion list may request a reconsideration in accordance with Sec.  [thinsp]498.22(a).     ++ In paragraph (n)(2), we propose that if CMS or the prescriber under paragraph (n)(1) is dissatisfied with a reconsidered determination under Sec.  498.5(n)(1), or a revised reconsidered determination under Sec.  498.30, CMS or the prescriber is entitled to a hearing before an administrative law judge (ALJ).     ++ In paragraph (n)(3), we propose that if CMS or the prescriber under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the prescriber may request review by the Departmental Appeals Board (DAB) and the prescriber may seek judicial review of the DAB's decision.     These revisions are designed to include preclusion list determinations within the scope of appeal rights described in Sec.   498.5 However, we solicit comment on whether a different appeals process is warranted and, if so, what its components should be.     In addition, given that a beneficiary's access to a drug may be denied because of the application of the preclusion list to his or her prescription, we believe the beneficiary should be permitted to appeal alleged errors in applying the preclusion list. c. Specific Regulatory Changes     Given the foregoing discussion, we propose the following regulatory changes:      In Sec.  423.100, we propose to ***delete*** the definition of ``other authorized prescriber'' and add the following:     ++ Preclusion List means a CMS compiled list of prescribers who:     (1) Meet all of the following requirements: (A) The prescriber is currently revoked from the Medicare program under Sec.  424.535     (B) The prescriber is currently under a reenrollment bar under Sec.  424.535(c).     (C) CMS determines that underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:     (i) The seriousness of the conduct underlying the prescriber's revocation;     (ii) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and     (iii) Any other evidence that CMS deems relevant to its determination; or     (2) Meet both of the following requirements:     (i) The prescriber has engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare.     (ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:     (i) The seriousness of the conduct involved.     (ii) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and     (iii) Any other evidence that CMS deems relevant to its determination      In paragraph (c)(5)(i), we propose that a Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug. This requirement is consistent with existing policy.      In paragraph (c)(5)(ii), we propose that the sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).      In paragraph (c)(5)(ii)(A), we propose that if the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to--

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    ++ Confirm that the NPI is active and valid; or     ++ Correct the NPI.      In paragraph (c)(5)(ii)(B), we propose that if the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.      In paragraph (iii), we propose that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor--     ++ Has complied with paragraph (ii) of this section;     ++ Has verified that a submitted NPI was not in fact active and valid; and     ++ The agreement between the parties explicitly permits such recoupment.      In paragraph (iv), we propose that with respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.      In paragraph (c)(6)(i), we propose to state: ``Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in Sec.  423.100 '' This would help ensure that Part D sponsors comply with our proposed requirement that claims involving prescribers who are on the preclusion list should not be paid.      In paragraph (c)(6)(ii), we propose to state as follows: ``Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in Sec.  423.100 '' As with paragraph (c)(6)(i), this would help ensure that Part D sponsors comply with our proposed requirement that payments not be made for prescriptions written by prescribers who are on the preclusion list.      In paragraph (c)(6)(iii), we propose to state: ``A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in Sec.  423.100, for the date of service.'' This is to help ensure that-- (1) the prescriber can be properly identified, and (2) prescribers who are on the preclusion list are not included in PDEs.      In paragraph (c)(6)(iv), we propose to address the provisional coverage period and notice provisions as follows:     ``(iv)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) of this section or deny a request for reimbursement under paragraph (c)(6)(ii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.     (B) Upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraphs (c)(6)(i) or (ii) of this section, a Part D sponsor or its PBM must do the following: (1) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:     (i) A 90-day provisional supply coverage period during which the sponsor must cover all drugs dispensed to the beneficiary pursuant to prescriptions written by the individual on the preclusion list. The provisional supply period begins on the date-of-service the first drug is dispensed pursuant to a prescription written by the individual on the preclusion list.     (ii) Written notice within 3 business days after adjudication of the first claim or request for the drug in a form and manner specified by CMS.     (2) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(B)(1)(ii) of this section.''      In new Sec.  423.120(c)(6)(v), we propose that CMS would send written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice would contain the reason for the inclusion on the preclusion list and would inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list in accordance with 42 CFR part 498.      In new Sec.  423.120(c)(6)(vi), we propose that CMS has the discretion not to include a particular individual on (or, if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS would take into account--(1) the degree to which beneficiary access to Part D drugs would be impaired; and (2) any other evidence that CMS deems relevant to its determination.      In Sec.  498.3(b), we propose to add a new paragraph (20) stating that a CMS determination that a prescriber is to be included on the preclusion list constitutes an initial determination.      In Sec.  498.5, we propose to add a new paragraph (n) that would state as follows:     ++ In paragraph (n)(1), we propose that any prescriber dissatisfied with an initial determination or revised initial determination that he or she is to be included on the preclusion list may request a reconsideration in accordance with Sec.  [thinsp]498.22(a).     ++ In paragraph (n)(2), we propose that if CMS or the prescriber under paragraph (n)(1) is dissatisfied with a reconsidered determination under Sec.  498.5(n)(1), or a revised reconsidered determination under Sec.  498.30, CMS or the prescriber is entitled to a hearing before an ALJ.     ++ In paragraph (n)(3), we propose that if CMS or the prescriber under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the prescriber may request review by the DAB and the prescriber may seek judicial review of the DAB's decision. 11. Preclusion List--Part C/Medicare Advantage Cost Plan and PACE Provisions a. Background (1) 2016 Final Rule     On November 15, 2016, CMS published a final rule in the Federal Register titled ``Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' (81 FR 80169). This rule contained a number of requirements related to provider enrollment, including, but not limited to, the following:      We added a new Sec.  422.222 to require providers and suppliers that furnish health care items or services to

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a Medicare enrollee who receives his or her Medicare benefit through an MA organization to be enrolled in Medicare and be in an approved status no later than January 1, 2019. (The term ``MA organization'' refers to both MA plans and MA plans that provide drug coverage, otherwise known as MA-PD plans.) We also updated Sec. Sec.  417.478, 460.70, and 460.71 to reflect this requirement.      We added a requirement in new Sec.  422.204(b)(5) that required MA organizations to comply with the provider and supplier enrollment requirements referenced in Sec.  422.222 A similar requirement was added to Sec.  422.504      We revised Sec. Sec.  422.510, 422.752, 460.40, and 460.50 to state that organizations and programs that do not ensure that providers and suppliers comply with the provider and supplier enrollment requirements may be subject to sanctions and termination.      We revised Sec.  422.501 to require that MA organization applications include documentation demonstrating that all applicable providers and suppliers are enrolled in Medicare in an approved status. We believed that these new requirements, as they pertained to MA, were necessary to help ensure that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment. We also believed it would assist our efforts to prevent fraud, waste, and abuse, and to protect Medicare enrollees, by allowing us to carefully screen all providers and suppliers (especially those that potentially pose an elevated risk to Medicare) to confirm that they are qualified to furnish Medicare items and services. Indeed, although Sec.  422.204(a) requires MA organizations to have written policies and procedures for the selection and evaluation of providers and suppliers that conform with the credentialing and recredentialing requirements in Sec.  422.204(b), CMS has not historically had direct oversight over all network providers and suppliers under contract with MA organizations. While there are CMS regulations governing how and when MA organizations can pay for covered services, those are tied to statutory provisions. We concluded that requiring Medicare enrollment in addition to the existing MA credentialing requirements would permit a closer review of MA providers and suppliers, which could, as warranted, involve rigorous screening practices such as risk-based site visits and, in some cases, fingerprint-based background checks, an approach we already take in the Medicare Part A and Part B provider and supplier enrollment arenas. The fact that CMS also has access to information and data not available to MA organizations was also relevant to our decision. (2) Preparations for Part C Enrollment     As with our Part D enrollment requirement, we promptly commenced outreach efforts after the publication of the November 15, 2016 final rule. We communicated with Part C provider associations and MA organizations regarding, among other things, the general purpose of the enrollment process, the rationale for Sec.  422.222, and the mechanics of completing and submitting an enrollment application. According to recent CMS internal data, approximately 933,000 MA providers and suppliers are already enrolled in Medicare and meeting the MA provider enrollment requirements. However, roughly 120,000 MA-only providers and suppliers remain unenrolled in Medicare, and concerns have been raised by the MA community over the enrollment requirement, principally over the burden involved in enrolling in Medicare while having to also undergo credentialing by their respective health plans.     We understand and share these concerns. We believe that the Medicare enrollment requirement could result in a duplication of effort and, consequently, impose a burden on MA providers and suppliers as well as MA organizations and beneficiaries in the form of limiting access to providers. While we maintain that Medicare enrollment, in conjunction with MA credentialing, is the most thorough means of confirming a provider's compliance with Medicare requirements and of verifying the provider's qualifications to furnish services and items, we believe that an appropriate balance can be achieved between this program integrity objective and the desire to reduce the burden on the provider and supplier communities. Given this, we propose to utilize the same ``preclusion list'' concept in MA that we are proposing for Part D (described in section III.B.9 ) and to eliminate the current enrollment requirement in Sec.  422.222 We believe this approach would allow us to concentrate our efforts on preventing MA payment for items and services furnished by providers and suppliers that could pose an elevated risk to Medicare beneficiaries and the Trust Funds, an approach, as previously mentioned, similar to the risk-based process in Sec.  424.518 This would, we believe, minimize the burden on MA providers and suppliers. b. Proposed Provisions (1) Process     The process we envision and propose would, similar to the proposed Part D process, consist of the following components:      Step 1: We would research our internal systems and other relevant data for individuals and entities that have engaged in behavior for which CMS:     ++ Has revoked the individual's or entity's enrollment and the individual or entity is under a reenrollment bar; or     ++ Could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare.     In light of the significance of any activity that would result in a revocation under Sec.  424.535(a), we believe that individual and entities that have engaged in inappropriate behavior should be the focus of our Part C program integrity efforts.      Step 2--CMS would review, on a case-by-case basis, each individual and entity that:     ++ Is currently revoked from Medicare and is under a reenrollment bar. We would examine the reason for the revocation.     ++ Has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if he or she had been enrolled in Medicare.     Similar to our approach with Part D and for the same reason, the individuals and entities to be reviewed would be those that-- according to CMS' internal systems MA organization data, state board information, and other relevant data for individuals and entities who are or who could become eligible to furnish health care services or items. To avoid confusion, we refer to such parties in our proposed Part C preclusion list provisions as ``individuals'' and ``entities'' rather than ``providers'' and ``suppliers.'' This is because the latter two terms could convey the impression that the party in question must be actively furnishing health care services or items to be included on the preclusion list.     Similar to the Part D approach, we are also seeking comment on an alternative by which CMS would first identify through encounter data those providers or suppliers furnishing services or items to Medicare beneficiaries. This would significantly reduce the universe of prescribers who are on the preclusion list and reduce the government's surveillance of prescribers. We

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anticipate that this could create delays in CMS' ability to screen providers or suppliers due to data lags and may introduce some program integrity risks. We are particularly interested in hearing from the public on the potential risks this could pose to beneficiaries.     Based on the results of Steps 1 and 2, we would compile a preclusion list of individuals and entities that fall within either of the following categories:     ++ Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.     ++ Have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.     We propose to update Sec.  422.2 to add a definition of ``preclusion list'' consistent with both the foregoing discussion as well as our proposed definition of the same term for the Part D program.     We propose to adopt this preclusion list approach as an alternative to enrollment in part to reflect the more indirect connection of providers and suppliers in Medicare Advantage. We seek comment on whether some of the bases for revocation should not apply to the preclusion list in whole or in part and whether the final regulation (or future guidance) should specify which bases are or are not applicable and under what circumstances.     In addition, we note that while there would be separate regulatory provisions for Part C and Part D, there would not be two separate preclusion lists: one for Part C and one for Part D. Rather, there would be a single preclusion list that includes all affected individuals and entities. Having one joint list, we believe, would make the preclusion list process easier to administer.     (2) Denial of Payment     Section 422.222(a) currently states that providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement applies to all of the following providers and suppliers:      Network providers and suppliers.      First-tier, downstream, and related entities (FDR).      Providers and suppliers in Cost HMOs or CMPs, as defined in 42 CFR part 417.      Providers and suppliers participating in demonstration programs.      Providers and suppliers in pilot program.      Locum tenens suppliers.      Incident-to suppliers.     We propose to revise this requirement to state than an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the preclusion list (as defined in Sec.  422.2). We also propose to remove the language beginning with ``This requirement applies to all of the following providers and suppliers'' along with the list of applicable providers, suppliers, and FDRs. This is consistent with our previously mentioned intention to use the terms ``individuals'' and ``entities'' in lieu of ``providers'' and ``suppliers.''     We also propose that both basic and supplemental benefits should be subject to the payment prohibition that is tied to the preclusion list. We believe that restricting the payment prohibition to only one of these two categories would undercut the effectiveness of our preclusion list proposal.     We solicit comment on the following issues:     ++ Whether the actions referenced in Sec.  424.535(a) are appropriate grounds for inclusion on the preclusion list.     ++ Whether actions other than those referenced in Sec.  424.535(a) should constitute grounds for inclusion on the preclusion and, if so, what those specific grounds are.     ++ Suggestions for means of monitoring potentially abusive MA practices involving providers and suppliers, and appropriate processes for including such providers and suppliers on the preclusion list.     As stated earlier in reference to prescribers, the preclusion list would be updated on a monthly basis. Individuals and entities would be added or removed from the list based on CMS' internal data or other informational sources that indicate, for instance-- (1) persons eligible to provide medical services who have recently been convicted of a felony that CMS determines to be detrimental to the best interests of the Medicare program; and (2) entities whose reenrollment bars have expired. As a particular individual's or entity's status with respect to the preclusion list changes, the applicable provisions of Sec.   422.222 would control.     Individuals and entities that were revoked from Medicare or, for unenrolled individuals and entities, had engaged in conduct that could serve as a basis for an applicable revocation prior to the effective date of this rule (if finalized) could, if the requirements of Sec.   422.222(a) are met, be added to the preclusion list upon said effective date even though the underlying action (for instance, felony conviction) occurred prior to that date. The proposed payment denials under Sec.  422.222(a), however, would only apply to health care items or services furnished on or after the date the individual or entity was added to the preclusion list; that is, payment denials would not be made retroactive to the date of the revocation or, for unenrolled individuals and entities, the conduct that could serve as a basis for an applicable revocation occurring before the effective date of the final rule. Likewise, health care items and services furnished by individuals and entities revoked from Medicare or engaging in conduct that could serve as a basis for an applicable revocation after the rule's effective date and that are subsequently added to the preclusion list would not be subject to retroactive payment denials under Sec.   422.222(a); only the date on which the affected individual or entity is added to the preclusion list would be used to determine payment and the start date of payment denials under this proposal. We believe that this approach is the most consistent with principles of due process. (3) MA Organization Compliance     Section 422.222 currently states that MA organizations that do not ensure that providers and suppliers comply with paragraph (a) may be subject to sanctions under Sec.  422.750 and termination under Sec.   422.510 We propose to revise this to state that MA organizations that do not comply with paragraph (a) may be subject to sanctions under Sec.  422.750 and termination under Sec.  422.510 This is to help ensure that MA organizations do not make improper payments for items and services furnished by individuals and entities on the preclusion list. (4) Related Revisions     As discussed previously, in the November 15, 2016 final rule, we added or updated a number of other MA regulatory provisions (for example, Sec.  422.501 and 422.510) in order to fully incorporate our new enrollment requirements. Because we are proposing to replace these enrollment requirements with an approach centered upon a preclusion list--and to help

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ensure that providers, suppliers, MA organizations, PACE organizations, and other applicable stakeholders comply with our proposed requirements--we believe that these other MA regulatory provisions must also be revised to reflect this change. To this end, we propose the following revisions:      Section 422.204(a) states that an MA organization must have written policies and procedures for the selection and evaluation of providers and suppliers. These policies must conform with the credentialing and recredentialing requirements in Sec.  422.204(b). Under paragraph (b)(5), an MA organization must follow a documented process with respect to providers and suppliers that have signed contracts or participation agreements that ensures compliance with the provider and supplier enrollment requirements in Sec.  422.222 To achieve consistency with our preclusion list proposals and to help facilitate MA organizations' compliance therewith, we propose to:     ++ Establish a new Sec.  422.204(c) that would require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in Sec.  422.222     ++ ***Delete*** Sec.  422.204(b)(5) because it applies to the Part C enrollment process, which we are proposing to eliminate. Further, revising paragraph (b)(5) to address the preclusion list requirements could cause confusion, for paragraph (b) references providers and suppliers. We thus believe that creating a new paragraph (c) would better clarify our expectations.      In 42 CFR part 417, subpart L, we address certain contractual requirements concerning health maintenance organizations (HMOs) and competitive medical plans (CMPs) that contract with CMS to furnish covered services to Medicare beneficiaries. Under Sec.   417.478(e), the contract between CMS and the HMO or CMP must, among other things, provide that the HMO or CMP agrees to comply with ``Sections 422.222 and 422.224, which require all providers and suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, to be enrolled in Medicare in an approved status and prohibits payment to providers and suppliers that are excluded or revoked.'' Paragraph (e) adds that this requirement includes ``locum tenens suppliers and, if applicable, incident-to suppliers.''     Furthermore, Sec.  417.484(b)(3) requires that the contract must provide that the HMO or CMP agrees to require all related entities to agree that ``All providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in Medicare in an approved status.'' We accordingly propose the following revisions:     ++ We propose to revise Sec.  417.478(e) to state as follows:     ++ In new paragraph (e)(1), we propose to state that the prohibitions, procedures and requirements relating to payment to individual and entities on the preclusion list (defined in Sec.  422.2 of this part) apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.     ++ In new paragraph (e)(2), we propose to state that in applying the provisions of Sec. Sec.  422.2, 422.222, and 422.224 under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.     ++ We propose to revise Sec.  417.484(b)(3) to state: ``That payments must not be made to individuals and entities that are included on the preclusion list (as defined in Sec.  422.2).''      In 42 CFR part 460, we address requirements relating to Programs of All-Inclusive Care for the Elderly (PACE). The PACE program is a state option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE. We propose to make the following changes to Part 460:     ++ Section 460.40 states that, in addition to other remedies authorized by law, CMS may impose any of the sanctions specified in Sec. Sec.  460.42 and 460.46 if CMS determines that a PACE organization commits certain violations, one of which is outlined in paragraph (j) and reads: ``Employs or contracts with any provider or supplier that is a type of individual or entity that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.'' We propose to revise paragraph (j) to state: ``Makes payment to any individual or entity that is included on the preclusion list, defined in Sec.  422.2 of this chapter.''     ++ Section 460.50(b) addresses grounds for which CMS or the state administering agency may terminate a PACE program agreement if CMS or the state administering agency determines that the conditions of paragraphs (b)(1) and (2) are met. In (b)(1), one of two conditions, outlined in paragraphs (b)(1)(i) and (ii), must be met. Paragraph (b)(1)(ii) states: ``The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including employing or contracting with any provider or supplier that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.'' We propose to revise paragraph (b)(1)(ii) by changing the current language beginning with ``including'' to read ``including making payment to an individual or entity that is included on the preclusion list, defined in Sec.  422.2 of this chapter.'' We note that this change would not prohibit a PACE organization from employing or contracting with an individual or entity on the preclusion list. As previously discussed, the focus of our preclusion list proposals is on the denial of payment.     ++ Section 460.68(a) lists certain categories of individuals who a PACE organization may not employ, as well as individuals and organizations with whom a PACE organization may not contract. Among these parties are those listed in paragraph (a)(4); specifically, those ``that are not enrolled in Medicare in an approved status, if the providers or suppliers are of the types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act.'' We propose to ***delete*** paragraph (a)(4), given our proposed removal of the Part C enrollment requirement.     ++ Section 460.70(a) states that a PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, except for emergency services as described in Sec.  460.100; various requirements that a contract between a PACE organization and a contractor must meet are listed in Sec.  460.70(b). Paragraph (b)(1) states that the PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, those listed in paragraphs (b)(1)(i) through (iv). Paragraph (b)(1)(iv) reads: ``Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.'' Consistent with our proposed ***deletion*** of Sec.  460.68(a)(4), we propose to ***delete*** Sec.  460.70(b)(1)(iv). We note that we are not proposing to prohibit individuals and entities on the preclusion list from furnishing services

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and items to PACE participants; we are merely proposing to prohibit payment for such services and items if provided by an individual or entity on the preclusion list.     ++ Section 460.71(b) states that a PACE organization must develop a program to ensure that all staff furnishing direct participant care services meets the requirements outlined in paragraph (b). One of these requirements, listed in paragraph (b)(7), reads: ``Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.'' Similar to our proposed ***deletion*** of Sec.  460.68(a)(4), we propose to ***delete*** paragraph (b)(7).     ++ Section 460.86 addresses payments to excluded or revoked providers and suppliers as follows:     ++ Paragraph (a) states that a PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in Sec.  460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program.     ++ Paragraph (b) states: ``If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program, the PACE organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program.''     We propose to revise these paragraphs as follows:     ++ Paragraph (a) would state: ``A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in Sec.  460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in Sec.  422.2 of this chapter.'' We are not proposing to include the current regulatory language ``or revoked'' in our revised paragraph. This is because, as outlined previously, there could be situations under revised Sec.  422.222 where a revoked individual or entity would not be included on the preclusion list.     ++ Paragraph (b) would state: ``If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in Sec.  422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''      Section 422.501(c) states that in order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity (or an individual authorized to act for the entity (the applicant)), must fully complete all parts of a certified application. As part of the application, paragraph (c)(1)(iv) requires ``(d)ocumentation that all providers or suppliers in the MA or MA-PD plan that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in an approved status.'' Also, paragraph (c)(2) requires the following: ``The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that all providers and suppliers referenced in Sec.  422.222 are enrolled in Medicare in an approved status.''     We propose to:     ++ Revise paragraph (c)(1)(iv) to read: ``Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''     ++ Revise paragraph (c)(2) to replace the language beginning with ``including providing documentation . . . '' with ``including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''      Section 422.752(a) lists certain violations for which CMS may impose sanctions (as specified in Sec.  422.750(a)) on any MA organization with a contract. One violation, listed in paragraph (a)(13), is that the MA organization ``(f)ails to comply with Sec.   422.222 and 422.224, that requires the MA organization to ensure that providers and suppliers are enrolled in Medicare and not make payment to excluded or revoked individuals or entities.'' We propose to revise paragraph (a)(13) to read: ``Fails to comply with Sec. Sec.  422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals or entities, nor to individuals or entities on the preclusion list, defined in Sec.  422.2 ''      Section 422.510(a)(4) lists various grounds by which CMS may terminate a contract with an MA organization. Paragraph (a)(4)(xiii) refers to the MA organization's failure ``to meet the preclusion list requirements in accordance with Sec. Sec.  422.222 and 422.224 '' We propose to revise this paragraph to read: ``Fails to meet the preclusion list requirements in accordance with Sec. Sec.  422.222 and 422.224 ''      Section 422.504 outlines provisions that the contract between the MA organization and CMS must contain. Under paragraph (a)(6), the MA organization must agree to adhere to, among other things, ``Medicare provider and supplier enrollment requirements.'' Pursuant to paragraph (i)(2)(v), moreover, the MA organization agrees to require all first tier, downstream, and related entities to agree that ``they will require all of their providers and suppliers to be enrolled in Medicare in an approved status consistent with Sec.   422.222 '' We propose to revise these two paragraphs as follows:     ++ Paragraph (a)(6) would be revised to replace the language ``Medicare provider and supplier enrollment requirements'' with ``the preclusion list requirements in 422.222 ''     ++ Paragraph (i)(2)(v) would be revised to replace the language following ``they will'' with ``ensure that payments are not made to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''      Section 422.224, which applies to MA organizations and pertains to payments to excluded or revoked providers or suppliers, contains provisions very similar to those in Sec.  460.86:     ++ Paragraph (a) states that an MA organization ``may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in Sec.  422.113) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program except as provided.''     ++ Paragraph (b) states: ``If an MA organization receives a request for

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payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program, the MA organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program.     We propose to revise these paragraphs as follows:     ++ Paragraph (a) would state: ``An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in Sec.  422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in Sec.  422.2     ++ Paragraph (b) would state: ``If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in Sec.  422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''     In addition to the aforementioned proposals, CMS proposes to amend existing data submission requirements for risk adjustment to require MA organizations to include provider NPIs as part of encounter data submissions; CMS intends to use the NPI data to identify individuals and entities that, depending on the results of CMS investigation, may be included on the preclusion list proposed in this section. Pursuant to section 1853(a)(1)(C) and (a)(3)(B) of the Act, CMS adjusts the capitation rates paid to MA organizations to account for such risk factors as age, disability status, gender, institutional status, and health status and requires MA organizations to submit data regarding the services provided to MA enrollees. Implementing regulations at 42 CFR 422.310 set forth the requirements for the submission of risk adjustment data that CMS uses to risk-adjust payments. MA organizations must submit data, in accordance with CMS instructions, to characterize the context and purposes of items and services provided to their enrollees by a provider, supplier, physician, or other practitioner (OMB Control No. 0938-1152). Currently, risk adjustment data is submitted in two formats: comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data); and data in abbreviated formats (often referred to as RAPS data).     CMS requires that MA organizations and other entities submit encounter data using the X12 837 5010 format to fulfill the reporting requirements at 42 CFR 422.310, where ``X12'' refers to healthcare transactions, ``837'' refers to an electronic format for institutional (``837-I'') and professional (``837-P'') encounters, and ``5010'' refers to the most recent version of this national standard. The X12 837 5010 is one of the national standard HIPAA transaction and code set formats for electronic transmission of healthcare transactions. Records that MA organziations and other submitters send to CMS in the X12 837 5010 format are known as ``encounter data records.''     One of the required data elements on the X12 837 5010 encounter data record is the ``Billing Provider.'' The Billing Provider is identified through several data fields (for example, name field and address field), but a key data field for identifying the Billing Provider is the National Provider Identifier (NPI). The NPI was established as a national standard for a unique health identifier for health care providers, as part of HIPAA Administrative Simplification efforts for electronic transactions among trading partners. CMS announced its decision to implement the NPI for Medicare, in the final rule 69 FR 3434, published January 23, 2004. Billing Provider NPIs are required for X12N 837 5010 transactions (both institutional and professional), as established in the national implementation guides (known by the shorthand ``TR3 guides''): Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Institutional (837) and Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Professional (837). However, CMS has not incorporated this Billing Provider NPI requirement into its Part C MA regulations for submission of risk adjustment data. CMS has incorporated the Part D program requirement that plan sponsors submit NPIs on the Prescription Drug Event Record (77 FR 22072, published April 12, 2012).     We are proposing to amend Sec.  422.310 by adding a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance. While the NPI is a required data element for the X12 837 5010 format (as set forth in the TR3 guides cited in the Background), CMS has not codified a regulatory requirement that MA organizations include the Billing Provider NPI in encounter data records. The proposed amendment would implement that requirement.     We propose to include the phrase ``per CMS guidance'' to allow CMS to take into account situations where there is no bill (no claim for payment) in an MA organization's system. For example, CMS allows submission of chart review records (also submitted to CMS in the X12 837 5010 format) only for the purpose of submitting, correcting, and ***deleting*** diagnoses from encounter data records for the purposes of risk adjustment payment, based on medical record reviews (chart reviews). Thus, chart review records and encounters that are capitated (when there is no bill) would have different guidance for populating the Billing Provider NPI field than encounters for which a bill was received and adjudicated by the MA organization. (5) Appeals     We propose to add a provision to Sec.  422.222(a) that would permit individuals or entities that are on the preclusion list to appeal their inclusion on this list in accordance with 42 CFR part 498. Given the aforementioned payment denial that would ensue with the individual's or entity's inclusion on the preclusion list, due process warrants that the individual or entity have the ability to appeal this initial determination. Any appeal under this proposed provision, however, would be limited strictly to the individual's or entity's inclusion on the preclusion list. It would neither include nor affect appeals of payment denials or enrollment revocations, for there are separate appeals processes for these actions. Individuals and entities that file an appeal pursuant to Sec.  422.222(a) would be able to avail themselves of any other appeals processes permitted by law.     CMS would send written notice to the individual or entity of their inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the individual or entity of their appeal rights.

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    We also propose to update the following regulatory provisions regarding appeals. Note that these provisions would include references to preclusion list inclusions under Sec.  422.222 (MA) and, as previously mentioned, Sec.  423.120(c)(6).      We propose to revise Sec.  498.3(b) to add a new paragraph (20) stating that a CMS determination that an individual or entity is to be included on the preclusion list constitutes an initial determination. This change would help enable individuals and entities to utilize the appeals processes described in Sec.  498.5:      In Sec.  498.5, we propose to add a new paragraph (n) that would state as follows:     ++ In paragraph (n)(1), we propose that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with Sec.  [thinsp]498.22(a).     ++ In paragraph (n)(2), we propose that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under Sec.  498.5(n)(1), or a revised reconsidered determination under Sec.  498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.     ++ In paragraph (n)(3), we propose that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the Departmental Appeals Board (DAB) and the individual or entity may seek judicial review of the DAB's decision.     These revisions are designed to include preclusion list determinations within the scope of appeal rights described in Sec.   498.5 However, we solicit comment on whether a different appeals process is warranted and, if so, what its components should be.     In addition, given that a beneficiary's access to health care items or services may be impaired because of the application of the preclusion list to his or her item or service, we believe the beneficiary should be permitted to appeal alleged errors in applying the preclusion list. We solicit comment whether additional beneficiary protections, such as notices to enrollees when an individual or entity that has recently furnished services or items to the enrollee is placed on the preclusion list or a limited and temporary coverage approval when an individual or entity is first placed on the preclusion list but is in the middle of a course of previously covered treatment, should also be included these rules upon finalization. (6) Technical Changes     The title of Sec.  422.222 reads: ``Enrollment of MA organization network providers and suppliers; first-tier, downstream, and related entities (FDRs); cost HMO or CMP, and demonstration and pilot programs.'' We propose to change this to simply state ``Preclusion list'' so as to accord with our previously mentioned proposed changes. For this same reason, we propose to:     ++ Change the title of Sec.  422.224 from ``Payment to providers or suppliers excluded or revoked'' to ``Payment to individuals and entities excluded by the OIG or included on the preclusion list.''     ++ Change the title of Sec.  460.86 from ``Payment to providers or suppliers excluded or revoked'' to ``Payment to individuals or entities excluded by the OIG or included on the preclusion list.'' c. Specific Regulatory Changes     Given the foregoing discussion, we propose the following regulatory changes:      In Sec.  417.478, we propose to revise paragraph (e) as follows:     ++ In new paragraph (e)(1), we propose to state that the prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list (defined in Sec.  422.2 of this chapter) apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.     ++ In new paragraph (e)(2), we propose to state that in applying the provisions of Sec. Sec.  422.2, 422.222, and 422.224 under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.      In Sec.  417.484, we propose to revise paragraph (b)(3) to state: ``That payments must not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''      In Sec.  422.2, we propose to add a definition of ``preclusion list'' that reads as follows:     ++ Preclusion list means a CMS compiled list of individuals and entities that:     (1) Meet all of the following requirements:     (i) The individual or entity is currently revoked from Medicare under Sec.  424.535     (ii) The individual or entity is currently under a reenrollment bar under Sec.  424.535(c).     (iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS would consider the following factors:     (A) The seriousness of the conduct underlying the individual's or entity's revocation.     (B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program.     (C) Any other evidence that CMS deems relevant to its determination; or     (2) Meet both of the following requirements:     (i) The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.     (ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:     (i) The seriousness of the conduct involved.     (ii) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and     (iii) Any other evidence that CMS deems relevant to its determination      We propose to ***delete*** Sec.  422.204(b)(5).      We propose to establish a new Sec.  422.204(c) that would require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in Sec.  422.222      We propose to ***delete*** the existing version of Sec.   422.222(a) and replace it with the following:     ++ In Sec.  422.222, we propose to change the title thereof to ``Preclusion list''.     ++ In paragraph (a)(1), we propose to state that an MA organization shall not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in Sec.  422.2     ++ In paragraph (a)(2), we propose to replace the existing language therein with a provision stating that CMS would send written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in Sec.  422.2, in accordance with Part 498.     ++ In paragraph (b), we propose to state that an MA organization that does

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not comply with paragraph (a) of Sec.  422.222 may be subject to sanctions under Sec.  422.750 and termination under Sec.  422.510      In Sec.  422.224, we propose to:     ++ Change the title thereof to ``Payment to individuals and entities excluded by the OIG or included on the preclusion list.''     ++ Revise paragraph (a) to state: ``An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in Sec.  422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in Sec.  422.2''.     ++ Revise paragraph (b) to state: ``If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in Sec.  422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''      We propose to revise Sec.  422.310 to add a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance.      In Sec.  422.501(c), we propose to:     ++ Revise paragraph (c)(1)(iv) to read: ``Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''     ++ Revise paragraph (c)(2) to replace the language beginning with ``including providing documentation . . .'' with ``including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''      In section 422.504, we propose to:     ++ Replace the language in paragraph (a)(6) that reads ``Medicare provider and supplier enrollment requirements'' with ``the preclusion list requirements in Sec.  422.222 and Sec.  422.224 ''     ++ Revise paragraph (i)(2)(v) to read, ``they will ensure that payments are not made to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''      In Sec.  422.510(a)(4), we propose to revise paragraph (xiii) to read: ``Fails to meet the preclusion list requirements in accordance with Sec. Sec.  422.222 and 422.224 ''      In Sec.  422.752, we propose to revise paragraph (a)(13) to read: ``Fails to comply with Sec. Sec.  422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities included on the preclusion list, defined in Sec.  422.2 ''      In Sec.  460.40, we propose to revise paragraph (j) to state: ``Makes payment to any individual or entity that is included on the preclusion list, defined in Sec.  422.2 of this chapter.''      In Sec.  460.50, we propose to revise paragraph (b)(1)(ii) by changing the current language following ``including'' to read ``making payment to an individual or entity that is included on the preclusion list, defined in Sec.  422.2 of this chapter.'' ''      We propose to ***delete*** Sec.  460.68(a)(4).      We propose to ***delete*** Sec.  460.70(b)(1)(iv).      We propose to ***delete*** Sec.  460.71(b)(7).      In Sec.  460.86, we propose to revise paragraphs (a) and (b) to state as follows:     ++ Paragraph (a) would state: ``A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in Sec.  460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in Sec.  422.2 of this chapter.''     ++ Paragraph (b) would state: ``If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in Sec.  422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''     ++ We also propose to change the title of Sec.  460.86 to ``Payment to individuals and entities that are excluded by the OIG or are included on the preclusion list.''      In Sec.  498.3(b), we propose to add a new paragraph (20) stating that a CMS determination that an individual or entity is to be included on the preclusion list constitutes an initial determination.      In Sec.  498.5, we propose to add a new paragraph (n) that would state as follows:     ++ In paragraph (n)(1), we propose that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with Sec.  [thinsp]498.22(a).     + In paragraph (n)(2), we propose that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under (n)(1), or a revised reconsidered determination under Sec.  498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.     ++ In paragraph (n)(3), we propose that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the DAB and the individual or entity may seek judicial review of the DAB's decision. 12. Removal of Quality Improvement Project for Medicare Advantage Organizations (Sec.  422.152)     Section 1852(e) of the Act requires that Medicare Advantage (MA) organizations have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to enrollees in the organization's MA plans. The statute requires that the MA organization include a Chronic Care Improvement Program (CCIP) as part of the overall QI Program     Our regulations at Sec.  422.152 outline the QI Program requirements for MA organizations, which include the development and implementation of both Quality Improvement Projects (QIPs), at paragraphs (a)(3) and (d), and a CCIP, at paragraphs (a)(2) and (c). Both provisions require that the MA organization's QIP and CCIP address areas or populations identified by CMS.     The January 2005 final rule (70 FR 4587) addressed the QI provisions added to section 1852(e) of the Act by the Medicare Modernization Act of 2003 (MMA). In the final rule, we specified in Sec.  422.152 that MA organizations must have ongoing QI Programs, which include chronic care programs. In addition, CMS provided MA organizations the flexibility to shape their QI efforts to the needs of their enrollees.

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    In the April 2010 final rule (75 FR 19677), CMS indicated concern that MA organizations were choosing QIPs and CCIPs that did not address QI areas that best reflected enrollee needs. Additionally, there were concerns that some projects focused more on improving processes rather than improving clinical outcomes. Therefore, we modified the regulation to provide for CMS to identify focus areas for QIPs and population areas for CCIPs. MA organizations retained the flexibility to identify topics for development of QIPs and CCIPs based on the needs of their population, but also had to implement QIPs and CCIPs as directed by CMS, which could identify general areas of focus that supported CMS quality strategies and initiatives.     During this time, CMS was also concerned that MA organizations were employing inconsistent methods in developing criteria for QIPs and CCIPs. As a result, CMS further modified the regulation to require MA organizations to report progress in a manner identified by CMS. This allowed CMS to review results and extrapolate lessons learned and best practices consistently across the MA program.     After making these regulation modifications, CMS issued a number sub-regulatory QIP and CCIP guidance documents to ensure that MA organizations measured progress in a consistent and meaningful way. For example, the new Plan-Do-Study-Act QI model required MA organizations to place some structure and parameters around their QIPs and CCIPs, ultimately leading to more consistency.     Over time, CMS found its implementation of the QIP and CCIP requirements had become burdensome and complex, rather than streamlining and conforming MA organizations' implementation of QIPs and CCIPs. For example, the complex sub-regulatory guidance led to a wide range of MA organization interpretations, resulting in extraneous, irrelevant, voluminous, and redundant information being reported to CMS. We gained little value from this information. As a result, we scaled down our sub-regulatory guidance in order to gain more concise and useful information with which to evaluate the outcomes and show any sort of attribution. However, we also found that the complex guidance did not necessarily produce better outcomes in the review of annual updates.     Continued evaluation through annual review of plan reported updates of the QIPs and CCIPs has led CMS to believe that the QIPs in particular do not add significant value. Through annual review of plan- reported updates, CMS has found that a number of QIPs implemented are duplicative of activities MA organizations are already doing to meet other plan needs and requirements, such as the CCIP and internal organizational focus on STAR Rating metrics. For example, we designated ``Reducing All-Cause Hospital Readmissions'' as the 2012 QIP topic. The QIPs for this topic often duplicated other CMS and MA organization care coordination initiatives aimed to improve transition of care across health care settings and reduce hospital readmissions. We found that many plans were already engaged in activities to reduce hospital readmissions because they are annually scored on their performance in this area (and many other areas) through Healthcare Effectiveness Data and Information Set (HEDIS). HEDIS are a set of plan performance and quality measures. Each year, MA organizations are required to report HEDIS data and are evaluated annually based on these measures. High performance on these measures also plays a large role in achieving high Star Ratings, which has beneficial payment consequences for MA organizations. This suggests that CMS direction and detailed regulation of QIPs is unnecessary as the Star Ratings program use of HEDIS measures (and other measures) incentivizes MA organizations sufficiently to focus on desired improvements and outcomes.     Therefore, we believe the removal of the QIP and the continued CMS direction of populations for required CCIPs would allow MA organizations to focus on one project that supports improving the management of chronic conditions, a CMS priority, while reducing the duplication of other QI initiatives. We propose to ***delete*** Sec. Sec.   422.152(a)(3) and 422.152(d), which outline the QIP requirements. In addition, in order to ensure that remaining cross references for other provisions in this section remain accurate, we will reserve paragraphs (a)(3) and (d). The removal of these requirements would reduce burden on both MA organizations and CMS.     Even with this proposed removal of the QIP requirements, the MA requirements for QI Programs would remain in place and be robust and sufficient to ensure that the requirements of section 1852(e) of the Act are met. As a part of the QI Program, each MA organization would still be required to develop and maintain a health information system; encourage providers to participate in CMS and HHS QI initiatives; implement a program review process for formal evaluation of the impact and effectiveness of the QI Program at least annually; correct all problems that come to its attention through internal, surveillance, complaints, or other mechanisms; contract with an approved Medicare Consumer Assessment of Health Providers and Systems (CAHPS[supreg]) survey vendor to conduct the Medicare CAHPS[supreg] satisfaction survey of Medicare plan enrollees; measure performance under the plan using standard measures required by CMS and report its performance to CMS; develop, compile, evaluate, and report certain measures and other information to CMS, its enrollees, and the general public; and develop and implement a CCIP. Further, CMS emphasizes here that MA organizations must have QI Programs that go beyond only performance of CCIPs that focus on populations identified by CMS. The CCIP is only one component of the QI Program, which has the purpose of improving care and provides for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality under section 1852(e) of the Act.     We believe this proposed change will allow MA organizations to maintain existing health improvement initiatives and take steps to reduce the risk of redundancies or duplication. The remaining elements of the QI Program, including the CCIP, will still maintain the intended purpose of the QI Program: That plans have the necessary infrastructure to coordinate care and promote quality, performance, and efficiency on an ongoing basis.     This proposal does not eliminate the CCIP requirements that MA organizations address populations identified by CMS and report project status to CMS as requested. Per the April 2010 rule (75 FR 19677), we still believe that these requirements are necessary to ensure that MA organizations are developing projects that positively impact populations identified by CMS and that progress is documented and reported in a way that is consistent with our requirements.     In conclusion, we are proposing to amend Sec.  422.152 by:      ***Deleting*** and reserving paragraphs (a)(3) and (d).     We solicit comments on this proposal, including whether additional revision to Sec.  422.152 is necessary to eliminate redundancies CMS has identified in this preamble. 13. Reducing Provider Burden--Comment Solicitation     Health care providers are key partners in the delivery of Medicare benefits, and we are exploring ways to reduce burden

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on providers (meaning institutions, physicians, and other practitioners) arising from requests for medical record documentation by MA organizations, particularly in connection with MA program requirements. We are interested in stakeholder feedback on the nature and extent of this burden of producing medical record documentation and on ideas to address the burden. We are particularly interested in burden experienced by solo providers. Please note that this is a solicitation for comment only and does not commit CMS to adopt any ideas submitted nor to making any changes to CMS audits or activities, including risk adjustment data validation (RADV) processes.     By law, CMS is required to adjust payments to MA organizations for their enrollees' risk factors, such as age, disability status, gender, institutional status, and health status. To this end, MA organizations are required in regulation (Sec.  422.310) to submit risk adjustment data to CMS--including diagnosis codes--to characterize the context and purposes of items and services provided to MA organization plan enrollees. Risk adjustment data refers to data submitted in two formats: Comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data) and data in abbreviated formats (often referred to as RAPS data). Under Sec.   422.310, risk adjustment data that is submitted must be documented in the medical record and MA organizations will be required to submit medical records to validate the risk adjustment data. Finally, at Sec.   422.310(d)(4), MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.     To address concerns from providers about burdensome requests from MA organizations for their patients' medical record documentation, we are soliciting comment from stakeholders to more fully understand the issue and for ideas to accomplish reductions in provider burden. Specifically, we seek comment on the following:      The nature and extent of medical record requests, including the following:     ++ Reasoning behind the request sent by the MA organization to the provider.     ++ Amount of time afforded to providers to respond to such requests.     ++ Frequency of requests for providers to submit medical records.     ++ Volume of medical records in a given request.     ++ Method of collection and submission of medical records.     ++ How narrowly or broadly the requests are framed (for example, whether the request is for a single visit, a specific condition, and for what timeframe).     ++ Extent to which requests are made pursuant to a CMS-conducted RADV audit, other CMS activities, or for other purposes (please specify what the other purposes are).     ++ Considerations that may be unique to solo providers.     ++ Impact on burden due to increased adoption of electronic health record systems.     ++ Specific examples of medical record requests (for example, anecdotes and/or the requests themselves, appropriately redacted of confidential information and PII/PHI).      The nature and extent of requests related to medical record attestations, including the following:     ++ Reasoning behind the attestation request.     ++ Amount of time afforded to providers to respond to such requests.     ++ Frequency of requests for providers to sign attestations.     ++ Volume of requests.     ++ Level and duration for which attestations are requested (for example, for each medical record, for all medical records for a beneficiary for a particular date of service or for a particular year).     ++ Whether there is reduced burden associated with electronic signatures.     ++ Specific examples of medical record attestations and attestation requests.      Ideas for improving the process around MA organizations requesting medical records and/or attestations that are not directly pursuant to CMS-conducted RADV audits. Specify the type of change the idea would necessitate: a statutory, regulatory, subregulatory, operational, or CMS-issued guidance such as best practices for MA organizations when requesting medical records and/or attestations, and how such a change may interact with other provisions, such as state law or Joint Commission requirements. If the ideas involve novel legal questions, analysis regarding our authority is welcome for our consideration. For each idea, describe the extent of provider burden reduction, quantitatively where possible, and any other consequences that implementing the idea may have on beneficiaries, providers, MA organizations, or CMS. Further, we encourage all relevant parties to respond to this request: MA organizations, providers, associations for these entities, and companies assisting MA organizations, providers, and hospitals with handling medical record requests.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements a. Background     Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111-152) amends section 1857(e) of the Act to add medical loss ratio (MLR) requirements to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D-12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 23, 2013 Federal Register (78 FR 31284), we published a final rule that codified the MLR requirements for Part C MA organizations, and Part D sponsors (including organizations offering cost plans that provide the Part D benefit) in the regulations at 42 CFR part 422, subpart X and part 423, subpart X.     For contract year 2014 and subsequent contract years, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (see Sec. Sec.  422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement in section 1857(e)(4) of the Act creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.     Section 1001(5) of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 10101(f) of the Health Care Reconciliation Act, also established a new MLR requirement under section 2718 of the Public Health Service Act (PHSA) that applies to issuers of employer group and individual market

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private insurance. We will refer to the MLR requirements that apply to issuers of private insurance as the ``commercial MLR rules.'' Regulations implementing the commercial MLR rules are published at 45 CFR part 158.     This proposed rule sets forth our proposed modifications to certain MLR requirements in the Medicare Part C and Part D programs. b. Proposed Regulatory Changes to the Calculation of the Medical Loss Ratio (Sec. Sec.  422.2420, 422.2430, 423.2420, and 423.2430) (1) Fraud Reduction Activities     As explained in the February 22, 2013 proposed rule (78 FR 12428), we used the commercial MLR rules as a reference point for developing the Medicare MLR rules. We sought to align the commercial and Medicare MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. Although we believe it is important to maintain consistency between the commercial and Medicare MLR requirements, we also recognized that some areas of the commercial MLR rules would need to be revised to fit the unique characteristics of the MA and Part D programs.     One area of alignment between the commercial and Medicare MLR rules is the treatment of expenditures related to fraud reduction efforts, which we defined to include both fraud prevention and fraud recovery in both rules (see 78 FR 12433). The Medicare MLR regulations adopted the same definitions of activities that improve healthcare quality (also referred to as quality improvement activities, or QIA), as had been adopted in the commercial MLR regulations at 45 CFR 158.150 and 158.151, in order to facilitate uniform accounting for the costs of these activities across lines of business (see 78 FR 12435). Consistent with this policy of alignment, the Medicare MLR regulations at Sec. Sec.  422.2430(b)(8) and 423.2430(b)(8) adopted the commercial MLR rules' exclusion of fraud prevention activities from QIA. The Medicare MLR regulations (Sec. Sec.  422.2420(b)(2)(ix) and 423.2420(b)(2)(viii)) further aligned with the commercial MLR rules' treatment of fraud-related expenditures by allowing the amount of claim payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, to be included in the MLR numerator as an adjustment to incurred claims. The Medicare MLR proposed rule (78 FR 12433) explained that we considered this approach to be appropriate because without such an adjustment, the recovery of paid fraudulent claims would reduce an MLR and could create a disincentive to engage in fraud reduction efforts. Allowing an adjustment to incurred claims to reflect claims payments recoveries up to the limit of fraud reduction expenses would help mitigate whatever disincentive might occur if fraud reduction expenses were treated solely as nonclaims and nonquality improving expenses. The Medicare MLR proposed rule echoed the December 7, 2011 commercial MLR final rule with comment period (76 FR 76577), where we had earlier expressed the view that allowing an unlimited adjustment for fraud reduction expenses would undermine the purpose of requiring issuers to meet the MLR standard.     We have reconsidered this position based on the specific characteristics of the MA and Part D programs, and are now proposing certain changes to the treatment of expenses for fraud reduction activities in the Medicare MLR calculation. First, we are proposing to revise the MA and Part D regulations by removing the current exclusion of fraud prevention activities from QIA at Sec. Sec.  422.2430(b)(8) and 423.2430(b)(8). Second, we are proposing to expand the definition of QIA in Sec. Sec.  422.2430 and 423.2430 to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. Third, we are proposing to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses, in Sec. Sec.  422.2420(b)(2)(ix) and 423.2420(b)(2)(viii). We note that the commercial MLR rules and the Medicaid MLR rules are outside the scope of this proposed rule.     We are proposing these changes to the Medicare MLR rules because we believe that limiting or excluding amounts invested in fraud reduction undermines the federal government's efforts to combat fraud in the Medicare program, and reduces the potential savings to the government, taxpayers, and beneficiaries that robust fraud prevention efforts in the MA and Part D programs can provide. Fraud prevention activities can improve patient safety, deter the use of medically unnecessary services, and can lead to higher levels of health care quality, which is part of the reason why we require such activities as a condition of participation in the MA and Part D programs.     MA organizations and Part D sponsors are required at Sec. Sec.   422.503(b)(4)(vi) and 423.504(b)(4)(vi), respectively, to adopt an effective compliance program which includes measures that prevent, detect, and correct fraud. We believe that the proposed change to include all expenditures in connection with fraud reduction activities as QIA-related expenditures in the MLR numerator best aligns with this Medicare contracting requirement. We are concerned that the current rules could create a disincentive to invest in fraud reduction activities, which is only partly mitigated by the current adjustment to incurred claims for amounts recovered as a result of fraud reduction activities, up to the amount of fraud reduction expenses. We believe that it is particularly important that MA organizations and Part D sponsors invest in fraud reduction activities as the Medicare trust funds are used to finance the MA and Part D programs. We believe that including the full amount of expenses for fraud reduction activities as QIA will provide additional incentive to encourage MA organizations and Part D sponsors to develop innovative and more effective ways to detect and deter fraud.     We continue to believe that the minimum MLR requirement in section 1857(e)(4) of the Act is intended to create an incentive to reduce administrative costs, marketing, profits, and other such uses of the funds that plan sponsors receive, and to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. However, we also believe that MA organizations' and Part D sponsors' fraud reduction activities can potentially provide significant value to the government and taxpayers by reducing trust fund expenditures. When MA organizations and Part D sponsors prevent fraud and recover amounts paid for fraudulent claims, this lowers the overall cost of providing coverage to MA and Part D enrollees. Because MA organizations' and Part D sponsors' monthly payments are based in part on their claims experience in prior years, if MA organizations and Part D sponsors pay fewer fraudulent claims, this should be reflected in their subsequent cost projections, which would ultimately result in lower payments to MA organizations and Part D sponsors out of the Medicare trust funds, and could also result in lower premiums or additional supplemental benefits for beneficiaries.     Given the proposed change to include expenditures for fraud reduction activities in the QIA portion of the MLR numerator, we no longer believe that it

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would be necessary or appropriate to include in incurred claims the amount of claim payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses. As noted previously, we originally included an adjustment to incurred claims for claims payments recovered through fraud reduction efforts based on the rationale that, because the recovery of paid fraudulent claims reduces the amount of incurred claims in the MLR numerator, if expenditures for fraud reduction efforts were treated solely as nonclaims and nonquality improvement activities, this could create a disincentive to engage in fraud reduction activities. The adjustments to incurred claims under current Sec. Sec.  422.2420(b)(2)(ix) and 423.2420(b)(2)(viii) mitigate the potential disincentive to invest in fraud reduction activities insofar as MA organizations' and Part D sponsors' recoveries of paid fraudulent claims do not result in a reduction to incurred claims. Because this adjustment to incurred claims is only available to the extent that an MA organization or Part D sponsor recovers paid fraudulent claims, it encourages MA organizations and Part D sponsors to invest in tracking down and recouping amounts that have already been paid, rather than in preventing payment of fraudulent claims. Under our proposal, claim payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses, would no longer be included in the MLR numerator as an adjustment to incurred claims. Instead, all expenditures for fraud reduction activities would be included in the MLR numerator as QIA, even if such expenditures exceed the amount recovered through fraud reduction efforts. As a result, MA organizations and Part D sponsors will no longer have an incentive to use contract revenue to pursue recovery of paid fraudulent claims instead of investing in fraud prevention. We believe that effective fraud reduction strategies will include efforts to prevent payment of fraudulent claims, and we believe that the proposed inclusion of all fraud reduction activities as QIA in the MLR numerator will strengthen the incentive to engage in these vital activities.     In summary, we are proposing the following regulatory revisions:      Remove and reserve Sec. Sec.  422.2420(b)(2)(ix) and 423.2420(b)(2)(viii).      In Sec. Sec.  422.2430 and 423.2430, redesignate existing paragraphs (a)(1) and (a)(2) as (a)(2) and (a)(3), respectively.      In Sec. Sec.  422.2430 and 423.2430, add new paragraph (a)(4) that lists activities that are automatically included in QIA.      Designate the introductory text of Sec. Sec.  422.2430(a) and 423.2430(a) as paragraph (a)(1), and revise newly designated paragraph (a)(1) to specify that, for an activity to be included in QIA, it must either fall into one of the categories listed in newly redesignated (a)(2) and meet all of the requirements in newly redesignated (a)(3), or be listed in paragraph (a)(4).      Remove and reserve Sec. Sec.  422.2430(b)(8) and 423.2430(b)(8).     We solicit comment on these proposed changes, particularly whether our proposal is based on the best understanding of the motives and incentives applicable to MA organizations and Part D sponsors to engage in fraud reduction activities. We also solicit comment on the types of activities that should be included in, or excluded from, fraud reduction activities. In addition, we solicit comment on alternative approaches to accounting for fraud reduction activities in the MLR calculation. In particular, we are interested in receiving input on:      Whether fraud reduction activities should be included in quality improvement activities as proposed, or whether we should create a separate MLR numerator category for fraud reduction activities;      Whether fraud reduction activities should be subject to any or all of the exclusions at Sec. Sec.  422.2430(b) and 422.2430(b). Although our proposal removes the exclusion of fraud prevention activities from QIA at Sec. Sec.  422.2430(b)(8) and 423.2430(b)(8), it is possible that fraud reduction activities would be subject to one of the other exclusions under Sec. Sec.  422.2430(b) and 423.2430(b), such as the exclusion that applies to activities that are designed primarily to control or contain costs (Sec. Sec.  422.2430(b)(1) and 423.2430(b)(1)) or the exclusion of activities that were paid for with grant money or other funding separate from premium revenue (Sec. Sec.   422.2430(b)(1) and 423.2430(b)(3).) (2) Medication Therapy Management (MTM) (Sec. Sec.  422.2430 and 423.2430)     In the May 23, 2013 final rule (78 FR 31294), we stated that Medication Therapy Management (MTM) activities (defined at Sec.   423.153(d)) qualify as QIA, provided they meet the requirements set forth in Sec. Sec.  422.2430 and 423.2430 To meet these requirements, the activity must fall into one of the categories listed in current paragraph (a)(1) of those regulations, which means the activity must: (1) Improve health quality; (2) increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results; (3) be directed toward individual enrollees, specific groups of enrollees, or other populations as long as enrollees do not incur additional costs for population-based activities; and (4) be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. In our prior MLR rulemaking, we did not attempt to determine whether all MTM programs that comply with Sec.  423.153(d) would necessarily meet the QIA requirements at Sec.  422.2430 (for MA- PD contracts) and Sec.  423.2430 (for stand-alone Part D contracts). Subsequent to publication of the May 23, 2013 final rule, we have received numerous inquiries seeking clarification regarding whether MTM programs are QIA. To address those questions and resolve any ambiguities or uncertainties, we are now proposing to specifically address MTM programs in the MLR regulations.     We propose to modify our regulations at Sec. Sec.  422.2430 and 423.2430 by adding new paragraph (a)(4)(i), which specifies that all MTM programs that comply with Sec.  423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans (described in Sec.  422.2420(a)(2)) are QIA. Each Part D sponsor is required to incorporate an MTM program into its plans' benefit structure, and the MTM Program Completion Rate for Comprehensive Medication Reviews (CMR) measure has been included in the Star Ratings as a metric of plan quality since 2016. We believe that the MTM programs that we require improve quality and care coordination for Medicare beneficiaries. We also believe that allowing Part D sponsors to include compliant MTM programs as QIA in the calculation of the Medicare MLR would encourage sponsors to ensure that MTM is better utilized, particularly among standalone PDPs that may currently lack strong incentives to promote MTM.     Furthermore, we have expressed concern that Part D sponsors may be restricting MTM eligibility criteria to limit the number of qualified enrollees, and we believe that explicitly including MTM program expenditures in the MLR numerator as QIA-related expenditures could provide an incentive to reduce any such restrictions. This is particularly important in providing individualized disease management in conjunction with the ongoing opioid

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crisis evolving within the Medicare population. We hope that, by removing any restrictions or uncertainty about whether compliant MTM programs will qualify for inclusion in the MLR numerator as QIA, the proposed changes will encourage Part D sponsors to strengthen their MTM programs by implementing innovative strategies for this potentially vulnerable population. We believe that beneficiaries with higher rates of medication adherence have better health outcomes, and that medication adherence can also produce medical spending offsets, which could lead to government and taxpayer savings in the trust fund, as well as beneficiary savings in the form of reduced premiums. We solicit comment on these proposed changes. (3) Additional Technical Changes to Calculation of the Medical Loss Ratio (Sec. Sec.  422.2420 and 423.2420)     We are also proposing technical changes to the MLR provisions at Sec. Sec.  422.2420 and 423.2420 In Sec.  422.2420(d)(2)(i), we are replacing the phrase ``in Sec.  422.2420(b) or (c)'' with the phrase ``in paragraph (b) or (c) of this section''. In Sec.  423.2430, the regulatory text includes two paragraphs designated as (d)(2)(ii). We propose to resolve this error by amending Sec.  423.2420 as follows:      Revise paragraph (d)(2)(i) by adding at the end the text of the first paragraph designated as (d)(2)(ii).      Remove the first paragraph designated as (d)(2)(ii). c. Proposed Regulatory Changes to Medicare MLR Reporting Requirements (Sec. Sec.  422.2460 and 423.2460)     Our general approach when developing the current Medicare MLR regulations was to align the Medicare MLR requirements with the commercial MLR requirements. Consistent with this policy, we attempted to model the Medicare MLR reporting format on the tools used to report commercial MLR data in order to limit the burden on organizations that participate in both markets. However, as noted previously, we also recognized that there are some areas where the unique characteristics of the MA and Part D programs make it appropriate for the Medicare MLR reporting requirements to deviate from the rules that apply to commercial MLR reporting. Most beneficiaries are enrolled in plans offered by MA organizations and Part D sponsors that also participate in the commercial market, and these entities are familiar with the commercial MLR forms that they have had to submit since 2012 for the 2011 benefit year. In practice, however, these forms and reports have not been identical. We have become concerned, after having received two annual Medicare MLR reports at the time that this proposed rule is being published, that requiring health insurance issuers to complete a substantially different set of forms for Medicare MLR purposes has created an unnecessary additional burden. Our proposal to reduce the burden of the current Medicare requirement for MLR reporting aligns with the directive in the January 30, 2017 Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.     It is with these concerns in mind that we are proposing to reduce the current reporting burden to require the minimum amount of information needed for MLR reporting by organizations with contracts to offer Medicare benefits. Specifically, we are proposing that the Medicare MLR reporting requirements would be limited to the following data fields, as shown in Table 12: Organization name, contract number, adjusted MLR (which would be populated as ``Not Applicable'' or ``N/A'' for non-credible contracts as determined in accordance with Sec. Sec.   422.2440(d) and 423.2440(d)), and remittance amount. We solicit comment on these proposed changes.

           Table 12--MLR Reporting for Fully Credible, Partially Credible, and Non-Credible Contracts ----------------------------------------------------------------------------------------------------------------                                                                                    Adjusted MLR     Remittance                           Organization                             Contract No.         (%)           amount ---------------------------------------------------------------------------------------------------------------- ABC, Inc........................................................           H1234            90.1              $0 XYZ, LLC........................................................           S4321            84.8          17,420 MAO1, LLC.......................................................           H4321             N/A             N/A ----------------------------------------------------------------------------------------------------------------

    We believe that it is important to note that although we are proposing a significant reduction in the amount of data that MA organizations and Part D sponsors must report to us, we are not proposing to change our authority under Sec.  422.2480 or Sec.   423.2480 to conduct selected audit reviews of the data reported under Sec. Sec.  422.2460 and 423.2460 to determine that remittance amounts under Sec. Sec.  422.2410(b) and 423.2410(b) and sanctions under Sec. Sec.  422.2410(c), 422.2410(d), 423.2410(c), and 423.2410(d) were accurately calculated, reported, and applied. Moreover, MA organizations and Part D sponsors would continue to be required to retain documentation supporting the MLR figure reported and to make available to CMS, HHS, the Comptroller General, or their designees any information needed to determine whether the data and amounts submitted with respect to the Medicare MLR are accurate and valid, in accordance with Sec. Sec.  422.504 and 423.505     In addition, we have realized that the MLR Reporting Requirements at Sec.  422.2460 do not include provisions that correspond to the provisions currently codified at Sec.  423.2460(b) and (c). In the February 22, 2013 proposed rule (78 FR 12435), we proposed that the total revenue reported by MA organizations and Part D sponsors for MLR purposes would be net of all projected reconciliations, and that each MA and Part D contract's MLR would only be reported once and would not be reopened as a result of any payment reconciliation processes. In the May 23, 2013 final rule (78 FR 31293), we finalized these proposals without change. Although we explicitly proposed that both MA organizations and Part D sponsors would be required to report their revenues net of all projected reconciliations (78 FR 12435), and we did not indicate that only Part D sponsors would be affected by our proposal for each contract's MLR to be reported once and not reopened as a result of any payment reconciliation process (our discussion of this proposal in the final rule addressed how this policy would apply to both MA organizations and Part D sponsors (78 FR 31293)), regulatory provisions implementing the finalized proposals were only included in the Part D regulations, where they currently appear at Sec.   423.2460(b) and (c); corresponding regulatory text was not added to the MA regulations. We are proposing to make a technical change to Sec.   422.2460 by

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incorporating provisions which parallel the language of current paragraphs (b) and (c) of Sec.  423.2460 for purposes of the reporting requirements for contract year 2014 and subsequent contract years. This proposed technical change does not establish any new rules or requirements for MA organizations; it merely updates regulatory references that were overlooked in previous rulemaking.     In summary, we are proposing to revise the regulations at Sec. Sec.  422.2460 and 423.2460 as follows:      In Sec.  422.2460, redesignate the existing regulation text as paragraph (a).      Revise newly designated Sec. Sec.  422.2460(a) and 423.2460(a) by adding ``from 2014 through 2017'' after the phrase ``For each contract year'' in the first sentence to limit the more detailed MLR reporting requirement to that period, making minor grammatical changes to clarify the text, and by adding ``under this part'' to modify the phrase ``for each contract''.      In Sec.  423.2460, redesignate existing paragraphs (b) and (c) as paragraphs (c) and (d), respectively.      In Sec. Sec.  422.2460 and 423.2460, add a new paragraph (b) to require MA organizations and Part D plan sponsors with--     ++ Fully credible and partially credible experience to report the MLR for each contract for the contract year along with the amount of any owed remittance; and     ++ Non-credible experience, to report that such experience was non- credible.     For each, the proposed text cross-references the applicable regulations for the determination of credibility, and for the general remittance requirement.      In newly redesignated Sec.  423.2460(c), revise the text to refer to total revenue included in the MLR calculation rather than reports of that information.      Add new paragraphs (c) and (d) to Sec.  422.2460 that mirror the text in Sec.  423.2460(c) and (d), as redesignated and revised. d. Proposed Technical Changes to Medicare MLR Review and Non-Compliance and the Release of MLR Data (Sec. Sec.  422.2410, 422.2480, 422.2490, 423.2410, 423.2480, and 423.2490)     We are proposing technical changes to the General Requirements, MLR review and non-compliance, and Release of MLR data provisions at Sec. Sec.  422.2410, 422.2480, 422.2490, 423.2410, 423.2480, and 423.2490 These changes are being proposed in conformity with the more substantive regulatory text changes being proposed herein. These proposed technical changes do not establish any new rules or requirements for MA organizations or Part D sponsors. The proposed technical changes revise references to MLR reports in conformity with our proposal to scale back Medicare MLR reporting so that we only require the submission of a limited number of data points, as opposed to a full report. 2. Medicare Advantage Contract Provisions (Sec.  422.504)     Under the authority of section 1857(b) of the Act, CMS may enter into a contract with a Medicare Advantage (MA) organization, through which the organization agrees to comply with applicable requirements and standards. CMS has established and codified provisions of contracts between the MA organization and CMS at Sec.  422.504 This proposed rule seeks to correct an inconsistency in the text that identifies the contract provisions deemed material to the performance of an MA contract.     Section 422.504(a) sets forth regulations and instructions at paragraphs (1) through (15) that are material to the performance of the MA contract in accordance to Sec.  422.504(a)(16). This is inconsistent with the introductory regulatory text at Sec.  422.504(a), which provides, ``An MA organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract.'' Further, both paragraphs (a) and (a)(15) fail to mention paragraphs (a)(17) and (a)(18).     We propose to correct the inconsistent language by revising the language in the introductory text in Sec.  422.504(a) and ***deleting*** paragraph Sec.  422.504(a)(16). With this revision, We will renumber current paragraphs Sec. Sec.  422.504(a)(17) and (a)(18). The proposed revision to the paragraph (a) introductory text would provide that compliance with all contract terms listed in paragraph (a) is material. 3. Late Contract Non-Renewal Notifications (Sec. Sec.  422.506, 422.508, and 423.508)     Pursuant to section 1857(c)(1) of the Act, CMS enters into contracts with MA organizations for a period of 1 year. As implemented by CMS pursuant to that provision, these contracts automatically renew absent notification by either CMS or the MA organization to terminate the contract at the end of the year. Section 1860D-12(b)(3)(B) of the Act makes this same process applicable to CMS contracts with Part D plan sponsors. CMS has implemented these provisions in regulations that permit MA organizations and Part D plan sponsors to non-renew their contracts, with CMS approval and consent necessary depending on the timeframe of the sponsoring organization's notice to CMS that a non- renewal is desired. We are proposing to clarify its operational policy that any request to terminate a contract after the first Monday in June is considered a request for termination by mutual consent.     Under Sec.  422.506(a)(2)(i) and Sec.  423.507(a)(2)(i), contract non-renewals effective at the end of the 1-year contract term must be submitted to CMS in writing by the first Monday in June. There may be instances where CMS accepts a late non-renewal notice after the first Monday in June for an MA contract if the non-renewal is consistent with the effective and efficient administration of the contract under Sec.   422.506(a)(3). There is no corresponding regulatory provision affording CMS such discretion for Part D contracts.     We have seen that many MA organizations do not understand that CMS treats non-renewals requested after the first Monday in June as an organization's request for a mutual termination pursuant to Sec.   422.508 when determining whether it is in the best interest of the Medicare program to permit non-renewals in applying Sec.   422.506(a)(3). Organizations that request a non-renewal of their contract after the first Monday in June, must receive written confirmation from CMS of the termination by mutual consent pursuant to Sec.  422.508(a) (and Sec.  423.508(a) if an MA-PD plan) to be effectively relieved of their obligation to participate in the MA or Part D programs during the upcoming contract year. CMS has received a number of late non-renewal requests and has received questions from MA organizations inquiring why their request was not treated as a contract non-renewal, but rather as a termination by mutual consent.     We propose to modify Sec.  422.506(a)(3) to remove language that indicates late non-renewals may be permitted by CMS so that there would only be one process--mutual termination under Sec. Sec.  422.508--that is applicable if CMS is not taking action under Sec.  422.506(b) or Sec.  422.510 Also, we propose to amend Sec. Sec.  422.508 and 423.508 to clarify that organizations that request to non-renew a contract after the first Monday in June are in effect requesting that CMS agree to mutually terminate their contract. 4. Contract Request for a Hearing (Sec. Sec.  422.664(b) and 423.652(b))     Under the authority of section 1857(a) of the Act, CMS enters into contracts with MA organizations which authorize

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them to offer MA plans to Medicare beneficiaries. Similarly, CMS contracts with Part D plan sponsors according to section 1860D-12(a) of the Act. CMS determines that an organization is qualified to hold an MA contract through the application process established at 42 CFR 422, Subpart K. CMS evaluates the qualifications of potential Part D plan sponsors according to Subpart K of 42 CFR, part 423. If CMS denies an application, organizations have the right to appeal CMS's decision (under Sec.  422.502(c)(3)(iii) and Sec.  423.503(c)(3)(iii) using the procedures in subparts N of part 422 and part 423). This proposed rule seeks to correct an inconsistency in the text that identifies CMS's deadline for rendering its determination on appeals of application denials.     According to Sec.  422.660(c) and Sec.  423.650(c), CMS must issue a determination on appealed application denials by September 1 in order to enter into an MA contract for coverage starting January 1 of the following year. We codified this September 1 deadline in the April 15, 2010, final rule (45 FR 19699). As stated in the in the 2009 proposed rule (74 FR 54650 and 54651), we proposed to modify Sec.  422.660(c) and Sec.  423.660(c), which then specified that the notice of any decision favorable to a Part C or D applicant must be issued by July 15 for the contract in question to be effective on January 1 of the following year. However, in that rulemaking, we inadvertently overlooked other regulatory provisions that address the date by which a favorable decision must be made on an appeal of a CMS determination that an entity is not qualified for a Part C or Part D contract.     There is an inconsistency in regulations regarding the date by which an MA organization must receive a decision from CMS on an appeal. Section 422.660(c) specifies that a notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract to be effective on January 1. However, Sec.  422.664(b)(1) specifies that if a final decision is not reached by July 15, CMS will not enter into a contract with the applicant for the following year. Similarly, there is an inconsistency in regulations regarding the date by which a Part D sponsor must receive a CMS decision on an appeal. Section 423.650(c) specifies that a notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 to be effective on January 1. However, Sec.  423.652(b)(1) specifies that if a final decision is not reached on CMS's determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.     We propose to modify Sec.  422.664(b)(1) and Sec.  423.652(b)(1) to align with the September 1 date codified in Sec.  422.660(c) and Sec.   423.650(c), which was codified on April 15, 2010. 5. Physician Incentive Plans--Update Stop-Loss Protection Requirements (Sec.  422.208)     Pursuant to section 1852(j)(4), MA organizations that operate physician incentive plans must meet certain requirements, which CMS has implemented in Sec.  422.208 MA organizations must provide adequate and appropriate stop-loss insurance to all physicians or physician groups that are at substantial financial risk under the MA organization's physician incentive plan (PIP). The current stop-loss insurance deductible limits are identified in a table codified at Sec.   422.208(f)(2)(iii).     Under the current regulation, an MA organization that operates a PIP must provide stop-loss protection for 90 percenter of actual costs of referral services that exceed the per patient deductible limit to all physicians and physician groups at financial risk under the PIP. The stop-loss protection may be per patient or aggregate. The current regulation contains a chart that identifies per-patient stop-loss deductible limits for single combined; separate institutional; and separate professional insurance. The current regulation establishes requirements for stop-loss attachment points (deductibles) based on the patient panel size and does not distinguish between at-risk or non-at- risk patients in that panel. There is no requirement for an MA organization to provide stop-loss protection when the physician or physician group has a panel of risk patients of more than 25,000; we are not proposing to change to this requirement. In recent years, CMS has received a number of requests to update the stop-loss insurance limits associated with PIP arrangements to better account for medical costs and utilization changes that have occurred since the final rule was published in the June 29, 2000 Federal Register (65 FR 40325) on.     We are not proposing to change the requirements that the MAO (in connection with the PIP) must provide aggregate stop-loss protection for 90 percentage of actual costs of referral services that are greater than 25 percent of potential income to all physicians and physician groups at financial risk under the PIP and that no stop-loss protection is required when the panel size of the physician or physician group is above 25,000. We are proposing three changes to update the existing regulation:      Update the stop-loss deductible limits at Sec.   422.208(f)(2)(iii) and codify the methodology that CMS would use to update the stop-loss deductible limits in the future to account for changes in medical cost and utilization;      Authorize, at paragraph Sec.  422.208(f)(3), MA organizations to use actuarially equivalent arrangements to protect against substantial financial loss under the PIP due to the risks associated with serving particular groups of patients.      Modify paragraph 422.208(f)(2) to allow non-risk patient equivalents (NPEs), such as Medicare Fee-For-Service patients (FFS), who obtain some services from the physician or physician group to be included when determining the deductible.     We do not believe that other substantive requirements set forth in the PIP regulation, such as the determination of substantial financial risk based on a risk threshold of 25 percent of potential payments (see Sec.  422.208(d)(2)), need to be updated regularly or have been rendered obsolete in the years since the regulation was initially adopted. Although we are not proposing a change to the determination of ``substantial financial risk,'' we appreciate that the regulatory standard (25% of potential payments) in Sec.  422.208(d)(2) was adopted many years ago. Therefore, we seek comment on whether the definitions of ``substantial financial risk'' and ``risk threshold'' contained in the current regulation should be revisited, including whether the current identification of 25 percent of potential payments codified in paragraph (d)(2) remains appropriate as the standard in light of changes in medical cost. b. Update Deductible Limits and Codify Methodology     Because of increases in medical costs and changes in utilization since the current regulatory standards for PIP stop-loss insurance were adopted, we are concerned that the current regulation requires stop- loss insurance on more generous and more expensive terms than is necessary. Our goal in developing this proposal was to identify the point at which most, if not all, physicians and physician groups would be subject to the substantial loss so that the requirement for the provision of

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stop-loss protection and the parameters of that protection would be tailored to address that risk. We intend to avoid regulatory requirements that require protection that is broader than the minimum required under the statute. In developing the new minimum attachment points for the stop-loss protection that is required under the statute, one goal is to provide flexibility to MA organizations and the physicians and physician groups that participate in PIPs in selecting between combined stop-loss insurance and separate professional services and institutional services stop loss insurance.     In order to develop the specific attachment points, we engaged in a data-driven analysis using Part A and Part B claims data from 340,000 randomly selected beneficiaries from 2016. We assumed a multi-specialty practice and we estimated medical group income based on FFS claims, including payments for all Part A and Part B services. We used the central limit theorem to calculate the distribution of claim means for a multi-specialty group of any given panel size. This distribution was used to obtain, with 98% confidence, the point at which a multi- specialty group of a given panel size would, through referral services, lose more than 25% of its income derived from services that the physician or physician group personally rendered. We used projections of total income based on services provided personally by individual physicians and directly by physician groups because that is how we interpret ``potential payments'' as defined in the existing regulation. The point at which loss would exceed 25% of potential payments was set as the single combined per patient deductible in Table 13, which we describe in our proposed text at Sec.  422.208(f)(2)(iii); we are not proposing to codify the table, but to codify the methodology for creating it so that the table itself may be updated by CMS as necessary. Nonetheless, Table 13 would be the table applicable for contract years beginning on or after January 1, 2019 until CMS reapplied the methodology and published an updated table under our proposal. We performed the analysis for multiple panel sizes, which are listed on Table 13. Table 13 also includes a `net benefit premium' (NBP) column, which is used under our proposal to identify the attachment points for separate stop-loss insurance for institutional services and professional services. This NBP column is not needed for identification of the minimum attachment point (maximum deductible) for combined aggregate insurance. The NBP is computed by dividing the total amount of stop-loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

           Table 13--Combined Stop-Loss Insurance Deductibles ------------------------------------------------------------------------                                                            Net benefit           Panel size                Single combined      premium  (NBP)                                       deductible              PMPY ------------------------------------------------------------------------ 400...........................  $5,000................            $5,922 800...........................  10,000................             4,891 1400..........................  15,000................             4,122 2,000.........................  20,000................             3,514 3,300.........................  30,000................             2,612 4,600.........................  40,000................             1,984 5,800.........................  50,000................             1,539 6,900.........................  60,000................             1,216 7,900.........................  70,000................               977 10,100........................  100,000...............               553 12,300........................  150,000...............               267 13,500........................  200,000...............               159 14,800........................  300,000...............                79 16,100........................  500,000...............               428 16,800........................  1,000,000.............                12 17,400-25,000.................  2,000,000.............                 4 >25,000.......................  No Stop Loss..........                 0 ------------------------------------------------------------------------

    We propose, at paragraph Sec.  422.208 (f)(2)(iii), other significant provisions. Proposed paragraph Sec.  422.208 (f)(2)(iii)(A) provides that the table (published by CMS using the methodology proposed in paragraph Sec.  422.208(f)(2)(iv)) identifies the maximum attachment point/maximum deductible for per-patient-combined insurance coverage that must be provided for 90% of the costs above the deductible or an actuarial equivalent amount. For panel sizes and deductible amounts not shown in the tables, we propose that linear interpolation may be used to identify the required deductible for panel sizes between the table values. In addition, proposed paragraph Sec.   422.208(f)(2)(iii)(B) provides that the table applies only for capitated risk.     In order to provide the attachment points for separate per patient insurance for institutional services and professional services, we propose to use the NBP from Table 13. This second table provides separate deductibles for physician and institutional services. Table 14 was calculated using a methodology similar to the calculation of Table 13. The source for our estimate of medical group income and institutional income is derived from CMS claims files which includes payments for all Part A and Part B services. The central limit theorem was used to obtain the distribution of claim means, and deductibles were obtained at the 98 percent confidence level. We propose to codify the methodology and assumptions for Table 14 in Sec.  422.208 (f)(2)(vi) and (f)(2)(vii). BILLING CODE 4120-01-P

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[GRAPHIC] [TIFF OMITTED] TP28NO17.013

BILLING CODE 4120-01-C     The physician or physician group would look up the combined deductible in the second column of Table 13 and select the corresponding NBP in the

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third column. If necessary, linear interpolation would be used. Finally, the physician or physician group would select any cell in the table in Table 14 whose numerical entry is greater than or equal to that NBP. The row and column labels for this cell are the corresponding professional and institutional deductibles for that selection. Any such selection would meet the requirement of the basic rule stated in paragraph (f)(2)(i). We are proposing to codify the use of this table of deductibles for separate stop-loss insurance professional services and institutional services based on the NBP in paragraph (f)(2)(v).     We solicit comment on our proposal, specifically the following:      Whether our proposed regulation text at paragraphs (f)(2)(iv), (vi) and (vii) details the methodology for developing Tables 13 and 14 in sufficient detail.      Whether our proposed regulation text clearly identifies how the tables would be used.      Whether we should finalize a specific schedule, such as annually or every 3 years for updating the tables using the proposed methodologies in order to ensure that the maximum deductibles are consistent with medical cost and utilization trends. d. Actuarially Equivalent Arrangements     Over the past several years, MA organizations, have requested an update to the tables as well as additional flexibilities around protection arrangements other than combined and separate per-patient stop-loss insurance. CMS believes that providing the flexibility to MA organizations to use actuarially equivalent arrangements is appropriate as the nature of the PIP negotiated between the MA organization and physicians or physician groups might necessitate other arrangements to properly and adequately protect physicians from substantial financial risk. Examples where actuarially equivalent modifications might be necessary, include: Global capitation arrangements that include some, but not all Parts A and B services; stop-loss policies with different coinsurances; stop-loss policies that use medical loss ratios (MLR), which generally pay specific stop-loss amounts only to the extent that the overall aggregate MLR for the physician group exceeds a certain amount; stop-loss policies for exclusively primary care physicians; and risk arrangements on a quota share basis, which occurs when less than full capitation risk is transferred from a plan to a physician or physician group. Therefore, we propose to add Sec.  422.208(f)(3) to permit MA organizations to use other stop-loss protection arrangements; the proposal would allow actuaries to develop actuarially equivalent special insurances that are: Appropriately developed for the population and services furnished; in accordance with generally accepted actuarial principles and practices; and certified as meeting these requirements by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board. Under this proposal, CMS would review the attestation of the actuary certifying the special insurance arrangement. We solicit comment whether these proposed standards provide sufficient flexibility to MA organizations and physicians. c. Non-Risk Patient Equivalents Included in Panel Size     We believe that the number of a physician group's non-risk patients should be taken into account when setting stop loss deductibles for risk patients. For example a group with 50,000 non-risk patients and 5,000 risk patients needs less protection than a group with only 3,000 non-risk patients and 5,000 risk patients. We propose, at Sec.   422.208(f)(2)(iii) and (v), to allow non-risk patient equivalents (NPEs), such as Medicare Fee-For-Service patients, who obtain some services from the physician or physician group to be included in the panel size when determining the deductible. Under our proposal, NPEs are equal to the projected annual aggregate payments to a physician or physician group for non-global risk patients, divided by an estimate of the average capitation per member per year (PMPY) for all non-global risk patients, whether or not they are capitated. Both the numerator and denominator are for physician services that are rendered by the physician or physician group. We propose that the deductible for the stop-loss insurance that is required under this regulation would be the lesser of: (1) The deductible for globally capitated patients plus up to $100,000 or (2) the deductible calculated for globally capitated patients plus NPEs. The deductible for these groups would be separately calculated using the tables and requirements in our proposed regulation at paragraph (f)(2)(iii) and (v) and treating the two groups (globally capitated patients and globally capitated patients plus NPEs) separately as the panel size. We propose the same flexibility for combined per-patient stop-loss insurance and the separate stop-loss insurances. We solicit comment on this proposal. 6. Changes to the Agent/Broker Compensation Requirements (Sec. Sec.   422.2274 and 423.2274)     Sections 103(b)(1)(B) and 103(b)(2) of the Medicare Improvements for Patients and Providers Act (MIPPA) revised section 1851(j)(2)(D) of the Act to charge the Secretary with establishing guidelines to ``ensure that the use of compensation creates incentives for agents/ brokers to enroll individuals in the MA plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revised section 1860D-4(l)(2) of the Act to apply these same guidelines to Part D sponsors. We believe agents/brokers play a significant role in providing guidance and are, as such, in a unique position to influence beneficiary choice. CMS implemented these MIPPA-related changes in a May 23, 2014 final rule (79 FR 29960). The 2014 final rule revised the provisions previously established in the interim final rule (IFR) adopted on September 18, 2008 (73 FR 554226).     The IFR had established the previous compensation structure for agents/brokers as it applied to the MA and Part D programs. In particular, the IFR limited compensation for renewal enrollments to no greater than 50 percent of the rate paid for the initial enrollment on a 6-year cycle. This structure had proven to be complicated to implement and monitor, as it required the MA organization or Part D sponsor to track the compensation paid for every enrollee's initial enrollment and calculate the renewal rate based on that initial payment. To the extent that there was confusion about the required levels of compensation or the timing of compensation, it seemed that there was an uneven playing field for MA organizations and Part D sponsors operating in the same geographic area.     In addition to the many inquiries from MA organizations and Part D sponsors regarding the correct calculation of agent/broker compensation, CMS found it necessary to take compliance actions against MA organizations and Part D sponsors for failure to comply with the compensation requirements. CMS's audit findings and monitoring efforts performed after implementation of the IFR showed that MA organizations and Part D sponsors were having difficulty correctly administering the compensation requirements.     Also, we were concerned that the structure as it existed before the 2014 revisions created an incentive for agents/brokers to move enrollees from a plan of one parent organization to a plan of another parent organization, even for like plan-type changes. That

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compensation structure resulted in different payments when a beneficiary moved from one plan to another like plan in a different organization. In such situations, the new parent organization would pay the agent 50 percent of the current initial rate of the new parent organization; not 50 percent of the initial rate paid by the prior parent organization. Thus, in cases where the fair market value (FMV) for compensation had increased, or the other parent organization paid a higher commission, an incentive existed for the agent to move beneficiaries from one parent organization to another, rather than supporting the beneficiary's continued enrollment in the prior parent organization.     In a 2014 proposed rule (79 FR 1918), we proposed to simplify agent/broker compensation rules to help ensure that plan payments were correct and establish a level playing field that further limited the incentive for agents/brokers to move enrollees for financial gain rather than for the beneficiary's best interest. In the final rule published on May 23, 2014, we codified technical changes to the language established by the IFR relating to agent/broker compensation, choosing instead to link payment rates for renewal enrollments to current FMV rates rather than the rate paid for the original (that is, initial) enrollment. These changes also effectively removed the 6-year cycle from the payment structure. We codified these changes in Sec. Sec.  422.2274(a), (b), and (h) for MA organizations and Sec. Sec.  423.2274(a), (b), and (h) for Part D sponsors.     At that time, we should have also proposed to remove the language at Sec.  422.2274(b)(2)(i), Sec.  422.2274(b)(2)(ii), Sec.   423.2274(b)(2)(i), and Sec.  423.2274(b)(2)(ii), but we failed to do so. Since then, this language is no longer relevant, as the current compensation structure is not based on the initial payment. However, it has created confusion among plan staff and brokers.     We propose to make a technical correction to the existing regulatory language at Sec.  422.2274(b) and Sec.  423.2274(b). We propose to remove the language at Sec. Sec.  422.2274(b)(2)(i), 422.2274(b)(2)(ii), 423.2274(b)(2)(i), and 423.2274(b)(2)(ii). Additionally, we would renumber the existing provisions under Sec.   422.2274(b) and Sec.  423.2274(b) for clarity. 7. Changes to the Agent/Broker Requirements (Sec. Sec.  422.2272(e) and 423.2272(e))     Section 1851(h)(7) of the Act directs CMS to act in collaboration with the states to address fraudulent or inappropriate marketing practices. In particular, section 1851(h)(7)(A)(i) of the Act requires that MA organizations only use agents/brokers who have been licensed under state law to sell MA plans offered by those organizations. Section 1860D-4(l)(4) of the Act references the requirements in section 1851(h)(7) of the Act and applies them to Part D sponsors. We have codified the requirement in Sec. Sec.  422.2272(c) and 423.2272(c).     In the April 15, 2011, final rule (76 FR 21503 and 21504), we codified a provision in Sec. Sec.  422.2272(e) and 423.2272(e) that required MA organizations and Part D sponsors to terminate any employed agent/broker who became unlicensed. The provision also required MA organizations and Part D sponsors to notify any beneficiaries enrolled by the unqualified agent/broker of that agent/broker's status. Finally, the provision specified that the MA organization or Part D sponsor must comply with any request from the beneficiary regarding the beneficiary's options to confirm enrollment or make a plan change if the beneficiary requests such upon notification of the agent/broker's status.     Since implementation of the provision in Sec. Sec.  422.2272(e) and 423.2272(e), we have become aware that the regulation does not allow latitude for punitive action in situations when a license lapses. The MA organization or Part D sponsor may terminate the agent/broker and immediately rehire the individual thereafter if licensure has been already reinstated or prohibit the agent/broker from ever selling the MA organization's or Part D sponsor's products again. Discussions with the industry indicate that these two options are impractical due to their narrow limits. We believe agents/brokers play a significant role in providing guidance to beneficiaries and are in a unique position to positively influence beneficiary choice. However, the statute directs CMS to require MA organizations and Part D sponsors to only use agents/ brokers who are licensed under state law. We do not intend to change the regulation, at Sec. Sec.  422.2272(c) and 423.2272(c), requiring agent/broker licensure as a condition of being hired by a plan, and will continue to review the licensure status of agents/brokers during those monitoring activities that focus on MA organizations' and Part D sponsors' marketing activities. CMS believes MA organizations and Part D sponsors should determine the level of disciplinary action to take against agents/brokers who fail to maintain their license and have sold MA/Part D products while unlicensed, so long as the MA organization or Part D plan complies with the remaining statutory and regulatory requirements.     We propose to ***delete*** Sec. Sec.  422.2272(e) and 423.2272(e), the provisions that limit what MA organizations and Part D sponsors can do when they have discovered that a previously licensed agent/broker has become unlicensed. Nonetheless, CMS may pursue compliance actions upon discovery of MA organizations and Part D sponsors who allow unlicensed agents/brokers to continue selling their products in violation of Sec. Sec.  422.2272(c) and 423.2272(c).     Note that ***deleting*** paragraph (e) from Sec. Sec.  422.2272 and 423.2272 removes language describing the opportunity beneficiaries have to select a different MA or Part D plan when the broker who enrolled them was unlicensed at the time the beneficiaries enrolled. Removing paragraph (e) from Sec. Sec.  422.2272 and 423.2272 does not eliminate the special enrollment period (SEP) that enrollees receive when it is later discovered that their agent/broker was not licensed at the time of the enrollment as that SEP exists under the authority of Sec.   422.62(b)(4). 8. Codification of Certain Medicare Premium Adjustments as Initial Determinations (Sec.  405.924)     Current regulations at Sec.  405.924(a) set forth Social Security Administration (SSA) actions that constitute initial determinations under section 1869(a)(1) of the Act. These actions at Sec.  405.924(a) include determinations with respect to entitlement to Medicare hospital (Part A) or supplementary medical insurance (Part B), disallowance of an application for entitlement; a denial of a request for withdrawal of an application for Medicare Part A or Part B, or denial of a request for cancellation of a request for withdrawal; or a determination as to whether an individual, previously determined as entitled to Part A or Part B, is no longer entitled to these benefits, including a determination based on nonpayment of premiums.     In addition to the actions set forth at Sec.  405.924(a), SSA, the Office of Medicare Hearings and Appeals (OMHA), and the Departmental Appeals Board (DAB) also treat certain Medicare premium adjustments as initial determinations under section 1869(a)(1) of the Act. These Medicare premium adjustments include Medicare Part A and Part B late enrollment and reenrollment premium increases made in accordance with sections 1818, 1839(b) of the Act, Sec. Sec.  406.32(d),

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408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301 Due to the effect that these premium adjustments have on individuals' entitlement to Medicare benefits, they constitute initial determinations under section 1869(a)(1) of the Act.     Accordingly, we are proposing to add a new paragraph (5) to Sec.   405.924(a) to clarify that these premium adjustments, made in accordance with sections 1818 and 1839(b) of the Act, Sec. Sec.   406.32(d) and 408.22 of this chapter, and 20 CFR 418.1301, constitute initial determinations under section 1869(a)(1) of the Act. Because this proposed change seeks only to codify existing processes related to premium adjustments, and not to alter existing processes or procedures, it applies only to Part A and Part B late enrollment and reenrollment penalties. Based on 1860D-13(b)(6)(C) of the Act, CMS does not consider Part D late enrollment and reenrollment penalties to be initial determinations. As a result, their appeal rights stop at the reconsideration level. 9. Eliminate Use of the Term ``Non-Renewal'' To Refer to a CMS- Initiated Termination (Sec. Sec.  422.506, 422.510, 423.507 and 423.509)     Section 1857(c)(2) of the Act provides the bases upon which CMS may make a decision to terminate a contract with an MA organization. Under section 1860D 12(b)(3) of the Act, these same bases are available for a CMS termination of a Part D sponsor contract, as section 1860D-12(b)(3) of the Act incorporates into the Part D program the Part C bases by reference to section 1857(c)(2). Also, sections 1857(h) and 1860D 12(b)(3)(F) of the Act provide the procedures CMS must follow in carrying out MA organization or Part D sponsor contract terminations.     Although the Act only expressly refers to terminations, through rulemaking and subregulatory guidance, we have created two different processes relating to severing the contractual agreement between CMS and an MA organization or Part D sponsor. In accordance with sections 1857(h) and 1860D-12(b)(3)(F) of the Act, we have adopted regulations providing for distinct contract termination and bases and procedures for nonrenewal if contracts. Our regulations at Sec. Sec.  422.506 and 422.510 provide for the nonrenewal and termination, respectively, of CMS contracts with MA organizations. The Part D regulations provide for similar procedures with respect to Part D sponsor contracts at Sec. Sec.  423.507 and 423.509     Each nonrenewal provision is divided into two parts, one governing nonrenewals initiated by a sponsoring organization and another governing nonrenewals initiated by CMS. Two features of the nonrenewal provisions have created multiple meanings for the term ``nonrenewal'' in the operation of the Part C and D programs, contributing, in some instances, to confusion within CMS and among contracting organizations surrounding the use of the term. The first feature is the difference between non renewals initiated by sponsoring organizations and those initiated by CMS with respect to the need to establish cause for such an action. The second is the partial overlap between CMS' termination authority and our nonrenewal authority. We propose to revise our use of terminology such that that the term ``nonrenewal'' only refers to elections by contracting organizations to discontinue their contracts at the end of a given year. We propose to remove the CMS initiated nonrenewal authority stated at paragraph (b) from both Sec. Sec.   422.506 and 423.507 and modify the existing CMS initiated termination authority at Sec. Sec.  422.510 and 423.509 to reflect this change.     MA organizations and Part D plan sponsors may elect to end the automatic renewal provision in Part C or Part D contracts and discontinue those contracts with CMS without cause, simply by providing notice in the manner and within the timeframes stated at Sec.   422.506(a) and Sec.  423.507(a). Thus, organizations are free to make a business decision to end their Medicare contract at the end of a given year and need not provide CMS with a rationale for their decision. By contrast, CMS may not end an MA organization or Part D plan sponsor's contract through nonrenewal without establishing that the contracting organization's performance has met the criteria for at least one of the stated bases for a CMS initiated contract nonrenewal in paragraphs (b) of those sections.     Contracting organizations often respond to changes in the Medicare markets or changes in their own business objectives by making decisions to end or modify their participation in the Part C and D programs. Thus, these organizations exercise their nonrenewal rights under Sec.   422.506(a) and Sec.  423.507(a) much more frequently than CMS conducts contract non renewals under Sec.  422.506(b) and Sec.  423.507(b). As a result, within CMS and among industry stakeholders, the term ``nonrenewal'' has effectively come to refer almost exclusively to MA organization and Part D plan sponsor initiated contract non renewals.     The termination authority allows us to provide notice of such an action at any time and make it effective at least 30 days after providing such notice to the contracting organization. By contrast, CMS may issue a nonrenewal notice of a contract no later than August 1, and the nonrenewal takes effect at the end of the current contract year. Yet, the result of both actions taken by CMS is the discontinuation, for cause (although the basis of that cause might be different), of an organization's MA or Part D contract.     The similarities between nonrenewal and termination are demonstrated by the extensive but not complete overlap in bases for CMS action under both processes. For example, both nonrenewal authorities incorporate by reference the bases for CMS initiated terminations stated in Sec.  422.510 and Sec.  423.509 The remaining CMS initiated nonrenewal bases (any of the bases that support the imposition of intermediate sanctions or civil money penalties (Sec. Sec.   422.506(b)(iii) and Sec.  423.507(b)(1)(ii)), low enrollment in an individual MA plan or PDP (Sec. Sec.  422.506(b)(iv) and 423.507(b)(1)(iii)), or failure to fully implement or make significant progress on quality improvement projects (Sec.  422.506(b)(i))) were all promulgated in accordance with our statutory termination authority at sections 1857(c)(2) and 1860D-12(b)(3) of the Act and are all more specific examples of an organization's substantial failure to carry out the terms of its MA or Part D contract or its carrying out the contract in an inefficient or ineffective manner. Therefore, we propose striking these provisions from the nonrenewal portion of the regulation and adding them to the list of bases for CMS initiated contract terminations.     Finally, there are aspects of the notice requirements related to the CMS initiated nonrenewal authority that are useful in the administration of the Part C and D programs and which we propose preserving in the revised termination provision. Specifically, Sec.   422.506(b)(2)(ii) requires notice to be provided by mail to a contracting organization's enrollees at least 90 days prior to the effective date of the nonrenewal, while Sec.  422.510(b)(1)(ii) requires affected plan enrollees to be notified within 30 days of the effective date of the termination. We see a continuing benefit to the administration of the Part C and D programs in retaining the authority to ensure that, when possible, enrollees can be made aware of their plan's discontinuation at least by October 1 of a given year so that they can make the necessary plan choice

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during the annual election period. Therefore, we propose adding provisions at Sec. Sec.  422.510(b)(2)(v) and 423.509(b)(2)(v) to require that enrollees receive notice no later than 90 days prior to the December 31 effective date of a contract termination when we make such determination on or before August 1 of the same year.

III. Collection of Information Requirements

    Under the Paperwork Reduction Act of 1995 (44 U.S.C 3501 et seq.), we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:      The need for the information collection and its usefulness in carrying out the proper functions of our agency.      The accuracy of our estimate of the information collection burden.      The quality, utility, and clarity of the information to be collected.      Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.     In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Wage Data

    To derive average costs, we used data from the U.S Bureau of Labor Statistics' (BLS') May 2016 National Occupational Employment and Wage Estimates for all salary estimates ([*http://www.bls.gov/oes/current/oes\_nat.htm*](http://www.bls.gov/oes/current/oes_nat.htm)). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

                          Table 15--National Occupational Employment and Wage Estimates ----------------------------------------------------------------------------------------------------------------                                                                                       Fringe         Adjusted               BLS occupation title                  Occupation      Mean hourly    benefits and   hourly wage ($/                                                        code         wage ($/hr)   overhead ($hr)        hr) ---------------------------------------------------------------------------------------------------------------- Business Operations Specialist..................         13-1000           34.54           34.54           69.08 Compliance Officers.............................         13-1041           33.77           33.77           67.54 Computer and Information Systems Managers.......         11-3021           70.07           70.07          140.14 Computer Programmer.............................         15-1131           40.95           40.95           81.90 Health Diagnostic and Treating Practitioners....         29-1199           40.77           40.77           81.54 Insurance Claim and Policy Processing Clerk.....         43-9041           19.61           19.61           39.22 Lawyers.........................................         23-1011           67.25           67.25          134.50 Medical and Health Service Manager..............         11-9111           52.58           52.58          105.16 Medical Secretary...............................         43-6013           16.85           16.85           33.70 Office and Administrative Support Workers, All           43-9199           17.33           17.33           34.66  Other.......................................... Physicians and Surgeons.........................         29-1060          101.04          101.04          202.08 Physicians and Surgeons, all other..............         29-1069           98.83           98.83          197.66 Software Developers and Programmers.............         15-1130           48.11           48.11           96.22 Word Processors and Typists.....................         43-9022           19.22           19.22           38.44 ----------------------------------------------------------------------------------------------------------------

    As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (Sec.   422.60(g))     In section II.A.9 of this proposed rule, we are proposing a limited expansion of passive enrollment authority. More specifically, the new provisions at Sec.  422.60(g) would allow CMS, in consultation with a state Medicaid agency, to implement passive enrollment procedures in situations where criteria identified in the regulation text are met. We propose the criteria based on our policy determination that passive enrollment is appropriate in those cases to promote integrated care and continuity of care for full-benefit dual eligible beneficiaries who are currently enrolled in an integrated D-SNP.     Under passive enrollment procedures, a beneficiary who is offered a passive enrollment is deemed to have elected enrollment in a plan if he or she does not affirmatively elect to receive Medicare coverage in another way. Plans to which individuals are passively enrolled under the proposed provision would be required to comply with the existing requirement under Sec.  422.60(g) to provide a notification. The notice must explain the beneficiaries' right to choose another plan, describe the costs and benefits of the new plan, how to access care under the plan, and the beneficiary's ability to decline the enrollment or choose another plan. Providing notification would include mailing notices and responding to any beneficiary questions regarding enrollment.     We anticipate that there will be relatively few instances each year in which passive enrollment occurs under the new provisions at Sec.   422.60(g). This is informed by our experience in implementing passive enrollments under the existing regulations at Sec.  422.60(g), where in recent years there have been only one to two contract terminations annually where CMS allows passive enrollment. We estimate that approximately one percent of the 373 active D-SNPs would meet the criteria identified in the regulation text, and operate in a market where all of the conditions of passive enrollment are met and where CMS, in consultation with a state Medicaid agency, implements passive enrollment. Therefore, under the new provisions at Sec.  422.60(g), we anticipate only four additional instances in which CMS allows passive enrollment each year.     We estimate it would take 10 hours at $69.08/hr for a business operations

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specialist to develop the initial notice. We also estimate it would take 1 minute for a business operations specialist to electronically generate and submit a notice for each beneficiary that is offered passive enrollment. We estimate that approximately 5,520 full-benefit dual eligible beneficiaries would be sent a notice in each instance in which passive enrollment occurs, which reflects the average enrollment of currently active D-SNP plans. Four instances of passive enrollment annually would result in 22,080 beneficiaries being sent the notice (5,520 x 4 organizations) each year.     To develop the initial notice, we estimate a one-time burden of 40 hours (4 organizations x 10 hr) at a cost of $2,763.20 (40 hr x $69.08/ hr) or $690.80 per organization ($2,763.20/4 organizations). To electronically generate and submit a notice to each beneficiary, we estimate a total burden of 368 hours (22,080 beneficiaries x 1 min/60) at a cost of $25,421.44 (368 hr x $69.08/hr) or $6,355.36 per organization ($25,421.44/4 organizations) annually.     Since we estimate fewer than 10 respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995. However, we seek comment on our estimates for the overall number of respondents and the associated burden. 2. ICRs Regarding the Restoration of the MA Open Enrollment Period (Sec. Sec.  422.60, 422.62, 422.68, 423.38, and 423.40)     In section II.B.1 of this rule, we are proposing to codify the requirements for open enrollment and disenrollment opportunities at Sec. Sec.  422.60, 422.62, 422.68, 423.38, and 423.40 that would eliminate the existing MADP and establish a MA Open Enrollment Period (OEP). This new OEP revises a previous OEP which would allow MA- enrolled individuals the opportunity to make a one-time election during the first 3 months of the calendar year to switch MA plans, or disenroll from an MA plan and obtain coverage through Original Medicare. Although no new data would be collected, the burden associated with this requirement would be the time and effort that it takes an MA organization to process an increased number of enrollment and disenrollment requests by individuals using this OEP, which is first available in 2019.     To estimate the potential increase in the number of enrollments and disenrollments from the new OEP, we considered the percentage of MA- enrollees who used the old OEP that was available from 2007 through 2010. For 2010, the final year the OEP existed before the MADP took effect, we found that approximately 3 percent of individuals used the OEP. While the parameters of the old OEP and new OEP differ slightly, we believe that this percentage is the best approximation to determine the burden associated with this change. In January 2017, there were approximately 18,600,000 individuals enrolled in MA plans. Using the 3 percent adjustment, we expect that 558,000 individuals (18.6 million MA beneficiaries x 0.03), would use the OEP to make an enrollment change. a. Beneficiary Estimate (Current OMB Control Number 0938-0753 (CMS-R- 267))     We estimate it would take a beneficiary approximately 30 minutes (0.5 hours) at $7.25/hour to complete an enrollment request. While there may be some cost to the respondents, there are individuals completing this form who are working currently, may not be working currently or never worked. Therefore, we used the current federal minimum wage outlined by the U.S Department of Labor ([*https://www.dol.gov/whd/minimumwage.htm*](https://www.dol.gov/whd/minimumwage.htm)) to calculate costs. The burden for all beneficiaries is estimated at 279,000 hours (558,000 beneficiaries x 0.5 hour) at a cost of $2,022,750 (279,000 hour x $7.25/hour) or $3.63 per beneficiary ($2,022,750/558,000 beneficiaries). b. MA Organization Estimate (Current OMB Ctrl# 0938-0753 (CMS-R-267))     There are currently 468 MA organizations in 2017. Not all MA organizations are required to be open for enrollment during the OEP. However, for those that are, we estimate that this enrollment period would result in approximately 1,192 enrollments per organization (558,000 individuals/468 organizations) during the OEP each year.     We estimate it would take approximately 5 minutes at $69.08/hour for a business operations specialist to determine eligibility and effectuate the changes for open enrollment. The burden for all organizations is estimated at 46,500 hours (558,000 beneficiaries x 5 min/60) at a cost of $3,212,220 (46,500 hour x $69.08/hour) or $6,864 per organization ($3,212,220/468 MA organizations).     Once the enrollment change is completed, we estimate that it will take 1 minute at $69.08/hour for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each of the 558,000 beneficiaries. The total burden to complete the notices is 9,300 hours (558,000 notices x 1 min/ 60) at a cost of $642,444 (9,300 hour x $69.08/hour) or $1.15 per notice ($642,444/558,000 notices) or $1,372.74 per organization ($642,444/468 MA organizations).     The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at $69.08/hour for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. The total burden is estimated at 9,300 hours (558,000 notices x 1 min/60) at a cost of $642,444 (9,300 hour x $69.08/hour) or $1.15 per notice ($642,444/558,000 notices) or $1,372.74 per organization ($642,444/468 MA organizations).     Additionally, MA organizations will have to retain a copy of the notice in the beneficiary's records. The burden associated with this task is estimated at 5 minutes at $34.66/hour for an office and administrative support worker to perform record retention for the open enrollment period. In aggregate we estimate an annual burden of 46,500 hours (558,000 beneficiaries x 5 min/60) at a cost of $1,606,110 (46,500 hour x $34.66/hour) or $3,431.86 per organization ($1,606,110/ 468 MA organizations).     We estimate a total annual burden for all MA organizations resulting from this proposed provision to be 111,600 hours (46,500 hour + 9,300 hour + 9,300 hour + 46,500 hour) at a cost of $6,103,218 ($3,212,220 + $642,444 + $642,444 + $1,606,110). Per organization, we estimate an annual burden of 238 hours (111,600 hour/468 MA organizations) at a cost of $13,041 ($6,103,218/468 organizations). For beneficiaries we estimate a total annual burden of 279,000 hours at a cost of $2,022,750 and a per beneficiary burden of 30 minutes at $3.63     The proposed requirements and burden will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267). 3. ICRs Regarding Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (Sec. Sec.  422.66 and 422.68) OMB Control Number 0938-0753 (CMS-R-267)     In section II.A.8 of this rule we propose to revise Sec.  422.66 and 422.68 by: Codifying the requirements for default enrollment that are currently set out in subregulatory guidance,\60\

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revising current practice to limit the use of this type of enrollment mechanism, and clarifying the effective date for ICEP elections. This would provide an MA organization the option to enroll its Medicaid managed care enrollees who are newly eligible for Medicare into an integrated D-SNP administered by the same MA organization that operates the Medicaid managed care plan. While our proposal restricts its use to individuals in the organization's Medicaid managed care plan that can be enrolled into an integrated D-SNP, the estimated burden for an organization that desires to use default enrollment and obtain CMS approval would not change. For those MA organizations that want to use this enrollment mechanism and request and obtain CMS approval, the administrative requirements would remain unchanged from the current practice. Enrollment requirements and burden are currently approved by OMB under control number 0938-0753 (CMS-R-267). Since this proposed rule would not impose any new or revised requirements/burden, we are not making any changes to that control number. ---------------------------------------------------------------------------

    \60\ Chapter 2 of the Medicare Managed Care Manual found at [*https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/*](https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/). ---------------------------------------------------------------------------

4. ICRs Regarding Timing and Method of Disclosure Requirements (Sec. Sec.  422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) and 423.128(d)(2)) (OMB Control Number 0938-1051) a. Timing of Disclosure (Sec. Sec.  422.111(a)(3) and 423.128(a)(3))     In section II.B.4 of this rule, we propose to revise the timing and method of disclosing the information as required under Sec.   422.111(a) and (b) and the timing of such disclosures under Sec.   423.128(a) and (b). These regulations provide for disclosure of plan content information to beneficiaries. We would revise Sec. Sec.   422.111(a)(3) and 423.128(a)(3) by requiring MA plans and Part D sponsors to provide the information in Sec. Sec.  422.111(b) and 423.128(b) by the first day of the annual enrollment period, rather than 15 days before that period. Plans must still distribute the ANOC 15 days prior to the AEP. In other words, the proposed provision would provide the option of either submitting the EOC with the ANOC or waiting until the first day of the AEP, or sooner, for distribution. The provision simply gives plans that may need some flexibility the ability to rearrange schedules and defer a deadline. Consequently, there is no change in burden. b. Method of Disclosure (Sec. Sec.  422.111(h)(2) and 423.128(d)(2)) (OMB Control Number 0938-1051)     Sections 422.111(h)(2)(i) and 423.128(d)(2)(i) require that plans maintain a Web site which contains the information listed in Sec. Sec.   422.111(b) and 423.128(b). Section 422.111(h)(2)(ii) states that the posting of the EOC, Summary of Benefits, and provider network information on the plan's Web site ``does not relieve the MA organization of its responsibility under Sec.  422.111(a) to provide hard copies to enrollees.'' There is no parallel to Sec.   422.111(h)(2)(ii) in Sec.  423.128 for Part D sponsors. Further, Sec.   423.128(a) includes language providing that disclosures required under that section be ``in the manner specified by CMS.''     In Sec.  422.111(h)(2)(ii), we propose to modify the sentence which states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site does not relieve the plan of its responsibility to provide hard copies of these documents to beneficiaries ``upon request.'' In addition, we propose to add the phrase ``in the manner specified by CMS'' in paragraph (a). These proposed revisions would give CMS the authority to permit MA plans the flexibility to provide the information in Sec.  422.111(b) electronically when specified by CMS as a permissible delivery option, and better aligns with the provisions under Sec.  423.128 We intend to continue to specify hardcopy mailing, as opposed to electronic delivery, for most documents that convey the type of information described in paragraph (b). CMS intends that provider and pharmacy directories, the plan's Summary of Benefits, and EOC documents would be those for which electronic posting and delivery of a hard copy upon request are permissible. Electronic delivery would reduce plan burden by reducing printing and mailing costs. Additionally, the IT systems of the plans are already set up to format and print these documents. Also, plans must provide hard copies upon request. To estimate the cost of printing these documents, we note that the CMS Trustee's report, accessible at [*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/*](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/), lists 47.8 million beneficiaries in MA, Section 1876 cost,\61\ and Prescription Drug contracts for contract year 2019. ---------------------------------------------------------------------------

    \61\ Per 42 CFR 417.427, cost plans must comply with Sec.   422.111 and Sec.  423.128 ---------------------------------------------------------------------------

    Based on reports from the InternetSociety.org and Pew Research Center,\62\ we estimate that 33 percent of these beneficiaries who are in MA and Prescription Drug contracts would prefer to opt in to receiving hard copies to receiving electronic copies. Thus, the savings comes from the 67 percent of beneficiaries who are in MA and Prescription Drug contracts that will not opt in to having printed copies mailed to them, namely 67 percent x 47.8 = 32,026,000 individuals. ---------------------------------------------------------------------------

    \62\ Global Internet Report, 2017, Internet Society, [*http://www.internetsociety.org/globalinternetreport/2016/?gclid=EAIaIQobChMI-tz1nN\_W1QIVgoKzCh1EVggBEAAYASAAEgLpj\_D\_BwE*](http://www.internetsociety.org/globalinternetreport/2016/?gclid=EAIaIQobChMI-tz1nN_W1QIVgoKzCh1EVggBEAAYASAAEgLpj_D_BwE) and ``Tech Adoption Climbs Among Older Adults,'' Pew Research Center,   [*http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/*](http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/). ---------------------------------------------------------------------------

    The major expenses in printing an EOC include paper, toner, and mailing costs. The typical EOC has 150 pages. Typical wholesale costs of paper are between $2.50 and $5.00 for a ream of 500 sheets. We assume $2.50 per ream of 500 sheets. Since each EOC has 150 pages, we are estimating a cost of $0.75 per EOC [$2.50/(150 pages per EOC/500 sheets per ream)]. Thus, we estimate that the total savings from paper is $24,019,500 (32,026,000 EOCs x $0.75 per EOC).     Toner costs can range from $50 to $200 and each toner can last 4,000 to 10,000 pages. We conservatively assumes a cost of $50 for 10,000 pages. Each toner would print 66.67 EOCs (10,000 pages per toner/150 pages per EOC) at a cost of $0.005 per page ($50/10,000 pages) or $0.75 per EOC ($0.005 per page x 150 pages). Thus, we estimate that the total savings on toner is $24,019,500 ($0.75 per EOC x 32,026,000 EOCs).     Regarding mailing costs, since a ream of paper with 2,000 8.5 inches by 11 inches pages weighs 20 pounds or 320 ounces it then follows that 1 sheet of paper weighs 0.16 ounces (320 ounces/2,000 pages). Therefore, a typical EOC of 150 pages weighs 24 ounces (0.016 ounces/page x 150 pages) or 1.5 pounds. Since commercial mailing rates are 13.8 cents per pound, the total savings in mailings is $6,629,382 ($0.138/pounds x 1.5 pound x 32,026,000 EOCs).     In aggregate, we estimate a savings (to plans for not producing and mailing hardcopy EOCs) of $54,668,382 ($24,019,500 + $24,019,500 + $6,629,382). We will submit the proposed requirements and burden to OMB for approval under OMB control number 0938-1051 (CMS-10260). 5. ICRs Regarding the Removal of Quality Improvement Project for Medicare Advantage Organizations (Sec.  422.152) (OMB Control Number 0938-1023)     In section II.B.12 of this rule, we are proposing the removal of the Quality Improvement Project (QIP) requirements (and CMS-direction of QIPs) from the Quality Improvement (QI) Program

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requirements, which would result in an annual savings of $12,663.75 to MA organizations. The driver of the anticipated savings is the removal of requirements to attest having a QIP annually.     To derive our savings, we estimate that it takes 1 MA organization staff member (BLS: Compliance Officer) 15 minutes (0.25 hour) at $67.54/hour to submit a QIP attestation. Currently, there are 750 MA contracts, and each contract is required to submit a QIP attestation. Therefore, we anticipate that there will be 750 QIP attestations annually.     Using these assumptions, we estimate that the removal of the QIP provision will result in a total savings of 187.5 hours (750 contracts x 0.25 hour) at $12,663.75 (187.5 hour x $67.54/hour) or $16.89 per contact ($12,663.75/750 contracts).     The proposed requirements and burden will be submitted to OMB for approval under control number 0938-1023 (CMS-10209). 6. ICRs Regarding Medicare Advantage Quality Rating System (Sec. Sec.   422.162, 422.164, 422.166, 422.182, 422.184, and 422.186)     In section II.A.11 of this rule, we are proposing to codify the existing measures and methodology for the Part C and D Star Ratings program. The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS' Star Ratings-related PRA packages including: OMB control number 0938-0701 for CAHPS (CMS- 10203), OMB control number 0938-0732 for HOS (CMS-R-246), OMB control number 0938-1028 for HEDIS (CMS-10219), OMB control number 0938-1054 for Part C Reporting Requirements (CMS-10261), and OMB control number 0938-0992 for Part D Reporting Requirements (CMS-10185).     Since this rule would not impose any new or revised requirements/ burden, we are not making changes to any of the aforementioned control numbers. 7. ICRs Regarding Medicare Advantage Plan Minimum Enrollment Waiver (Sec.  422.514(b))     CMS regulations provide Medicare Advantage (MA) organizations, including provider sponsored organizations, with the opportunity to request a waiver of CMS's minimum enrollment requirements at Sec.   422.514(a) during the first 3 years of the contract. Regulations also require that MA organizations reapply for the minimum enrollment waiver in the second and third years of their contract. However, since CMS has not received or approved any waivers outside of the application process, CMS proposes to remove the requirement for MA organizations to reapply for the minimum enrollment waiver during years 2 and 3 of the contract under Sec.  422.514(b)(2) and (3). CMS also proposes to modify Sec.  422.514(b)(2) to clarify that CMS will only accept a waiver through the application process and allow the minimum enrollment waiver, if approved by CMS, to remain effective for the first 3 years of the contract. The requirement and burden associated with the submission of the minimum enrollment waiver in the application is currently approved by OMB under control number 0938-0935 (CMS-10237) which does not need to be revised. 8. ICRs Regarding Revisions to Sec. Sec.  422 and 423 Subpart V, Communication/Marketing Materials and Activities     In section II.B.5 of this rule, we are proposing to narrow the definition of ``marketing materials'' under Sec. Sec.  422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. We believe the proposed definitions appropriately safeguard potential and current MA/PDP enrollees from inappropriate steering of beneficiary choice, while not including materials that pose little risk to current or potential enrollees and are not traditionally considered ``marketing.'' Revisions to Sec. Sec.  422.2260 and 423.2260 would provide a narrower definition than is currently provided for ``marketing materials.'' Consequently, this change decreases the number of marketing materials that must be reviewed by CMS before use. Additionally, the proposal would more specifically outline the materials that are and are not considered marketing materials.     We believe the net effects of the proposed changes would reduce the burden to MA organizations and Part D sponsors by reducing the number of materials required to be submitted to us for review.     To estimate the savings, we reviewed the most recent 12-month period of marketing material submissions from the Health Plan Management System, July 2016 through and including June 2017. As documented in the currently approved PRA package, we also estimates that it takes a plan 30 minutes at $69.08/hour for a business operations specialist to submit the marketing materials. To complete the savings analysis, we also must estimate the number of marketing materials that would have been submitted to and reviewed by CMS under the current regulatory marketing definition (note that while all materials that meet the regulatory definition of marketing must be submitted to CMS, not all marketing materials are prospectively reviewed by CMS). Certain marketing materials qualify for ``File and Use'' status, which means the material can be submitted to CMS and used 5 days after submission, without being prospectively reviewed by CMS. We estimates 90 percent of marketing materials are exempt from our prospective review because of the file and use process. Thus, we only prospectively review about 10 percent of the marketing materials submitted.     Marketing materials are coded using 4- or 5-digit numbers, based on marketing material type. The relevant codes and counts are summarized in Table 16. BILLING CODE 4120-01-P

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[GRAPHIC] [TIFF OMITTED] TP28NO17.014

BILLING CODE 4120-01-C     By reducing the number of marketing materials submitted to CMS by 39,824 documents (80,110 current-40,286 excluded) we estimate a savings of

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19,912 hours (39,824 materials \* 0.5 hours per material) at a cost savings of $1,348,372.52 (19,912 hours \* 69.08 per hour). Some key points in the calculations are as follows:      There were a total of 80,110 marketing materials submitted to CMS during the 12-month period sampled. These materials already exclude PACE program marketing materials (30000 Code) which are governed by a different authority and not affected by the proposed provision. The 80,110 figure also excludes codes 16000 and 1700 Medicare-Medicaid Plan (MMP) materials. The MMP materials are not being counted as the decision for review rests with the states and CMS.      The statute is clear that ``applications,'' which CMS also refers to as enrollment or election forms, must be reviewed. Thus the 981 materials submitted under marketing code 1070, enrollment forms, must be subtracted from the 80,110.      Marketing code 1100 includes the combined ANOC/EOC as well as the D-SNP standalone ANOC. CMS intends to split the ANOC and EOC and will still require the ANOC be submitted as a marketing material, whereas the EOC will no longer be considered marketing and not require submission. To account for the ANOC submission, CMS estimates that 5,162 ANOCs will still require submission.      We do not expect any disenrollment or grievance forms (the 2000 and 3000 codes) to be required submissions under this proposal.      Marketing code 4000 covers all advertisements which constitute 55 percent (43,965) of the 80,110 materials. The majority of these advertisements deal with benefits and enrollment. We estimate 25 percent of the 43,965 code 4000 documents (that is, 10,991 documents) would fall outside of the new regulatory definition of marketing and no longer require submission. Thus, we must subtract these 32,974 (43,965 - 10,991) from the 80,110.      Marketing code 5000 covers formulary drugs. Although, as is currently the case, formularies will continue to be submitted to us for review in capacities outside of marketing, they will no longer fall under the new regulatory definition of marketing and hence would not be submitted separately for review as marketing materials.      Marketing code 6000 includes sales scripts which are predominantly used to encourage enrollment, and would likely still fall under the scope of the new marketing definition. As such, we must subtract 1,169 documents (code 6013) from the 80,110 total marketing materials.      Marketing code 8000 includes creditable coverage and late enrollment penalty (LEP) notices that will fall outside of the new regulatory definition of marketing and no longer require submission. Over the 12-month period sampled, this represents 559 material submissions.     The proposed requirements and burden will be submitted to OMB under control number 0938-1051 (CMS-10260). 9. ICRs Regarding Medical Loss Ratio Reporting Requirements (Sec. Sec.   422.2460 and 423.2460)     In section II.C.1 of this rule, we note that under current Sec. Sec.  422.2460 and 423.2460, for each contract year, MA organizations and Part D sponsors must report to CMS the information needed to verify the MLR and remittance amount, if any, for each contract, such as: Incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under Sec.  422.2410 or Sec.  423.2410 Our proposed amendments to Sec. Sec.  422.2460 and 423.2460 would reduce the MLR reporting burden by requiring that MA organizations and Part D sponsors report, for each contract year, only the MLR and the amount of any remittance owed to us for each contract with credible or partially credible experience. For each non-credible contract, MA organizations and Part D sponsors would be required to report only that the contract is non-credible.     Our analysis of the estimated administrative costs related to the MLR reporting requirements is based on the average number of MA and Part D contracts subject to the reporting requirements for each contract year. The average number of MA and Part D contracts subject to the annual MLR reporting requirements for contract years 2014 to 2018 is 587. The total number of MA and Part D contracts is relatively stable year over year. To calculate the estimated administrative costs of MLR reporting under the proposed amendments to Sec. Sec.  422.2460 and 423.2460, we assume that 587 MA and Part D contracts would be subject to the MLR reporting requirements in each contract year.     Our estimate for the amount of time that MAOs and Part D sponsors would spend on administrative tasks related to the MLR reporting requirements under this proposed rule is based on our current burden estimates that are approved by OMB under control number 0938-1232 (CMS- 10476), where we estimated that, on average, MA organizations and Part D sponsors would spend approximately 47 hours per contract on administrative work related to Medicare MLR reporting, including: Collecting data, populating the MLR reporting forms, conducting a final internal review, submitting the reports to the Secretary, and conducting internal audits. Inadvertently, our currently approved estimate did not specify (or break out) the portion of the overall reporting burden that could be attributed solely to the tasks of preparing and submitting the MLR report. We are correcting that oversight by estimating that the burden for preparing and submitting the MLR report is approximately 11.5 hours (or 24.4 percent of the estimated 47 total hours spent on all administrative work related to the MLR reporting requirements) per contact.     We arrived at the 11.5-hour estimate by considering the amount of time it would take an MA organization or Part D sponsor to perform each of the following tasks: (1) Review the MLR report filing instructions and external materials referenced therein and to input all figures and plan-level data in accordance with the instructions; (2) draft narrative descriptions of methodologies used to allocate expenses; (3) perform an internal review of the MLR report form prior to submission; (4) upload and submit the MLR report and attestation; and (5) correct or provide explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report.     We estimate that our proposal to scale back the MLR reporting requirements would reduce the amount of time spent on administrative work by 11 hours, from 47 hours to 36 hours.     Table 17 compares the estimated administrative costs related to the MLR reporting requirements under the current regulation and under this proposed rule. As indicated, this proposed rule estimates that MA organizations and Part D sponsors will spend on average 36 hours per MA or Part D contract on administrative work, compared to 47 hours per contract under the current rule. We estimate the average cost per hour of MLR reporting using wage data for computer and information systems managers, as we believe that the tasks associated with MLR reporting generally fall within the fields of data processing, computer programming, information systems, and systems analysis. Based on computer and information systems managers wage

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data from BLS, we estimate that MA organizations and Part D sponsors would incur annual MLR reporting costs of approximately $5,045 per contract on average under our proposal, as opposed to $6,587 per contract under the current regulations. Consequently, the proposed changes would, on average, reduce the annual administrative costs by $1,542 per contract. Across all MA and Part D contracts, we estimate that the proposed changes would reduce the annual administrative burden related to MLR reporting by 6,457 hours, resulting in a savings of $904,884.

                          Table 17--Estimated Administrative Burden Related to Medical Loss Ratio (MLR) Reporting Requirements --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                                                                              Estimated                                      Total number of contracts/    Estimated       Estimated     Estimated average cost      Estimated     average cost            Type of burden                      reports           average hours    total hours           per hour            total cost     per contract/                                                                   per report                                                                  report -------------------------------------------------------------------------------------------------------------------------------------------------------- Ongoing Costs (current regulations)  587......................              47          27,589  $140.14 ................      $3,866,322          $6,587 Ongoing Costs (proposed regulation   587......................              36          21,132  140.14 .................       2,961,438           5,045  changes). Change.............................  No change................              11           6,457  No change...............         904,884           1,542 -------------------------------------------------------------------------------------------------------------------------------------------------------- Notes: The source data has been modified to reflect estimated costs for MA organizations and Part D sponsors. Values may not be exact due to rounding.

    The proposed requirements and burden will be submitted to OMB for approval under control number 0938-1232 (CMS-10476). 10. ICRs Regarding Establishing Limitations for the Part D Special Enrollment Period for Dual Eligible Beneficiaries (Sec.  423.38(c)(4)) OMB Under Control Number 0938-0964     In section II.A.11 of this rule, we propose to revise Sec.   423.38(c)(4) to limit the SEP for dual- and LIS-eligible individuals. The provision would make the SEP for FBDE or other subsidy-eligible individuals available only in the following circumstances:      For beneficiaries who are making an allowable onetime-per- calendar-year election.      For beneficiaries who have been assigned to a plan by CMS or a state (that is, through auto enrollment, facilitated enrollment, passive enrollment, or reassignment) and decide to change plans following notification of the change or within 2 months of the election effective date.      For beneficiaries who have a change in their dual or LIS- eligible status.     In instances where an individual is not able to utilize the dual SEP because of the proposed limitations, we anticipate that there will be no change in burden. Under current requirements, if a beneficiary uses the dual SEP to disenroll from their plan, the plan would send a notice to the beneficiary to acknowledge the voluntary disenrollment request. If the beneficiary is subject to the dual SEP limitation, the plan would send a notice to deny their voluntary disenrollment request. The requirement to acknowledge the beneficiary request and address the resolution would be the same in both scenarios, but the content of the notice would be different. Enrollment processing and notification requirements are codified at Sec.  423.32(c) and (d) and are not being revised as part of this rulemaking. Therefore, no new or additional information collection requirements are being imposed. Moreover, the requirements and burden are currently approved by OMB under control number 0938-0964 (CMS-10141). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number. 11. ICRs Related to Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (Sec. Sec.  423.100, 423.120, and 423.128) OMB Under Control Number 0938-0964     In section II.A.15 of this rule, we propose to expedite certain generic substitutions and other midyear formulary changes and except applicable generic substitutions from the transition process. Excepting generic substitutions that would otherwise require transition fills from the transition process would lessen the burden for Part D sponsors because they would no longer need to provide such fills. Permitting Part D sponsors to immediately substitute newly approved generic drugs or to make other formulary changes sooner than has been required would allow Part D sponsors to take action sooner, but would not increase nor decrease paperwork.     While the proposed provisions would additionally require general notice that certain generic substitutions could take place immediately, Part D sponsors are already creating the documents in which that notice would appear such as formularies and EOCs. Similarly, Sec.   423.128(d)(2)(ii) already requires Web sites to include information about drug removals and changes to cost-sharing. In other words, the proposed general notice requirement would not require efforts in addition to routine updates to beneficiary communications materials and Web sites. In theory, if Part D sponsors that would have been denied requests to make generic changes could do so under the proposed provision, they would have somewhat more of a burden since the proposed provision does require notice including direct notice to affected enrollees. However, our practice has been to approve all or virtually all generic substitutions that would meet the requirements of this proposed provision--which again means that the proposed provisions would just permit those substitutions to take place sooner.     The general notice requirements and burden are currently approved by OMB under control number 0938-0964 (CMS-10141). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number. 12. ICRs Related to Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in Medicare Advantage, Cost Plans, and PACE a. Preclusion List Requirements for Part D Sponsors (1) Burden and Costs     In sections II.D.10 and 11. of this proposed rule, we are proposing in Sec.  423.120(c)(6) to require that Part D sponsors cover a provisional supply of a drug before they reject a claim based on a prescriber's inclusion on the preclusion list. The proposed provision would also require that Part D sponsors provide written notice to the beneficiary of the prescriber's presence on the preclusion list and take reasonable efforts to furnish written notice to the prescriber. The burden associated with these provisions would be the time and

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effort necessary for Part D adjudication systems to be programmed and for model notices to be created, generated, and disseminated. (a) Part D System Programming     We estimate that it would take all 30 sponsors and PBMs with Part D adjudication systems a total of approximately 93,600 hours in 2019 for software developers and programmers to program their systems to comply with the requirements of Sec.  423.120(c)(6). In 2020 and 2021, we do not anticipate any system costs. The sponsors and PBMs would need approximately 6 to 12 months to perform system changes and testing. The total hour figures are based on a 6-month preparation and testing period. There are roughly 1,040 full-time working hours in a 6-month period. Using an estimate of 3 full-time software developers and programmers at $96.22/hour resulted in the aforementioned 93,600 hour figure (3 workers x 1,040 hour x 30 sponsors/PBMs) at a cost of $9,006,192 (93,600 x $96.22/hour) for 2019. There would be no burden associated with 2020 and 2021. (b) Creation of Template Notices to Beneficiaries and Prescribers     As stated in the May 6, 2015 IFC, we estimate that 212 parent organizations would need to create two template notices to notify beneficiaries and prescribers under proposed Sec.  423.120(c)(6). We project that it would take each organization 3 hours at $69.08/hour for a business operations specialist to create the two model notices. For 2019, we estimate a one-time total burden of 636 hours (212 organizations x 3 hours) at a cost of $43,935 (636 hour x $69.08/hour) or $207.24 per organization ($43,935/212 organizations). There would be no burden associated with 2020 and 2021.     The proposed system programing and notice development requirements and burden will be submitted to OMB for approval under control number 0938-0964 (CMS-10141). (c) Preparation and Issuance of the Notices     We estimate that it would take an average of 5 minutes (0.083 hour) at $39.22/hour for an insurance claim and policy processing clerk to prepare and distribute the notices. We estimate that an average of approximately 800 prescribers would be on the preclusion list in early 2019 with roughly 80,000 Part D beneficiaries affected; that is, 80,000 beneficiaries would have been receiving prescriptions written by these prescribers and would therefore receive the notice referenced in Sec.   423.120(c)(6). In 2019 we estimate a total burden of 6,640 hours (0.083 hour x 80,000 responses) at a cost of $260,421 (6,640 hour x $39.22/ hour) or $1,228.40 per organization ($260,421/212 organizations).     In 2020 and 2021, we estimate that roughly 150 prescribers each year would be added to the preclusion list, though this would be largely offset by the same number of prescribers being removed from the list (for example, based on reenrollment after the expiration of a reenrollment bar or decision to remove them from the preclusion list) with 15,000 affected beneficiaries. In aggregate, we estimate an annual burden of 1,245 hours (15,000 beneficiaries x 0.083 hours) at a cost of $48,829 (1,245 hour x $39.22/hour) or $325.53 per prescriber ($48,829/ 150 prescribers).     The proposed notice preparation and distribution requirements and burden will be submitted to OMB for approval under control number 0938- 0964 (CMS-10141).

                    Table 18--Estimated Burden of Part D--Notice Preparation and Distribution                                                    [In hours] ----------------------------------------------------------------------------------------------------------------                                                        2019            2020            2021       3-year average ---------------------------------------------------------------------------------------------------------------- Provisional Supply--Programming.................          93,600               0               0          31,200 Provisional Supply--Template Creation...........             636               0               0             212 Provisional Supply--Letter Preparation..........           6,640           1,245           1,245           3,043                                                  ---------------------------------------------------------------     Total.......................................         100,876           1,245           1,245          34,455 ----------------------------------------------------------------------------------------------------------------

                    Table 19--Estimated Burden of Part D--Notice Preparation and Distribution                                                      [In $] ----------------------------------------------------------------------------------------------------------------                                                        2019            2020            2021       3-year average ---------------------------------------------------------------------------------------------------------------- Provisional Supply--Programming.................      $9,006,192              $0              $0      $3,002,064 Provisional Supply--Template Creation...........          43,935               0               0          14,645 Provisional Supply--Notice Preparation..........         260,421          48,829          48,829         119,360                                                  ---------------------------------------------------------------     Total.......................................       9,310,548          48,829          48,829       3,136,069 ----------------------------------------------------------------------------------------------------------------

(2) Savings     We believe that savings would accrue for the prescriber community from our proposed elimination of the requirement that prescribers enroll in Medicare in order to prescribe Part D drugs.     As previously explained in this proposed rule, approximately 420,000 prescribers have yet to enroll in Medicare via the CMS-855O application (OMB 0938-1135). We estimate that it would take 0.5 hours for a prescriber to complete a CMS-855O application. This is based on the following assumptions:      A medical secretary would take 0.42 hours to prepare the application.      A physician would take 0.08 hours to review and sign the application.     This would result in a per application cost of $30.32 ((0.42 hours x $33.70) + (0.08 hours x $202.08). Multiplying this figure by 420,000 applications results in a total savings of $12,734,400. We believe that these savings would accrue in 2019. (3) Net Costs and Savings     We believe that a result of our proposed elimination of the Part D

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enrollment requirement, the following net savings for prescribers would ensue:

                                           Table 20--Net Costs/Savings                                                      [In $] ----------------------------------------------------------------------------------------------------------------                                                        2019            2020            2021       3-year average ---------------------------------------------------------------------------------------------------------------- Costs...........................................      $9,310,548         $48,829         $48,829      $3,136,069 Savings.........................................      12,734,400               0               0       4,244,800 Net \*...........................................       3,423,852        (48,829)        (48,829)       1,108,731 ---------------------------------------------------------------------------------------------------------------- \* Net costs denoted in parentheses.

b. Preclusion List Requirements for Part C     As previously explained in this proposed rule, approximately 120,000 MA providers and suppliers have yet to enroll in Medicare via the CMS-855 application. Of these providers and suppliers, and based on internal CMS statistics, we estimate that 90,000 would complete the CMS-855I (OMB No. 0938-0685), which is completed by physicians and non- physician practitioners; 24,000 would complete the CMS-855B (OMB control number 0938-0685), which is completed by certain Part B organizational suppliers; and 6,000 would complete the CMS-855A (OMB No. 0938-0685), which is completed by Part A providers and certain Part B certified suppliers. Therefore, we believe that savings would accrue for providers and suppliers from our proposed elimination of our MA/ Part C enrollment. Table 21 estimates the burden hours associated with the completion of each form.

                                      Table 21--CMS-855 Application Burden ----------------------------------------------------------------------------------------------------------------                                      Number of                                     Hours for an                                   respondents no     Hours for      Hours for a     authorized          Submission type              longer       completion by   physician to     official to     Total hours                                     required to       office        review and      review and    for completion                                       enroll         personnel         sign            sign ---------------------------------------------------------------------------------------------------------------- CMS-855I........................          90,000             2.5             0.5             n/a               3 CMS-855B........................          24,000               4             n/a               1               5 CMS-855A........................           6,000               5             n/a               1               6 ----------------------------------------------------------------------------------------------------------------

    In projecting the savings involved, we assume a medical and health services manager would serve as the provider's or supplier's ``authorized official'' and would sign the CMS-855A or CMS-855B application on the provider's or supplier's behalf.     Therefore, we project the following total hour and cost burdens:      CMS-855I: We estimate a total reduction in hour burden of 270,000 hours (90,000 applicants x 3 hours). With the cost of each application processed by a medical secretary and physician as being $185.29 (($33.70 x 2.5 hours) + ($202.08 x 0.5 hours)), we estimate a savings of $16,676,100 (90,000 applications x $185.29).      CMS-855B: We estimate a total reduction in hour burden of 120,000 hours (24,000 applicants x 5 hours). With the cost of each application processed by a medical secretary and signed off by a medical and health services manager as being $239.96 (($33.70 x 4 hours) + ($105.16 x 1 hour)), we estimate a total savings of $5,759,040 (24,000 applications x $105.16).      CMS-855A: We estimate a total reduction in hour burden of 36,000 hours (6,000 applicants x 6 hours). With the cost of each application processed by a medical secretary and signed off by a medical and health services manager as being $273.66 (($33.70 x 5 hours) + ($105.16 x 1 hour)), we estimate a total savings of $6,567,840 (24,000 applications x $273.66).     Given the foregoing, we estimate that providers and suppliers would experience a total reduction in hour burden of 426,000 hours (270,000 + 120,000 + 36,000) and a total cost savings of $32,102,980 ($9,667,660 + $5,759,040 + $16,676,100). We expect these reductions and savings to accrue in 2019 and not in 2020 or 2021. Nonetheless, over the OMB 3- year approval period of 2019-2021, we expect an annual reduction in hour burden of 142,000 hours and an annual savings of $10,700,933 ($32,102,800/3) under OMB Control No. 0938-0685.     We also propose to revise Sec.  422.310 to add a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance. We do not expect any additional burden from this particular proposal, for this activity is consistent with existing policy. 13. ICRs Regarding the Part D Tiering Exceptions ((Sec. Sec.  423.560 and Sec.  423.578(a) and (c))     In section II.A.9 of this rule, we are proposing various changes to Sec.  423.578(a) and (c) related to the requirements for tiering exceptions criteria that Part D plan sponsors are required to establish. These changes include establishing a revised framework for treatment of tiering exception requests based on whether the requested drug is a brand name or generic drug or biological product, and where the same type of drug alternatives are located on the plan's formulary. The proposed changes also include clarification of appropriate cost- sharing assigned to approved tiering exception requests when preferred alternative drugs are on multiple lower-cost tiers. At the coverage determination level, if a plan issues a decision that is partially or fully adverse to the enrollee, it is already required to send written notice of that decision. The existing requirement to send written notice of an adverse coverage determination would

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not change under the proposed changes related to tiering exceptions. We do not expect the proposed changes to significantly impact the overall volume or the approval rate of tiering exceptions requests, which represent a consistently low percentage of total request volume.     While the requirement to send a written denial notice is subject to the PRA, the requirement and burden are currently approved by OMB under control number 0938-0976 (CMS-10146). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number. 14. ICRs Regarding the Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (Sec.  423.153(f))     As discussed in section of this rule, proposed Sec.  423.153(f) would implement provisions of section 704 of CARA, which allows Part D plan sponsors to establish a drug management program that includes ``lock-in'' as a tool to manage an at-risk beneficiary's access to coverage of frequently abused drugs. Part D plan sponsors would be required to notify at-risk beneficiaries about their plan's drug management program. Part D plan sponsors are already expected to send a notice to some beneficiaries when the sponsor decides to implement a beneficiary-specific POS claim edit for opioids (OMB under control number 0938-0964 (CMS-10141)). However, the OMB control number 0938- 0964 only accounts for the notices that are currently sent to beneficiaries who have a POS edit put in place to monitor opioid access (which would count as the initial notice described in the preamble and defined in Sec.  423.153(f)(4)) and would not capture the second notice that at-risk beneficiaries would receive confirming their determination as such or the alternate second notice that potentially at-risk beneficiaries would receive to inform them that they were not determined to be at risk.     Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. Given that there has not been a steady increase or decrease in edits, we have used the average, 923 edits annually, to assess burden under this rule. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber ``lock-in'' to OMS, to approximately 1,846 such limitations, we estimate 3,693 initial, and second notices (number of limitations (1,846) multiplied by the number of notices (2)) total corresponding to such edits/limitations. We estimate it would take an average of 5 minutes (0.083 hours) at $39.22/ hour for an insurance claim and policy processing clerk to prepare each notice. We estimate an annual burden of 307 hours (3,693 notices x 0.083 hour) at a cost of $12,040.54 (307 hour x $39.22/hour).     Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations, based on plan year 2017 plan participation) would be subject to this requirement. We estimate that it will take on average 5 hours at $81.90/hour for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total; not per document). This would result in a total burden of 1,095 hours (5 hours x 219 sponsors) at a cost of $89,680.50 (1,095 hour x $81.90/hour).     In aggregate, the burden to upload and prepare these additional notices is 1,402 hours (307 hours + 1,095 hours) at a cost of $101,721 ($12,040 + $89,681).     Proposed revisions to Sec.  423.38(c)(4) would limit the SEP for dual- or other LIS-eligible individuals who are identified as a potential at-risk beneficiary subject to the requirements of a drug management program, as outlined in Sec.  423.153(f). As already codified in Sec.  423.38(c)(4), this proposed SEP limitation would be extended to ``other subsidy-eligible individuals'' so that both full and partial subsidy individuals are treated uniformly. Once an individual is identified as a potential at-risk beneficiary, that individual will not be permitted to use this election period to make a change in enrollment.     Contingent with a Part D sponsor opting to implement a drug management program, Part D sponsors will identify, and submit to CMS, an individual's ``potential'' at-risk status and, if applicable, confirmed at-risk status. The Part D sponsor will include notification of the limitation of the duals' SEP in the required notice to the beneficiary that he or she has been identified as a potential at-risk beneficiary.     Therefore, the burden associated with the notification of the inability to use the duals' SEP is covered under the previous statement of burden.     Furthermore, we are proposing to codify that an at-risk beneficiary will have an election opportunity if their dual- or LIS-eligible status changes, that is, if they gain, lose or have a change in the level of the subsidy assistance. Also, if a beneficiary is eligible for another election period (for example, AEP, OEP, or other SEP), this SEP limitation would not prohibit the individual from making an election. This proposed provision, by creating a limitation for dually- and other LIS-eligible at-risk beneficiaries after the initial notification, would decrease sponsor burden in processing disenrollment and enrollment requests for dual- and LIS-eligible beneficiaries who wish to change plans.     We estimate that 1,846 beneficiaries would meet the criteria proposed to be identified as an at-risk beneficiary and have a limitation implemented. About 76 percent of the 1,846 beneficiaries are estimated to be LIS. Approximately 10 percent of LIS-eligible enrollees use the duals' SEP to make changes annually. Thus we estimate, at most, 140 changes per year (1,846 beneficiaries x 0.76 x 0.1) will no longer take place because of the proposed duals' SEP limitation. There are currently 219 Part D sponsors. This amounts to an average of 0.6 changes per sponsor per year (140 changes/219 sponsors). In 2016, there were more than 3.5888 Part D plan switches, and as such, a difference of 0.6 enrollments or disenrollments per sponsor will not impact the administrative processing infrastructure or human resources needed to process enrollments and disenrollments. Therefore, there is no change in burden for sponsors to implement this component of the provision.     We are proposing that reviews of at-risk determinations made under the processes at Sec.  423.153(f) be adjudicated under the existing Part D benefit appeals process and timeframes set forth in part 423 Subparts M and U. Consistent with existing rules for redeterminations, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the notice of the determination to make such request, must affirmatively request IRE review of an adverse plan level appeal decision made under a plan sponsor's drug management program, and would have rights to an expedited redetermination. Revisions to regulations in part 423 Subparts M (Sec. Sec.  423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, and 423.638) and U (Sec. Sec.  423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122 and 423.2126) are being proposed to account for reviews of at-risk determinations. The filing of an appeal is an information collection requirement that is associated with an administrative action pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). Consequently, the

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burden for preparing and filing the appeal is exempt from the requirements and collection burden estimates of the PRA; however, the burden estimate for appeals is included in the regulatory impact analysis.     In aggregate, these components of this provision would result in an annual net cost of $101,012.     The aforementioned requirements and burden, excluding beneficiary appeals, will be submitted to OMB for approval under control number 0938-0964 (CMS-10141).

                               Table 22--Estimated Burden for the CARA Provisions                                                    [In hours] ----------------------------------------------------------------------------------------------------------------                                                        2019            2020            2021       3-year average ---------------------------------------------------------------------------------------------------------------- Preparation and Upload Notices..................           1,402               0               0           467.3 SEP Limitation..................................               0               0               0               0 Appeals.........................................             N/A             N/A             N/A             N/A                                                  ---------------------------------------------------------------     Total.......................................           1,402               0               0           467.3 ----------------------------------------------------------------------------------------------------------------

                               Table 23--Estimated Burden for the Cara Provisions                                                      (In $) ----------------------------------------------------------------------------------------------------------------                                                                                                       3-Year                                                        2019            2020            2021           average ---------------------------------------------------------------------------------------------------------------- Preparation and Upload Notices..................        $101,012              $0              $0       $33,670.7 SEP Limitation..................................               0               0               0               0 Appeals.........................................             N/A             N/A             N/A             N/A                                                  ---------------------------------------------------------------     Total.......................................         101,012               0               0        33,670.7 ----------------------------------------------------------------------------------------------------------------

C. Summary of Proposed Information Collection Requirements and Burden

                                           Table 24--Proposed Annual Recordkeeping and Reporting Requirements --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                                                 Total  Regulatory section(s) in title 42 of   OMB control                                                             annual    Labor cost  of    Total cost                 the CFR                    No. \*       Respondents      Responses     Burden per  response      burden       reporting          ($)                                                                                                                (hours)        (hours) -------------------------------------------------------------------------------------------------------------------------------------------------------- 422.60, 422.62, 422.68, 423.38, and       0938-0753             468         558,000  5 min.................       46,500          $69.08      $3,212,220  423.40 eligibility determination. 422.60, 422.62, 422.68, 423.38, and       0938-0753             468         558,000  1 min.................        9,300           69.08         642,444  423.40 notification. 422.60, 422.62, 422.68, 423.38, and       0938-0753             468         558,000  1 min.................        9,300           69.08         642,444  423.40 report to CMS. 422.60, 422.62, 422.68, 423.38, and       0938-0753             468         558,000  5 min.................       46,500           34.66       1,606,110  423.40 record keeping. 422.152 QIP...........................    0938-1023             468           (750)  (15 min)..............        (188)           67.54        (12,664) 422.2260 and 423.2260 marketing           0938-1051             805        (67,061)  (30 min)..............     (26,959)           69.08     (1,862,397)  materials. 422.2460 and 423.2460 MLR reporting...    0938-1232             587           (587)  (11 hr)...............      (6,457)          140.14       (904,884) 423.120(c)(6) create model notices....    0938-0964             212             212  3 hr..................          636           69.08          43,935 423.120(c)(6) 2019 prepare and            0938-0964             212          80,000  0.083 hr..............        6,640           39.22         260,421  distribute the notices. 423.120(c)(6) 2020 and 2021 prepare       0938-0964             212          15,000  0.083 hr..............        1,245           39.22          48,829  and distribute the notices. 423.153(f) notice preparation.........    0938-0964             219           3,693  0.083 hr..............          307           39.22          12,041 423.153(f) notice upload..............    0938-0964             219           3,693  5 hr..................        1,095           81.90          89,681 423.153(f) contract: Part D plan          0938-0964              31              31  10 hr.................          310          134.50          41,695  sponsors. 423.153(f) contract: MA-PDs...........    0938-0964             188             188  20 hr.................        3,760          134.50         505,720                                        -----------------------------------------------------------------------------------------------------------------     Subtotal: Private Sector Burden...  ...........             805       2,266,419  varies................       91,989          varies       4,325,595                                        ----------------------------------------------------------------------------------------------------------------- 422.62, 423.38, and 423.40 complete       0938-0753      18,600,000         558,000  30 min................      279,000            7.25       2,022,750  enrollment.                                        -----------------------------------------------------------------------------------------------------------------

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      Subtotal: Burden on Beneficaries..  ...........      18,600,000         558,000  30 min................      279,000            7.25       2,022,750                                        ----------------------------------------------------------------------------------------------------------------- 422.111(a)(3) and (h)(2)(ii) and          0938-1051             n/a    (32,026,000)  n/a...................          n/a             n/a    (24,019,500)  423.128(a)(3) EOC paper. 422.111(a)(3) and (h)(2)(ii) and          0938-1051             n/a    (32,026,000)  n/a...................          n/a             n/a    (24,019,500)  423.128(a)(3) EOC toner. 422.111(a)(3) and (h)(2)(ii) and          0938-1051             n/a    (32,026,000)  n/a...................          n/a             n/a     (6,629,382)  423.128(a)(3) EOC mailing.                                        -----------------------------------------------------------------------------------------------------------------     Subtotal: Non-Labor Burden........  ...........             n/a    (32,026,000)  n/a...................          n/a             n/a    (54,668,382)                                        -----------------------------------------------------------------------------------------------------------------         Total.........................  ...........      18,600,805    (29,201,581)  varies................      370,989          varies    (48,320,037) -------------------------------------------------------------------------------------------------------------------------------------------------------- \* OMB control numbers and corresponding CMS ID numbers: 0938-0753 (CMS-R-267), 0938-1023 (CMS-10209), 0938-1051 (CMS-10260), 0938-1232 (CMS-10476), and   0938-0964 (CMS-10141).

D. Submission of PRA-Related Comments

    We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.     To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS' Web site at Web site address at [*https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*](https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html), or call the Reports Clearance Office at 410-786-1326.     We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the ADDRESSES section of this proposed rule and identify the rule (CMS-4182-P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.     See the DATES and ADDRESSES sections of this proposed rule for further information.

V. Regulatory Impact Analysis

A. Statement of Need

    This proposed rule approaches to improve the quality, accessibility and affordability of the Medicare Part C and Part D programs and to improve the CMS customer experience. While satisfaction with these programs remain high, these proposals are responsive to input we received from stakeholders while administering the program, as well as through a Request for Information process earlier this year. Additionally, this regulation includes a number of provisions that will help address the opioid epidemic and mitigate the impact of increasing drug prices in the Part D program.

B. Overall Impact

    We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), Section 1102(b) of the Social Security Act, Section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).     The Regulatory Flexibility Analysis (RFA), as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.     The health insurance industry was examined in depth in the RIA prepared for the proposed rule on establishment of the MA program (69 FR 46866, August 3, 2004). It was determined, in that analysis, that there were few, if any, ``insurance firms,'' including HMOs that fell below the size thresholds for ``small'' business established by the Small Business Administration (SBA). We assume that the ``insurance firms'' are synonymous with health plans that conduct standard transactions with other covered entities and are, therefore, the entities that will have costs associated with the new requirements finalized in this rule. At the time the analysis for the MA program was conducted, the market for health insurance was and remains, dominated by a handful of firms with substantial market share.     However, we estimate that the costs of this rule on ``small'' health plans do not approach the amounts necessary to be a ``significant economic impact'' on firms with revenues of tens of millions of dollars. Therefore, this rule would not have a significant economic impact on a substantial number of small entities.     In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule or regulation proposed under Title XVIII, Title XIX, or Part B of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.     Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $148 million or more.     Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final

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rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.     If regulations impose administrative costs on MA Plans and Part D Sponsors, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. There are currently 468 MA plans and Part D Sponsors.     We assume each plan will have one designated staff member who will read the entire rule.     Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits ([*https://www.bls.gov/oes/2016/may/naics4\_621100.htm*](https://www.bls.gov/oes/2016/may/naics4_621100.htm)). Assuming an average reading speed, we estimate that it would take approximately 15.6 hours for each person to review this proposed rule. For each MA plan that reviews the rule, the estimated cost is therefore, $1,640 (15.6 hours x $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $767,520 ($1,640 x 468 reviewers).     In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

C. Anticipated Effects

1. CARA Provisions     Proposed Sec.  423.153(f) would implement provisions of section 704 of CARA, which allows Part D plan sponsors to establish a drug management program that includes ``lock-in'' as a tool to manage an at- risk beneficiary's access to coverage of frequently abused drugs.     Under CARA, potentially at-risk beneficiaries are to be identified under guidelines developed by CMS with stakeholder input. Also, the Secretary must ensure that the population of at-risk beneficiaries can be effectively managed by Part D plans. CMS considered a variety of options as to how to define the clinical guidelines. We provide the estimated population of potential at-risk beneficiaries under different guidelines that take into account that the beneficiaries may be overutilizing opioids, coupled with use of multiple prescribers and/or pharmacies to obtain them, based on retrospective review, which makes the population appropriate to consider for ``lock-in'' and a description of the various options. We note that the measurement year for the estimates was 2015.     For background, the current Part D Opioid Overutilization policy and Overutilization Monitoring System (OMS) has been successful at reducing high risk opioid overutilization. Under this policy, plans retrospectively identify beneficiaries at high risk of an adverse event due to opioids and use of multiple prescribers and pharmacies. CMS created the OMS to monitor plans' effectiveness in complying with the policy. The OMS criteria incorporate the CDC Guideline for Prescribing Opioids for Chronic Pain (March 2016) (CDC Guideline) to identify beneficiaries who are possibly overutilizing opioids and are at high risk but the CDC Guideline is not a prescribing limit. CDC identifies 50 Morphine Milligram (MME) as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME.     Plans are expected to perform case management for each beneficiary identified in OMS and respond using standardized responses. If viewed as helpful by a prescriber, plans may implement a beneficiary-specific claim edit at the point-of-sale to prevent coverage of opioids outside of the amount deemed medically necessary by the prescriber. Plans may also implement an edit in the absence of prescriber response to case management.

                             Table 25--Guidelines To Identify At-Risk Beneficiaries ----------------------------------------------------------------------------------------------------------------   ---------------------------------------------------------------------------------------------------------------- Option                                  Average MME        Number of opioid prescribers and     Estimated number                                                              opioid dispensing pharmacies        of potentially                                                                                                   at-risk Part D                                                                                                    beneficiaries ---------------------------------------------------------------------------------------------------------------- 1................................  >=90................                 4+                 4+             33,053                                    >=90................                 6+                 1+ 2................................  >=90................                 4+                 4+             52,998                                    >=90................                 5+                 1+ 3................................  >=90................                 3+                 3+            103,832                                    >=90................                 5+                 1+ 4................................  >=90................                 3+                 3+            152,652                                    >=90................                 4+                 1+ 5................................  >=90................                 3+                 3+            319,133                                    >=90................                 3+                 1+ ----------------------------------------------------------------------------------------------------------------                                         Average MME         Number of opioid prescribers or     Estimated number                                                              opioid dispensing pharmacies        of potentially                                                                                                   at-risk Part D                                                                                                    beneficiaries ---------------------------------------------------------------------------------------------------------------- 6................................  >=50................                 5+                 5+            153,880                                    Any MME level.......                 7+                 7+ ----------------------------------------------------------------------------------------------------------------

    Under Option 1, CMS would propose to integrate the CARA lock-in provisions with our current Part D Opioid Overutilization Policy/ Overutilization Monitoring System (OMS). We will propose to initially define frequently abused drugs as all and only opioids for the treatment of pain. The guidelines to identify at-risk beneficiaries would be the current Part D OMS criteria finalized for 2018 after stakeholder input. Plans that adopt a drug management program would have to engage in case management of the opioid use of all enrollees who meet these criteria, which would be reported through OMS and plans must provide a response for each case. The estimated number of potential

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at-risk beneficiaries in 2019 using Option 1 is 33,053. Option 1 would allow plans to use pharmacy/prescriber lock in as an additional tool to address the opioid overutilization of identified at-risk beneficiaries.     Option 2, 3, 4, and 5 are operationally the same as Option 1, including 90 MME, but would identify approximately 52,998 to 319,133 beneficiaries in 2019 due to different clinical guidelines related to the number of opioid prescribers and opioid dispensing pharmacies. These options would result in up to 10 times the program size compared to Option 1.     Finally, under Option 6, the guidelines to identify potentially at- risk beneficiaries would not be fully integrated into our current OMS criteria. This option would identify beneficiaries whose opioid use is at the 50 MME level instead of 90, and the estimated number of potentially at-risk beneficiaries in 2019 is 153,880. Of these, approximately 29,000 would meet these criteria and the current OMS criteria. We seek comment on proposed Option 1 or if any of the alternative options may be currently viewed as manageable for Part D sponsors to implement.     In addition, while these criteria would identify far more potentially at-risk beneficiaries, we may have to implement these options in a way that plans that adopt a drug management program would not have to review the opioid use of all enrollees who meet these criteria. This would mean a change in the structure of the successful OMS or a separate administrative structure for prescription drug management programs.     As noted in section II. of this rule, we have chosen to propose Option 1. This approach is a cautious approach for the initial implementation year of the CARA ``lock-in'' provisions. We believe these provisions will result in the following savings to the program.     We estimate that the CARA provisions would result in a net savings of $10 million (the estimated savings of $13 million less the total estimated costs of $2,836,651 = $10,163,349, rounded to the nearest million) in 2019. The following are details on each of these savings.     We assume, based on past experience with OMS, that about 61 percent of at-risk beneficiaries may reduce prescriptions for frequently abused drugs and will no longer meet the clinical criteria. This means that prescriber and pharmacy lock-in would impact the remaining 39 percent of at-risk beneficiaries or 39 percent x 33,000 at-risk beneficiaries = 12,870 at-risk beneficiaries. We estimate that the average number of scripts per year on frequently abused drugs for those at-risk beneficiaries is about 48 and the average cost per script is about $106 in 2016. Our data show that those beneficiaries who would meet the proposed criteria for identification as an at-risk beneficiary and have a limitation placed on their access to opioids, have 4 opioids scripts per month on average. OACT anticipates between 10 and 30 percent reduction in prescriptions for frequently abused drugs would be possible through drug management programs and picked the average, 20 percent. Therefore, we believe there could be a 20 percent reduction in the prescriptions for frequently abused drugs for those 12,870 beneficiaries, resulting in a projected savings of about $13 million to Medicare in 2019.     Part D plan sponsors would also be required to send at-risk beneficiaries multiple notices to notify them of about their plan's drug management program. Part D plan sponsors are already expected to send a notice to some beneficiaries when the Part D plan sponsors decide to implement a beneficiary-specific POS claim edit for opioids. Therefore, we anticipate limited additional burden for Part D plan sponsors to send certain at-risk beneficiaries an additional notice to indicate their lock-in status.     Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. That results in approximately 923 edits annually. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber ``lock-in'' to OMS, to approximately 1,846 such limitations, we estimate 3,692 initial and second notices (number of limitations (1,846) multiplied by the number of notices (2)) total corresponding to such edits/limitations. For purposes of this estimate, we assume that all beneficiaries who receive initial notices will be placed on an access limitation. We estimate it would take an average of 5 minutes (0.083 hours) at $39.22/hour for an insurance claim and policy processing clerk to prepare each notice. The burden of 307 hours (3,692 notices x 0.083 hour) at a cost of $12,040.54 (307 hour x $39.22/hr) in 2019 was estimated in section III of this rule.     Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations) will be subject to this requirement. We estimate that it will take on average 5 hours at $81.90/hour for a computer programmer to upload the notices into their claims systems. This would result in a total burden of 1,095 hours (5 hours x 219 sponsors) at a cost of $89,680.50 (1,095 hour x $81.90/hr). In aggregate, the burden to prepare and upload these additional notices was estimated as 1,402 hours (307 hours + 1,095 hours) at a cost of $101,721 ($12,040 + $89,681) in 2019 in section III. of this proposed rule.     Part D plan sponsors may also renegotiate the contracts with network pharmacies and network prescribers in the case of MA-PDs. For Part D plan sponsors that contract with pharmacies only, we estimate it would take 10 hours at $134.50/hour for lawyers to conduct the PDP contract negotiations with network pharmacies. Considering 31 sponsors we estimate a total burden of 310 hours at a cost of $41,695 (310 hour x $134.50/hour). For MA-PDs who also contract with prescribers, we estimate that the annual burden for negotiating a contract with network providers who can prescribe controlled substances to be 3,760 hours (188 MA-PDs x 20 hours per sponsor) at a cost of $505,720 (3,760 hour x $134.50/hour). The total estimated burden associated with the contract negotiations from both PDP and MA-PD sources in 2019 was estimated as 4,070 hours (310 hours + 3,760 hours) at a cost of $547,415 ($41,695 + $505,720).     We estimate that, in order to implement pharmacy or prescriber lock-in, Part D plan sponsors would have to program edits into their pharmacy claims systems so that once they restrict an at-risk beneficiaries' access to coverage for frequently abused drugs through applying pharmacy or prescriber lock-in, claims at a non-selected pharmacies or associated with prescriptions for frequently abused drugs from non-selected prescribers would be rejected. We believe that most Part D plan sponsors with Medicaid or private lines of business will have existing lock-in programs in those lines of business to pull efficiencies from. We estimate it would take a total number of 26,280 labor hours across all 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations) at a wage of $81.90 an hour for computer programmers to program these edits into their existing systems. Thus, the total cost to program these edits is 26,280 hours x $81.90 = $2,152,332.     The right of an enrollee to appeal an at-risk determination will also have an associated cost. As explained, we estimate a total hourly burden of 178

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hours at an annual estimated cost of $35,183 in 2019. As previously discussed, we estimate that 1,846 beneficiaries would meet the criteria for being identified as an at-risk beneficiary. Based on validated program data for 2015, 24 percent of all adverse coverage determinations were appealed to level 1. Given the nature of drug management programs, the extensive level of case management conducted by plans prior to making the at-risk determination, and the opportunity for an at-risk beneficiary to submit preferences to the plan prior to lock-in implementation, we believe it is reasonable to assume that this rate of appeal will be reduced by at least 50 percent for at-risk determinations made under a drug management program. Therefore, this estimate is based on an assumption that about 12 percent of the beneficiaries estimated to be subject to an at-risk determination (1,846) will appeal the determination. Hence, we estimate that there will be 222 level 1 appeals (1,846 x 12 percent). We estimate it takes 48 minutes (0.8 hours) to process a level 1 appeal. There is a statutory requirement that a physician with appropriate expertise make the determination for an appeal of an adverse initial determination based on medical necessity. Thus, we estimate an hourly burden of 178 hours (222 appeals x 0.8) at a cost of $197.66 per hour for physicians to perform these appeals. Thus the total cost in 2019 is estimated as $35,183 = 178 hours x $197.66     In aggregate, this provision would result in a net savings of $13 million - ($101,721 + $547,415 + $2,152,332 + $35,183) = $13 million - $2,836,651 = $10,163,349 (or $10,000,000 if rounded to nearest million) in 2019. 2. Reducing the Burden of the Compliance Program Training Requirements (Sec. Sec.  422.503 and 423.504)     The proposed provision would amend the regulation so that first- tier, downstream and related entities (FDR) no longer are required to take the CMS compliance training, which lasts 1 hour, and so that MA organizations and Part D sponsors no longer have a requirement to ensure that FDRs have compliance training. However, it is still the sponsoring organization's responsibility to manage relationships with its FDRs and ensure compliance with all applicable laws, rules and regulations. Furthermore, we would continue to hold sponsoring organizations accountable for the failures of its FDRs to comply with Medicare program requirements.     We believe that by ***deleting*** this provision we will reduce burden for sponsoring organizations and their FDRs. We estimate that the burden reduction will be roughly 1 hour for each FDR employee who would be required to complete the CMS training on an annual basis, under the current regulation at Sec. Sec.  422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). We do not know how many employees were required to take the CMS training, nor do we know the exact numbers of FDRs that were subject to the requirement. Sponsoring organizations have discretion in not only which of their contracted organizations meet the definition of an FDR, but also discretion in which employees of that FDR are subject to the training. But we know from public comments that PBMs, hospitals, pharmacies, labs, physician practice groups and even some billing offices were routinely subjected to the training. Unfortunately, the Medicare Learning Network (MLN) Matters[supreg] Web site is not able to track the number of people that took CMS' training, so we cannot use that as a data source. CMS has reviewed the Organization for Economic Co-operation and Development's (OECD) 2015 statistics which show a total of 20,076,000 people employed in the health and social services fields in the United States, although certainly not all of them were subject to CMS' training requirement (See [*http://stats.oecd.org/index.aspx?DataSetCode=HEALTH\_STAT*](http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT)). Hospitals are one sector of the health industry that has been particularly vocal about the burden the current training requirement has placed on them and their staff. If we use hospitals as an example to estimate potential burden reduction, the OECD Web site states that there are 5,627 hospitals in the United States, employing 6,210,602 people. That is an average of 1,103 people per hospital. There are approximately 4,800 hospitals registered with Original Medicare. If we assume that each one of those hospitals holds at least one contract with a M A health plan and all of their employees were subjected to the training (4,800 x 1,103 x 1 hour) that is 5,294,400 hours of burden that would be eliminated by this proposal. If we add pharmacists, pharmacy technicians, billing offices, physician practice groups, we would expect further burden reduction. OECD has data for a few more sectors of the industry, including 295,620 pharmacists, 3,626,060 nurses and 820,251 physicians in the United States. Many of the physicians and nurses are likely represented in the 6 million employed by hospitals. Unfortunately we don't have data sources for all sectors of the industry. However, using hospital staff as a starting point and OECD's total figure of 20 million working in the health and social service fields, we estimate the burden reduction is likely 6 to 8 million hours each year. Again, we have no way to determine exactly how many FDRs there are or exactly how many staff would be expected to take the training under the current regulation, but we hope this example demonstrates the reduction in burden this proposal would mean for the industry. We request comment that would allow for more complete monetization of cost savings in the analysis of the final rule.     Although sponsors must still monitor FDRs and implement corrective actions when mistakes are found, we believe that they are currently already doing this. Therefore no additional burden complementing the reduction in burden is anticipated from this proposal to eliminate the CMS training. 3. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (Sec. Sec.  422.254 and 422.256)     For CY 2018 bids, 2,743 non-D-SNP non-employer plans (that is, HMO, HMO-POS, Local PPO, PFFS, and RPPO) used in house and/or consulting actuaries to address the meaningful difference requirement based on CY 2018 bid information. The most recent Bureau of Labor Statistics report states that actuaries made an average of $54.87 an hour in 2016, and we estimate that 2 hours per plan are required to fully address the meaningful difference requirement. The estimated hours are based on assumptions developed in consultation with our Office of the Actuary. We additionally allow 100 percent for benefits and overhead costs of actuaries, resulting in an hourly wage of $54.87 x 2 = $109.74 Therefore, we estimate a savings of 2 hours per plan x 2,743 plans = 5,486 hours reduction in hourly burden with a savings in cost of 5,486 hours x $109.74 = $602,033.64, rounded down to $0.6 million to be saved annually under this proposal.     The number of plan bids received by CMS may increase because of a variety of factors, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. However, CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but do not believe the number of similar plan options offered by the same MA organization in each county will necessarily increase significantly or create more confusion in beneficiary decision-making related specifically to

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the number of plan options. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision- making should help beneficiaries, caregivers, and family members make informed plan choices.     CMS does not believe this proposed change will have a significant impact on health care providers. The number of plans offered by organizations in each county are not expected to increase significantly as a result of this change and health care provider contracts with MA organizations typically include all of the organization's plans rather than having separate contracts for each plan. In addition, CMS does not expect a significant increase in time spent in bid review as a direct result of eliminating meaningful difference nor increased provider burden. 4. Physician Incentive Plans--Update Stop-Loss Protection Requirements (Sec.  422.208)     Some physician contracts with MA organizations provide that the MA organization pay the physician a capitated amount to assume financial responsibility for services (for example, hospital costs) that they do not personally render. CMS refers to capitations to physicians that include services the physicians do not render as ``global capitation.'' When physicians are globally capitated to the extent that they can lose more than 25 percent of their income, they are required to be covered by stop-loss insurance. We propose to replace the current insurance schedule in the regulation with updated stop-loss insurance requirements that would allow insurance with higher deductibles. The new schedule would result in a significant reduction to the cost of obtaining stop-loss insurance. The higher deductibles are consistent with the increase in medical costs due to inflation.     To determine the cost of different stop-loss insurance policies, we used claim distributions from original Medicare enrollees. Then, we assumed an average loading for administrative and profit of 20 percent. Using these assumptions, we estimate that plans and physicians would save an average of $100 per globally capitated member per year in total costs. The derivation of this $100 figure is as follows:     Under the current regulation at Sec.  422.208(f)(2)(iii), stop-loss insurance for the provider (at the MA organization's expense) is needed only if the number of members in the physician's group at global risk under the MA plan is less than 25,000. The average number of members in the under 25,000 group estimated under the current regulation is 6,000 members. Ideally, to obtain an average, we should weight the panel sizes in the chart at Sec.  422.208(f)(2)(iii) by the number of physician practices and the number of capitated patients per practice per plan. However, this information is not available. Therefore, we used the median of the panel sizes listed in the chart at Sec.   422.208(f)(2)(iii), which is about 8,000. Since the per member per year (PMPY) stop-loss premiums are greater for a smaller number of patients, we lowered this 8,000 to 6,000 to reflect the fact that the distribution of capitated patients is skewed to the left. We use this rough estimate of 6,000 for its estimates.     For these 6,000 members, the current regulation at Sec.   422.208(f)(2)(iii) (the chart) shows the physician needs stop-loss insurance for $37,000 in a combined attachment point (deductible). The $37,000 is obtained by using linear interpolation on the chart at Sec.   422.208(f)(2)(iii), replacing panel sizes with midpoints of ranges and rounding to the nearest 1,000. To find the premium for a stop-loss insurance with a deductible of $37,000, we use Table 26, which reflects current insurance rates, that is, what would be charged today. By using linear interpolations on the columns with $30,000 and $40,000 and rounding to the nearest $1,000, we see that the PMPY premium for insurance with $37,000 combined attachment points is $2,000 PMPY. This $2,000 premium reflects the baseline charge today for a combined deductible of $37,000. BILLING CODE 4120-01-P

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    Next, we compute the premium under the proposed rule. We still assume an average of 6,000 capitated members. However, the proposed rule allows higher deductibles corresponding to medical inflation. By using linear interpolation on the columns headed with 50,000 and 60,000 combined attachment points and rounding. We see that a deductible (combined attachment point) of $57,000 corresponds to 6,000 capitated members and a premium of $1,500 PMPY.     The savings in premium between using Sec.  422.208(f)(iii) to calculate deductibles (combined attachment point) and using Table A to calculate deductibles is $2000 - $1500 = $500 PMPY. We assume that the average loading for profit and administrative costs is roughly 20 percent. So our PMPY savings is 20 percent x 500 = $100 PMPY. The remaining $500 - $100 = $400 in savings is on net benefits. That reduction does not produce any savings since the plans and physicians are simply trading claims for premiums.     In 2007, we estimated that 7 percent of enrollees were receiving services under capitated arrangements. Although we do not have more current data, based on CMS observation of managed care industry trends, we believe that the percentage is now higher, and we assume that 11 percent of enrollees are now paid under global capitation. There are currently 18.6 million MA beneficiaries. We estimate that about 18.6 million x 11 percent = 2,046,000 MA members are paid under some degree of global capitation. Thus, the total aggregate projected annual savings under this proposal is roughly $100 PMPY x 2,046,000 million beneficiaries paid under global capitation = $204.6 million.     The $204.6 million savings is removed from the plan bid, but not the CMS benchmark. If the benchmark exceeds the bid, Medicare pays the MA organization the bid (capitation rate and risk adjustment) plus a percentage of the difference between the benchmark and the bid, called the rebate. The rebate is based on quality ratings and allows Medicare to share in the savings to the plans; our experience with rebates shows that the average rebate is on the order of 2/3. We assumed that of the $204.6 million in annual savings, Medicare would save 35 percent x $204.6 million = $71,610,000, and the remaining 65 percent x $204.6 million = $132,990,000 would be paid to the plans. The plan portion of the savings we project for this proposal would fund extra benefits or possibly reduce cost sharing for plan members.     The figures for 2019 were updated for 2020 to 2023 using enrollment and inflation factors found in the CMS trustees report, accessible at: [*https://www.cms.gov/reportstrustfunds*](https://www.cms.gov/reportstrustfunds). 5. Changes to the Agent/Broker Requirements (Sec. Sec.  422.2272(e) and 423.2272(e))     We propose to ***delete*** the limitation placed on MA organizations and Part D sponsors as to how they can respond to an agent/broker who has become unlicensed. We propose to ***delete*** a requirement that the MA plan or Part D plan terminate an unlicensed agent or broker and contact beneficiaries to notify them if they had been enrolled by the unlicensed agent or broker. We already require MA organizations and Part D sponsors to use only licensed agents/brokers. We have established the requirement to have a licensed agent or broker in a 2008 final rule (73 FR 54219). That burden assessment is not changing due to the proposal to remove paragraph (e) from these sections. The impact analysis for the specific provision at paragraph (e) of Sec. Sec.  422.2272 and 423.2272 was established in rule-making in April 2011 (76 FR 21534). As for the impact of review and compliance activities that remain to plans after removing the narrow scope of compliance actions available to MA organizations and Part D sponsors, we do not believe this change would have a significant increase in burden or financial impact. Removing this requirement allows state Department of Insurance (DOI) requirements to take precedence in this situation. While some MA organizations and Part D sponsors may choose to make operational changes to ensure compliance, these changes are not based on this rule, but are required to meet existing requirements. 6. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage     We propose to revise our regulations at Sec.  422.66 to permit default enrollment of Medicaid managed care plan members into an MA special needs plan for dual eligible beneficiaries. Upon a Medicaid managed care plan member becoming eligible for Medicare, qualification for enrollment into the MA special needs plan for dual eligibles is contingent on the following:      State support for the default enrollment process, and      The organization's ability to identify such individuals at least 90 days in advance of their Medicare eligibility; and      To issue written notification of the enrollment a minimum of 60 days in advance.     Our proposal represents the partial codification of existing policy on seamless conversion enrollment that has been specified in subregulatory guidance for contract years 2006 and subsequent years, but with additional parameters and limits. Among the new limits proposed for seamless conversion default enrollments are allowing such enrollments only from the organization's Medicaid managed care plan into an integrated D-SNP and requiring facilitation from applicable state (in the form of a contract term and provision of data). This will result in the discontinuation of the use of the seamless conversion enrollment mechanism by some of the approved MA organizations. However, as this enrollment mechanism is voluntary and not required for participation in the MA program, we do not believe the proposed changes would have any impact to the Medicare Trust Funds. We invite comments on the potential impact of the proposed changes on MA organizations, Medicaid managed care plans and beneficiaries. 7. Restoration of the MA Open Enrollment Period (Sec. Sec.  422.60, 422.62, 422.68, 423.38 & 423.40)     We expect that increasing the amount of time that MA-enrolled individuals are given to switch plans will result in slightly more beneficiaries selecting plans that receive Quality-Bonus Payments (QBP). This assessment reflects our observation that beneficiaries tend to choose plans with higher quality ratings when given the opportunity. The projected costs to the Government by extending the open enrollment period for the first 3 months of the calendar year are $9 million for CY 2019, $10 million in 2020, $10 million in 2021, $11 million in 2022, and $12 million in 2023.     In order to estimate the additional costs for the projection window 2019-2023, we first made an assumption that approximately 24,600 MA- enrolled individuals will switch health plans from one without a QBP to one with a QBP during the extended open enrollment period. The 24,600 enrollee assumption was determined by using a combination of published research and by observing historical enrollment information. Published research\1\ shows that 10 percent of MA enrollees voluntarily switch MA plans and that MA enrollees who voluntarily switch plans change to plans with slightly higher star ratings than their original plan, with a modest improvement of

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0.11 stars, on average. The Office of the Actuary confirmed these findings by analyzing CMS enrollment data and provided further detail. We estimate that of the 10 percent of MA plan enrollees who switch plans, 15 percent move to a higher rated plan. Of those who go to a higher rated plan, we estimate 40 percent move from a non-QBP plan to a QBP plan. We also estimate that one-fifth of these enrollees would take advantage of the new open enrollment period.     We apply these assumptions to the estimated MA enrollment for 2019, 20,512,000, which can be obtained from the CMS Trustee's Report available at [*https://www.cms.gov/reportstrustfunds/*](https://www.cms.gov/reportstrustfunds/). We find that 24,600 (20,512,000 x 10 percent x 15 percent x 40 percent x 20 percent) people are expected to enroll in the proposed open enrollment period.     The $9 million in additional costs for 2019 was calculated by multiplying the 24,600 impacted enrollment by the expected 2019 bonus amount ($637.20). The Office of the Actuary experiences an average rebate percentage of 66 percent and an 86 percent backing out of the projected Part B premium. Hence, the net savings to the trust funds is estimated as $9 million = 24,600 enrollees x $637.20 (Bonus payment) x 66 percent (rebate percentage) x 86 percent (Reduction in Part B premium), rounding to $9 million.     Then, we applied trends from the Trustees Report to the 2019 estimate in order to project the costs for years 2020 to 2023. The data from the Medicare Payments to Private Health Plans, by Trust Fund (Table IV.C.2 of the 2017 Medicare Trustees Report) was used as the basis for the trends. The trend estimates are presented in the Table 27 that demonstrates the calculations and displays the cost estimates for each year 2019-2023.

                                             Table 27--Calculation of Net Costs to the Medicare Trust Funds                                                          for the Extended Open Enrollment Period --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                                                                              Net costs                                                             2019  Base     Trend  factor   Trend  factor   Trend  factor   Trend  factor    (rounded to                           Year                                 year            2020            2021            2022            2023           nearest                                                              (million)                                                                       million) -------------------------------------------------------------------------------------------------------------------------------------------------------- 2019....................................................               9  ..............  ..............  ..............  ..............               9 2020....................................................               9           1.078  ..............  ..............  ..............              10 2021....................................................               9           1.078           1.084  ..............  ..............              10 2022....................................................               9           1.078           1.084           1.089  ..............              11 2023....................................................               9           1.078           1.084           1.089           1.086              12 --------------------------------------------------------------------------------------------------------------------------------------------------------

8. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations     We believe the proposed changes will result in a reduction of burden to Part D plan sponsors since they will have additional time to adjudicate requests for payment. We also expect a reduction in burden for the independent review entity (IRE) since the additional time for Part D plan sponsors to process these requests will result in fewer untimely payment redeterminations that must be auto-forwarded to the IRE. Based on recent program data, about 2,000 retrospective payment redetermination cases are auto-forwarded to the Part D IRE each plan year. If the proposed 14-day timeframe for payment redeterminations is implemented, we estimate that about 75 percent of the payment redetermination cases that are currently auto-forwarded to the Part D IRE due to the plan not being able to meet the adjudication timeframe will not be auto-forwarded under the 14 day timeframe; the longer timeframe will afford Part D plan sponsors an additional 7 days to process a payment request, including obtaining necessary supporting documentation, and to notify the enrollee of its decision. As a result, overall plan sponsor burden will be reduced by not having to auto- forward about 1,500 payment redetermination cases to the Part D IRE in a given plan year and the Part D IRE's workload will be reduced by the same number of cases. We estimate that it takes Part D plan sponsors an average of 15 minutes (0.25 hours) to assemble and forward a case file to the IRE, for an estimated savings of 375 hours (1500 cases x 0.25 hours). Using an adjusted hourly wage of $34.66 based on the Bureau of Labor Statistics May 2016 Web site for occupation code 43-9199, ``All other office and administrative support workers,'' (based on a mean hourly salary of $17.33, which when multiplied by a factor of two to include overhead, and fringe benefits, resulting in $34.66 an hour) the total estimated savings to plans is $12,998 (375 hours x $34.66). Since the proposed changes involve requests for payment where the enrollee has already received the drug, we do not believe the proposed changes will impose undue burden on enrollees. 9. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE     The proposed changes at Sec.  422.590(f) would result in a slight reduction of burden to Part C plans by no longer requiring a Notice of Appeal Status for each case file forwarded to the IRE. The estimated savings of this proposed change is based on reduced plan administration costs. Using the number of partially and fully adverse cases, we estimate Part C plans forwarded 47,108 cases to the IRE in 2015. We estimate it will take 5 minutes (0.083 hours) to complete this notice. We used an adjusted hourly wage of $34.66 based on the Bureau of Labor Statistics May 2016 Web site for occupation code 43-9199, ``All other office and administrative support workers,'' which gives a mean hourly salary of $17.33, which when multiplied by a factor of two to include overhead, and fringe benefits, resulting in $34.66 an hour. Thus, the reduction in administrative time spent would be 0.083 hours x 47,108 cases = 3,926 hours with a consequent savings of 3,926 hours x $34.66 per hour = $136,064.     We do not believe the proposed change will adversely impact health plan enrollees. The notice we are proposing to eliminate is duplicative and enrollees will be notified by the IRE that their case was received by the IRE for review. 10. Revisions to Sec. Sec.  422 and 423 Subpart V, Communication/ Marketing Materials and Activities     CMS is proposing to narrow the definition of ``marketing materials'' under Sec. Sec.  422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. CMS believes the proposed definitions appropriately safeguard potential and current MA/PDP enrollees from inappropriate steering of beneficiary choice, while not including materials

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that pose little risk to current or potential enrollees and are not traditionally considered ``marketing.'' The proposed change would add text to Sec. Sec.  422.2260 and 423.2260 and provide a narrower definition than is currently provided for ``marketing materials.'' Consequently, this definition decreases the number of marketing materials that must be reviewed by CMS before use. Additionally, the proposal would more specifically outline the materials that are and are not considered marketing materials.     We believe the net effects of the proposed changes would reduce the burden to MA organizations and Part D Sponsors by reducing the number of materials required to be submitted to CMS for review.     In section IV.F of this proposed rule, we estimated the reduced burden to industry at $1.3 million. There is also a reduced burden to the federal government since CMS staff are no longer obligated to review these materials. Although all marketing materials are submitted for potential review by the MA plans to CMS, not all materials are reviewed, since some MA plans, because of a history of compliance, have a ``file and use'' status which exempts their materials from routine reviews. We estimate that only 10 percent of submitted marketing materials are reviewed by CMS staff. Consequently, the savings to the federal government is 10 percent x 1.3 million = 0.13 million. 11. Part C & D Star Ratings     There has been a recent trend in the number of enrollees that have moved from lower Star Ratings contracts that do not receive a Quality Bonus Payment (QBP) to higher rated contracts that do receive a QBP as part of contract consolidations. The proposal is to codify the methodology of the assigned Star Ratings and to add requirements addressing when contracts have consolidated. The methodology and measures being proposed here are generally from recent practice and policies finalized under the section 1853(b) of the Act Rate Announcement. With regard to consolidations, the Star Ratings assigned would be based on the enrollment weighted average of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. We believe that the proposal would dissuade many plans from consolidating contracts since it would be possible for some plans to lose QBPs under certain scenarios. If less contracts consolidate to higher Star Ratings, less QBPs would be paid to plans and this would result in Trust Fund savings.     In order to estimate the savings amounts for the projection window 2019-2023, we first observed the number of enrollees that have been impacted by contract consolidations for the prior 3 contract years (2016 through 2018) using a combination of bid and CMS enrollment/ crosswalk data. The number of enrollees observed are those that have moved from a non-QBP contract to a QBP contract and were found to be approximately 830,000 in 2016, 530,000 in 2017, and 160,000 in 2018. We assumed that the number of enrollees moving from a non-QBP contract to a QBP contract would be 200,000 starting in 2019 and increasing by 3 percent per year throughout the projection period. The 200,000 starting figure was chosen by observing the decreasing trend in the historical data as well as placing the greatest weight on the most recent data point. The 3 percent growth rate is approximately the projected growth in the MA eligible population during the 2019-2023 period.     Similarly, we calculated the net per member per month (PMPM) dollar impact of the QBP for those enrollees in contracts that consolidated to be $44.73 in 2018. Again, the PMPM impact was projected for the 2019- 2023 period using the projected annual trend of 5 percent per year which is similar to the projected growth rate for MA expenditures and can be found in the 2017 Trustees Report. We also made an assumption that even under the proposed Star Rating methodology changes, there would still be 50 percent of the projected impacted enrollees that would consolidate or individually move from a non-QBP contract to a QBP contract when advantageous to the health plan (lessening the overall savings impact). Combining the assumptions previously described, as well as accounting for the average rebate percentage of 66 percent and backing out the projected Part B premium, the net savings to the trust funds were calculated to be $32 million for 2019, $35 million in 2020, $37 million in 2021, $40 million in 2022, and $44 million in 2023. The calculations for the five annual estimates are presented in Table 28.

                                             Table 28--Calculations of Net Savings per Year for Star Ratings --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                                               Average                                     Enrollment  (3%     PMPM cost  (5%    Number  months    Percent not       rebate       Backing  out     Net Savings               Year                  annual  trend)      annual  trend)        per year     consolidating    percentage      of  Part B         ($ in                                                                                                 (%)             (%)        premium  (%)      millions) -------------------------------------------------------------------------------------------------------------------------------------------------------- 2019............................  200,000...........  44.73 x 1.05 .....              12              50              66              86              32 2020............................  200,000 x 1.03 ...  44.73 x 1.05 \2\..              12              50              66              86              35 2021............................  200,000 x 1.03 \2\  44.73 x 1.05 \3\..              12              50              66              86              37 2022............................  200,000 x 1.03 \3\  44.73 x 1.05 \4\..              12              50              66              86              40 2023............................  200,000 x 1.03 \4\  44.73 x 1.05 \5\..              12              50              66              86              44 --------------------------------------------------------------------------------------------------------------------------------------------------------

12. Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types a. Anticipated Effects     In considering the cost implications of this proposal, we received varied perspectives from stakeholders. Part D plan sponsors, PBMs, and manufacturers contend limited dispensing networks with accreditation requirements generate cost savings and add value. Specialty pharmacies contend the added value avoids additional costs. Independent community pharmacies, and beneficiaries contend broader competition and transparency will generate savings.     Because this provision clarifies existing any willing pharmacy requirements, consistent with OACT estimates, we do not anticipate additional government or beneficiary cost impacts from this provision.

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          Table 29--Estimated[thinsp]Aggregate Costs and Savings to the Health Care Sector by Provision                                       for Calendar Years 2019 Through 2023 ----------------------------------------------------------------------------------------------------------------                                                             Calendar year  ($ in millions)        Total CYs 2019-            Provision                 Regulation     ---------------------------------------------   2023  ($ in                                      section(s)        2019     2020     2021     2022     2023      millions) ----------------------------------------------------------------------------------------------------------------                                       Federal Government (Medicare) Impacts ---------------------------------------------------------------------------------------------------------------- Any Willing Pharmacy Standard   Various............        0        0        0        0        0               0  Terms and Conditions and  Better Define Pharmacy Types. ----------------------------------------------------------------------------------------------------------------

b. Benefits     Proposed clarification of Any Willing Pharmacy rules, and clarification of the definition of retail pharmacy would account for recent changes in the pharmacy practice landscape and ensure that existing statutorily-required Any Willing Pharmacy provisions are extended to innovative pharmacy business and care delivery models.     Rural areas are predominantly served by independent community pharmacies. The National Community Pharmacist's Association (NCPA) estimates that ``independent pharmacies represent 52 percent of all rural retail pharmacies and there are over 1800 independent community pharmacies operating as the only retail pharmacy within their rural communities 63 64.'' Additionally, these pharmacies are increasingly interested to diversify their business models to dispense specialty drugs. Consequently, we believe this proposal may support small businesses in rural areas and may help maintain beneficiary access to specialty drugs from community pharmacies. ---------------------------------------------------------------------------

    \63\ National Community Pharmacist's Association letter to CMS Administrator, Seema Verma, June 7, 2017. Available at [*http://www.ncpa.co/pdf/ncpa-medicaid-recommend-cms-june-2017.pdf*](http://www.ncpa.co/pdf/ncpa-medicaid-recommend-cms-june-2017.pdf)).     \64\ National Community Pharmacist's Association comment letter to CMS-4159-P, March 2014. Available at //   [*www.ncpa.co/pdf/NCPA-*](http://www.ncpa.co/pdf/NCPA-) Comments-to-CMS-Proposed-Rule-2015FINAL-3.7.14.pdf ---------------------------------------------------------------------------

13. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (Sec.  423.265)     The proposed revision of 423.265 eliminates the requirement for two enhanced benefit plans offered by a PDP organization in a service area to be ``substantially different''. If finalized this will result in increased plan flexibilities and a potential increase in beneficiary plan choice. We expect this provision to reduce plan burden and could provide a very modest savings to plans sponsors of approximately $60,000. The savings represent an estimate of the time not spent by certifying actuaries to ensure that a meaningful difference threshold is met between two PDP EA offerings. Based on the preliminary CY 2018 landscape, if all PDP organizations that submitted an EA benefit design had also submitted the maximum of two EA plans, the result would be approximately 275 EA to EA plan pairings that would have required actuary time spent in evaluation of the meaningful difference requirement. We further estimate that it would take an actuary 2 hours to write a meaningful difference requirement. Based on the Bureau of Labor Statistics (BLS) latest wage estimates, [*https://www.bls.gov/oes/current/oes152011.htm*](https://www.bls.gov/oes/current/oes152011.htm), the mean hourly wage for actuaries, occupation code 15-2011 is $54.87 which when multiplied by 2 to allow 100 percent for overhead and fringe benefits is $109.74 an hour. Thus our total estimated burden is 275 EAs x 2 Hours per EA = 550 hours at a cost of 550 x $109.74 = $60357. While there is potential savings for PDP plan sponsors under this proposal, these savings could be offset for organizations who make the business decision to prepare and submit additional bids if this proposal is finalized. If the EA to EA threshold was the sole barrier to a PDP sponsor offering a second EA plan, (that is, the sponsor currently only offers one enhanced plan), based on the CY2018 PDP landscape, we could anticipate a modest increase of approximately 125 additional enhanced plans (15 percent increase). Although we believe it unlikely that all PDP sponsors would opt to add an additional plan. 14. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans and PACE     The costs and savings, as reflected in the total net savings, associated with our preclusion list proposals would be those identified in the collection of information section of this rule: Specifically, (1) the system costs associated with the Part D preclusion list; (2) costs associated with the preparation and sending of written notices to affected Part D prescribers and beneficiaries; and (3) the savings that would accrue from individuals and entities no longer being required to enroll in or opt-out of Medicare to prescribe Part D drugs or furnish Part C services and items. Specifically, we project a total net savings, as described in detail in the collection of information portion of this rule, over the first 3 years of this rule of $35,526,652 ($3,423,852 for Part D + $32,102,800 for Part C), or a 3- year annual average of $11,842,217). Costs associated with an alternative approach are found in the Alternatives Considered portion of this section. We would be responsible for the development and monitoring of the preclusion list using its own resources. This would be funded as part of our screening activities. We do not anticipate a change in the number of individuals or entities billing for service, for we would only be denying payment to those parties that meet the conditions of the preclusion list. Costs associated with an alternative approach are found in the Alternatives Considered section of this rule.     We welcome public comment on these estimates, for stakeholder feedback could assist us in developing more concrete projections. 15. Removal of Quality Improvement Project for Medicare Advantage Organizations (Sec.  422.152)     This provision would result in a total savings of $19,305 to the federal government. The driver of the savings is the removal of burden for federal employees to review Quality Improvement Project (QIP) attestations. MA organizations are required to annually attest that they have an ongoing QIP in progress and the Central Office reviews these attestation submissions. To estimate amounts, we considered how many QIP attestations are performed annually.     We estimate that--      Central Office staff will require one person reviewing for 0.25 hours to review a single QIP attestation. The Central Office staff typically have higher

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GS levels. We assume a GS grade 13, step 5, with a mean wage of $51.48, which with an allowance of 100 percent for overhead and fringe benefits becomes $102.96 This is based on the 2017 publicly available wages found on the Office of Personnel Management Web site at [*https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2017/general-schedule/*](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2017/general-schedule/).      We calculate the savings to the federal government by multiplying the number of anticipated QIP attestation submissions (750) times the number of CMS staff it takes to complete a review-- (1) times the adjusted wage for that staff ($102.96) (750 x 1 x $102.96 x 0.25 hour), which equals $19,305.     Thus, the total savings of this provision are $31,968, of which $12,663.75 are savings to the industry, as indicated in section III. of this proposed rule, and $19,305 are savings to the federal government. 16. Reducing the Burden of the Medical Loss Ratio Reporting Requirements     Our proposal to significantly reduce the amount of MLR data submitted to CMS would eliminate the need for CMS to continue to pay a contractor, approximately $390,000 a year for the following:      To perform initial analyses, or desk reviews, of the detailed MLR reports submitted by MA organizations.      Part D sponsors in order to identify omissions and suspected inaccuracies and to communicate their findings to MA organizations and Part D sponsors in order to resolve potential compliance issues.     In addition, because we would be receiving only the minimum amount of data from MAOs and Part D sponsors, we expect that we would reduce the amount we pay to contractors for software development, data management, and technical support related to MLR reporting. We currently pays a contractor $300,000 each year for these services. Although we expect that MAOs and Part D sponsors would continue to use the HPMS or a similar system to submit and attest to their simplified MLR submissions, we would no longer need to maintain and update MLR reporting software with validation features, to receive certain data extract files, or to provide support for desk review functionality. We estimate, by eliminating these services, we would reduce our payments to contractors by approximately $100,000 a year.     In total, we estimate that the proposed changes to the MLR reporting requirements will save the government $490,000 a year. As noted in the Collection of Information section of this proposed rule, the proposed changes to the MLR reporting requirement will save MA organizations and Part D sponsors $904,884 a year. Thus, the total annual savings of this proposal are $1,446,417: $490,000 to the government and $904,884 to MA organizations and Part D sponsors.     We do not anticipate that our proposal to modify the regulations at Sec. Sec.  422.2430 and 423.2430 to specify that Medication Therapy Management (MTM) programs that comply with Sec.  423.153(d) are quality improvement activities (QIA) will significantly reduce stakeholder burden. As explained in section II.C.1.b (2). of this proposed rule, we stated in the May 23, 2013 final rule (78 FR 31294) that MTM activities qualify as QIA, provided they meet the requirements set forth in Sec. Sec.  422.2430 and 423.2430 We expect that most if not all MTM programs that comply with Sec.  423.153(d) would already satisfy the QIA requirements set forth in current Sec. Sec.  422.2430 and 423.2430 Therefore, we do not anticipate that the proposal to explicitly include MTM programs in QIA will have a significant impact on burden. 17. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (Sec. Sec.  423.100, 423.120, and 423.128)     The proposed provisions would specifically permit Part D sponsors that meet our requirements to remove brand name drugs (or change their cost-sharing status) when replacing them with (or adding) newly approved generics without providing advance notice or submitting formulary change requests. We would also permit Part D sponsors to make such changes at any time of the year rather than waiting for them to take effect 2 months after the start of the plan year. A related proposal would except from our transition policy applicable generic substitutions and additions with cost-sharing changes. Lastly, we are proposing to decrease the days of enrollee notice and refill required in cases in which (aside from generic substitutions and drugs deemed unsafe or removed from the market) drug removal or changes in cost- sharing will affect enrollees.     The FDA has noted that generics are typically sold at substantial discounts from the branded price. (``Generic Drugs: Questions and Answers,'' see FDA Web site,   [*https://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm*](https://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm), accessed June 22, 2017.) However, we do not believe that significant savings will necessarily result from these proposed provisions, because historically Part D sponsors have been able to anticipate the generic launches well and migrate the brand scripts to generics smoothly once the generic drugs become available. The proposal could provide some administrative relief for Part D sponsors, although the savings won't be very significant.     In addition regardless of any first year effect, we do not believe there could be any significant effect for subsequent years. Our proposed changes would permit immediate specified generic substitutions throughout the plan year or a 30 rather than a 60 day notice period for certain substitutions. Part D sponsors submit for review each year an entirely new formulary and presumably the timing of substitutions would overlap across plan years a minimal amount of times. 18. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing a. Savings     Proposed codification of follow-on biological products as generics for the purposes of LIS cost sharing and non-LIS catastrophic cost sharing will reduce marketplace confusion about what level of cost- sharing Part D enrollees should be charged for follow-on biological products. By establishing cost sharing at the lower level, this provision would also improve Part D enrollee incentives to use follow- on biological products instead of reference biological products. As discussed previously, this would reduce costs to Part D enrollees and generate savings for the Part D program.     In addition, we believe that reducing confusion in the marketplace surrounding this issue will improve beneficiary protections while improving enrollee incentives to choose follow-on biological products over reference biological products. (This proposed provision to classify follow-on biological products as generic drugs are for the purposes of cost sharing for non-LIS cost sharing in the catastrophic portion of the benefit and LIS enrollees in any phase of the benefit.) Improved incentives to choose lower cost alternatives will reduce costs to Part D enrollees and the Part D program. OACT estimates this proposal will provide a modest savings of $10 million in 2019, with savings increasing by approximately $1 million each year through 2028.     OACT anticipates some natural shift from reference biological products to follow-on biological products, but follow-on biological products' price differential and market share are lower

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than that observed for small molecule generic drugs. Currently, Zarxio[supreg] data provide the only meaningful comparison available to date, as very limited data exist on the other six approved (as of September 14, 2017) follow-on biological products. The market dynamic between Neupogen[supreg] and Zarxio[supreg] has behaved consistent with OACT's anticipation and OACT expects other follow-on biological products to follow the similar pattern. Based on 2017 year-to-date data on the per script price difference between Neupogen[supreg] and Zarxio[supreg], OACT estimated follow-on biological products to be 16 percent less expensive than their reference biological product. OACT estimates this proposal will result in a minor shift of an additional 5 percent of prescriptions to follow-on biological products by LIS enrollees under this proposal. Consequently, savings are not estimated to be significant at this time.

          Table 30--Estimated[thinsp]Aggregate Costs and Savings to the Health Care Sector by Provision                                       for Calendar Years 2019 Through 2023 ----------------------------------------------------------------------------------------------------------------                                                             Calendar year ($ in millions)            Total CYs            Provision                 Regulation     ---------------------------------------------  2019-2023  ($                                      section(s)        2019     2020     2021     2022     2023    in millions) ----------------------------------------------------------------------------------------------------------------                                       Federal Government (Medicare) Impacts ---------------------------------------------------------------------------------------------------------------- Treatment of Follow-On          423.4 .............       10       11       12       13       14              60  Biological Products as  Generics for LIS Cost Sharing  and Non-LIS Catastrophic Cost  Sharing. ----------------------------------------------------------------------------------------------------------------

b. Benefits of Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing     Proposed codification of follow-on biological products as generics for the purposes of LIS cost sharing and non-LIS catastrophic cost sharing will reduce marketplace confusion about what level of cost- sharing Part D enrollees should be charged for follow-on biological products. By establishing cost sharing at the lower level, this provision would also improve Part D enrollee incentives to use follow- on biological products instead of reference biological products. As discussed previously, this would reducing costs to Part D enrollees and generate savings for the Part D program. 19. Changes to the Days' Supply Required by the Part D Transition Process     We do not believe our proposal in this section would impose any new burden on any stakeholder. Since Part D sponsors and their PBMs already have prescription drug pharmacy claims systems programmed to provide transition to plan enrollees in the outpatient setting, they would only have to make a technical change to these systems that consists of changing the required number of days' supply if it is not already 30 days. In addition, Part D sponsors and their PBMs would have to cease treating these enrollees in the LTC setting separately from enrollees in the outpatient setting for purposes of transition. We also do not believe this proposal would impose any new burden on LTC facilities and the pharmacies that serve them. If finalized, we believe this regulation would eliminate the additional time that LTC facilities and pharmacies have to transition Part D patients that we now believe they do not need to effectuate the transition.     We believe this provision will produce cost-savings to the Medicare Part D program because it requires fewer drugs to be dispensed under transition, particularly in the LTC setting. However, we are unable to estimate the cost-savings, because it largely depends upon which and how many drugs are dispensed as transition drugs to Part D beneficiaries in the LTC setting in the future. Also, we are unable to determine which PDEs involve transition supplies in LTC in order to provide an estimate of future savings based on past experience with transition supplies in LTC in the Part D program.

G. Alternatives Considered

1. Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing     The critical policy decision was how broadly or narrowly to classify follow-on biological products as generics. Overly broad classification might easily overstep the distinctions between generic drugs and follow-on biologics in statute and those drawn by the United States Food and Drug Administration (FDA), leading to confusion in the marketplace, and potentially jeopardizing Part D enrollee safety. Inappropriate utilization of biological products and increased need for additional medical services, in turn, increase costs to the Part D program. A narrow classification can appropriately resolve marketplace confusion while also improving Part D enrollee incentives to choose lower cost alternatives. 2. Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types     The critical policy decision was how to strike the right balance to clarify confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models without prematurely and inappropriately interfering with highly volatile market forces. 3. Preclusion List     We considered a preclusion list that would embody preventive provisions that would place on the preclusion list not just those providers and suppliers who are prescribing Part D drugs or who are providing services to Medicare beneficiaries who are receiving their Medicare benefit from a MA plan. The savings and cost estimates associated with that alternative are based on the following. Prescription drug event (PDE) and encounter data identifies providers who furnish Part C services and items and prescribe Part D drugs to Medicare beneficiaries. Given the frequency with which MA organizations and Part D sponsors typically submit data to CMS, we estimate a delay of approximately 1 month in obtaining this data. Delays in the availability of this data and the screening and evaluation of the providers and prescribers will result in delays in the identification and inclusion of providers or prescribers on the preclusion list, which would occur after the service, item or drug was provided to the Medicare beneficiary. We estimate that it will cost the Trust Fund approximately $44.7 million if we do not proactively screen providers and prescribers and delay screening until after the PDE and encounter data is

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available. We estimate an additional 1.4 million providers or prescribers would not be screened if we only rely on PDE and encounter data. The current Medicare provider population consists of approximately 2 million providers and historically we has revoked 0.4 percent of its existing Medicare enrolled providers., However this percentage could be higher or lower for the population of prescribers solely enrolled for prescribing. There are approximately 480,000 part C and D unenrolled providers and prescribers, 120,000 of which are billing Part C. Using the percentage of historical revocations, we estimate approximately 1,920 new revocations. Based on the approximate 1-month delay in the availability of the PDE and encounter data, three months for screening and an additional 3 months to evaluate the offenses, we anticipate approximately a 7-month delay in the provider or prescriber's inclusion on the preclusion list following the service, item or drug being provided to the beneficiary, if we do not perform proactive screening. The 7-month timeframe is dependent on whether the PDE and encounter data is timely. Using a cost avoidance of $3,324 per month average per provider and applying it to the estimated 1,920 new revocations, a delay in screening would cost the Trust Fund approximately $44.7 million (3,324 x 7 x 1,920). The $3,324 estimate is based on Medicare fee-for-service revocation data and may be higher or lower depending on whether the provider is an individual or organization and their provider type.

H. Accounting Statement

    As required by OMB Circular A-4 (available at [*https://obamawhitehouse.archives.gov/omb/circulars\_a004\_a-4/*](https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/)), in Table 31 we have prepared an accounting statement showing the savings and transfers associated with the provisions of this final rule for CYs 2019 through 2023. Table 31 is based on Table 32 which lists savings, costs, and transfers by provision.

 Table 31--Accounting Statement: Classifications of Estimated Savings, Costs, and Transfers From Calendar Years                                                   2019 to 2023                                                  [$ in millions] ----------------------------------------------------------------------------------------------------------------                                                             Savings                                    --------------------------------------------------------              Category                     Discount rate                                         Whom to whom                                    --------------------------        Period covered                                          7%           3% ---------------------------------------------------------------------------------------------------------------- Net Annualized Monetized Savings..        82.34        82.02  CYs 2019-2023...............  Federal government,                                                                                              MA organizations                                                                                              and Part D                                                                                              Sponsors. Annualized Monetized Savings......        87.26        86.79  CYs 2019-2023...............  Federal government,                                                                                              MA organizations                                                                                              and Part D                                                                                              Sponsors. Annualized Monetized Cost.........        -4.92        -4.77  CYs 2019-2023...............  Federal government,                                                                                              MA organizations                                                                                              and Part D                                                                                              Sponsors. Net Annualized Monetized Savings..        13.80        13.82  CYs 2019-2023...............  Trust Fund. Annualized Monetized Savings......        13.80        13.82  CYs 2019-2023...............  Trust Fund. Annualized Monetized Cost.........         0.00         0.00  CYs 2019-2023...............  Trust Fund. Net Annualized Monetized Savings..        68.54        68.20  CYs 2019-2023...............  Industry. Annualized Monetized Savings......        73.46        72.98  CYs 2019-2023...............  Industry. Annualized Monetized Cost.........        -4.92        -4.77  CYs 2019-2023...............  Industry. Transfers.........................       155.90       154.95  CYs 2019-2023...............  Federal Government,                                                                                              MA plans and Part D                                                                                              Sponsors. ---------------------------------------------------------------------------------------------------------------- Note: Monetized figures in 2018 dollars. Positive numbers indicate aggregate annual savings at the giving   percentage. Transfers are a separate line item. Savings and cost have been broken out separately for industry,   the trust fund and aggregate. For example, the industry provisions with positive amounts had a level monetized   amount of 72.32 at the 3 percent level but a cost of 11.87 at the 3 percent level resulting in an aggregate of   72.32 -11.87 = 60.45 Minor (cent) errors are due to rounding.

    The following Table 32 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table. BILLING CODE 4120-01-P

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I. Conclusion

    This proposed rule has a net savings of between $80 to $100 million for each of the next 5 years. The savings are equivalent to a level amount of about $80 million per year for both 7 percent and 3 percent interest rates. These aggregate savings are to industry ($68.20 million at the 3 percent level = $72.98 million savings--$4.77 million cost), and the Federal government and the Trust Fund ($13.82 million at the 3 percent level which reflects savings to the trust fund without any cost). Transfers between the Federal Government and Industry are between $230 and $320 million and are equivalent to a monetized level amount of about $270 million per year at the 3-percent and 7-percent levels. Both industry and the Federal government save from program efficiencies and reduced work.

J. Reducing Regulation and Controlling Regulatory Costs

    This rule, if finalized as proposed, is expected to be an E.O 13771 regulatory action. Details on the estimated costs and cost savings can be found in the preceding analysis.

IV. Response to Comments

    Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 405

    Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 417

    Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

    Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

    Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Incorporation by Reference, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 460

    Aged, Health care, Health records, Medicaid, Medicare, and Reporting and recordkeeping requirements

42 CFR Part 498

    Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

    For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405--FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

0 1. The authority citation for part 405 continues to read as follows:

    Authority:  Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C 263a).

0 2. Section Sec.  405.924 is amended by adding paragraph (a)(5) to read as follows:

Sec.  405.924  Actions that are initial determinations.

    (a) \* \* \*     (5) An adjustment of premium for hospital or supplementary medical insurance as outlined in Sec. Sec.  406.32(d), 408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301 \* \* \* \* \*

PART 417--HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

0 3. The authority citation for part 417 continues to read as follows:

    Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C 300e, 300e-5, and 300e-9), and 31 U.S.C 9701.

0 4. Section 417.430 is amended by revising paragraph (a)(1) to read as follows:

Sec.  417.430  Application procedures.

    (a) \* \* \*     (1) The application form must comply with CMS instructions regarding content and format and be approved by CMS as described in Sec.  422.2262 of this chapter. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between HHS and its designees and the HMO or CMP. \* \* \* \* \* 0 5. Section 417.472 is amended by adding paragraph (k) to read as follows:

Sec.  417.472  Basic contract requirements.

\* \* \* \* \*     (k) All cost contracts under section 1876 of the Act must agree to be rated under the quality rating system specified at subpart D of part 422, and for cost plans that provide the Part D prescription benefit, under the quality rating system specified at part 423 subpart D, of this chapter. Cost contacts are not required to submit data on or be rated on specific measures determined by CMS to be inapplicable to their contract or for which data are not available, including hospital readmission and call center measures. 0 6. Section 417.478 is amended by revising paragraph (e) to read as follows:

Sec.  417.478  Requirements of other laws and regulations.

\* \* \* \* \*     (e)(1) The prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list, defined in Sec.  422.2 of this chapter, apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.     (2) In applying the provisions of Sec. Sec.  422.2, 422.222, and 422.224 of this chapter under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs. 0 7. Section 417.484 is amended by revising paragraph (b)(3) to read as follows:

Sec.  417.484  Requirement applicable to related entities.

\* \* \* \* \*     (b) \* \* \*     (3) That payments must not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2 of this chapter.

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PART 422--MEDICARE ADVANTAGE PROGRAM

0 8. The authority citation for part 422 continues to read as follows:

    Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C 1302 and 1395hh).

0 9. Section 422.2 is amended by adding the definition of ``Preclusion list'' in alphabetical order to read as follows:

Sec.  422.2  Definitions.

\* \* \* \* \*     Preclusion list means a CMS-compiled list of individuals and entities that--     (1) Meet all of the following requirements:     (i) The individual or entity is currently revoked from Medicare under Sec.  424.535     (ii) The individual or entity is currently under a reenrollment bar under Sec.  424.535(c).     (iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:     (A) The seriousness of the conduct underlying the individual's or entity's revocation.     (B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program.     (C) Any other evidence that CMS deems relevant to its determination; or     (2) Meet both of the following requirements:     (i) The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.     (ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:     (A) The seriousness of the conduct involved.     (B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and     (C) Any other evidence that CMS deems relevant to its determination. \* \* \* \* \* 0 10. Section 422.54 is amended by revising paragraphs (c)(1)(i) and (d)(4)(ii) to read as follows:

Sec.  422.54  Continuation of enrollment for MA local plans.

\* \* \* \* \*     (c) \* \* \*     (1) \* \* \*     (i) Obtain CMS's approval of the continuation area, the communication materials that describe the option, and the MA organization's assurances of access to services. \* \* \* \* \*     (d) \* \* \*     (4) \* \* \*     (ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the communication materials. \* \* \* \* \* 0 11. Section 422.60 is amended-- 0 a. In paragraph (a)(2) by removing the reference ``Sec.  422.62(a)(3), (a)(4), and (a)(5) if'' and adding in its place the reference ``Sec.   422.62(a)(3) and (4) if''; and 0 b. Revising paragraph (g).     The revision reads as follows:

Sec.  422.60  Election process.

\* \* \* \* \*     (g) Passive enrollment by CMS--(1) Circumstances in which CMS may implement passive enrollment. CMS may implement passive enrollment procedures in any of the following situations:     (i) Immediate terminations as provided in Sec.   422.510(b)(2)(i)(B).     (ii) CMS determines that remaining enrolled in a plan poses potential harm to the members.     (iii) CMS determines, after consulting with the State Medicaid agency that contracts with the dual eligible special needs plan described in paragraph (g)(2)(i) of this section, and that meets the requirements of paragraph (g)(2) of this section, that the passive enrollment will promote integrated care and continuity of care for a full-benefit dual eligible beneficiary (as defined in Sec.  423.772 of this chapter and entitled to Medicare Part A and enrolled in Part B under title XVIII) who is currently enrolled in an integrated dual eligible special needs plan.     (2) MA plans that may receive passive enrollments. CMS may implement passive enrollment described in paragraph (g)(1)(iii) only into MA-PD plans that meet all the following requirements:     (i) Operate as a fully integrated dual eligible special needs plan as defined in Sec.  422.2, or a specialized MA plan for special needs individuals that meets a high standard of integration, as described in Sec.  422.102(e).     (ii) Have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the plan (or plans) from which the beneficiaries are passively enrolled.     (iii) Have an overall quality rating of at least 3 stars under the rating system described in Sec.  422.160 through Sec.  422.166 for the year prior to the plan year passive enrollments take effect or is a low enrollment contract or new MA plan as defined in Sec.  422.252     (iv) Not have any prohibition on new enrollment imposed by CMS.     (v) Have limits on premiums and cost-sharing appropriate to full- benefit dual eligible beneficiaries.     (vi) Have the operational capacity to passively enroll beneficiaries and agree to receive the enrollments.     (3) Passive enrollment procedures. Individuals will be considered to have elected the plan selected by CMS unless they--     (i) Decline the plan selected by CMS, in a form and manner determined by CMS, or     (ii) Request enrollment in another plan.     (4) Beneficiary notification. The MA organization that receives the passive enrollment must provide to the enrollee a notice that describes the costs and benefits of the plan and the process for accessing care under the plan and clearly explains the beneficiary's ability to decline the enrollment or choose another plan. Such notice must be provided to all potential passively enrolled enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.     (5) Special election period. Individuals not otherwise eligible for a special election period at the time of passive enrollment will be provided with a special election period, in accordance with Sec.   422.62(b)(4). 0 12. Section Sec.  422.62 is amended by-- 0 a. Revising paragraphs (a)(3) through (5); 0 b. Removing paragraphs (a)(6) and (7); and 0 c. Revising paragraph (b)(3)(ii).     The revisions read as follows:

Sec.  422.62  Election of coverage under an MA plan.

    (a) \* \* \*     (3) Open enrollment period for individuals enrolled in MA--(i) For 2019 and subsequent years. Except as provided in paragraphs (a)(3)(ii) and (iii) and (a)(4) of this section, an individual who is enrolled in an MA plan may make an election once during the first

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3 months of the year to enroll in another MA plan or disenroll to obtain Original Medicare. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in Sec.  423.38(e).     (ii) Newly eligible MA individual. For 2019 and subsequent years, a newly MA eligible individual who is enrolled in a MA plan may change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the third month of the entitlement. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in Sec.  423.38(e).     (iii) Single election limitation. The limitation to one election or change in paragraphs (a)(3)(i) and (ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section, or during a special election period specified in paragraph (b) of this section.     (4) Open enrollment period for institutionalized individuals. After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined in Sec.  422.2, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under Sec.  422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to Original Medicare, to a different MA plan, or from original Medicare to an MA plan.     (5) Annual 45-day period for disenrollment from MA plans to Original Medicare. Through 2018, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in Sec.  423.38(d) of this chapter.     (b) \* \* \*     (3) \* \* \*     (ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communication materials as outlined in subpart V of this part. \* \* \* \* \* 0 13. Section 422.66 is amended by revising paragraphs (c) and (d)(1) and (5) to read as follows:

Sec.  422.66  Coordination of enrollment and disenrollment through MA organizations.

\* \* \* \* \*     (c) Election by default: Initial coverage election period--(1) Basic rule. Subject to paragraph (c)(2) of this section, an individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.     (2) Default enrollment into MA special needs plan--(i) Conditions for default enrollment. During an individual's initial coverage election period, an individual may be deemed to have elected a MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX offered by the organization provided all the following conditions are met:     (A) At the time of the deemed election, the individual remains enrolled in an affiliated Medicaid managed care plan. For purposes of this section, an affiliated Medicaid managed care plan is one that is offered by the MA organization that offers the MA special needs plan for individuals entitled to medical assistance under Title XIX or is offered by an entity that shares a parent organization with such MA organization;     (B) The state has approved the use of the default enrollment process in the contract described in Sec.  422.107 and provides the information that is necessary for the MA organization to identify individuals who are in their initial coverage election period;     (C) The MA organization offering the MA special needs plan has issued the notice described in paragraph (c)(2)(iv) of this section to the individual;     (D) Prior to the effective date described in paragraph (c)(2)(iii) of this section, the individual does not decline the default enrollment and does not elect to receive coverage other than through the MA organization; and     (E) CMS has approved the MA organization to use default enrollment under paragraph (c)(2)(ii) of this section.     (ii) CMS approval of default enrollment. An MA organization must obtain approval from CMS before implementing any default enrollment as described in this section. CMS may suspend or rescind approval when CMS determines the MA organization is not in compliance with the requirements of this section.     (iii) Effective date of default enrollment. Default enrollment in the MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX is effective the month in which the individual is first entitled to both Part A and Part B.     (iv) Notice requirement for default enrollments. The MA organization must provide notification that describes the costs and benefits of the MA plan and the process for accessing care under the plan and clearly explains the individual's ability to decline the enrollment, up to and including the day prior to the enrollment effective date, and either enroll in Original Medicare or choose another plan. Such notification must be provided to all individuals who qualify for default enrollment under paragraph (c)(2) of this section no fewer than 60 calendar days prior to the enrollment effective date described in paragraph (c)(2)(iii) of this section.     (d) \* \* \*     (1) Basic rule. An MA plan offered by an MA organization must accept any individual (regardless of whether the individual has end- stage renal disease) who requests enrollment during his or her Initial Coverage Election Period and is enrolled in a health plan offered by the MA organization during the month immediately preceding the MA plan enrollment effective date, and who meets the eligibility requirements at Sec.  422.50 \* \* \* \* \*     (5) Election. An individual who requests seamless continuation of coverage as described in paragraph (d)(1) of this section may complete a simplified election, in a form and manner approved by CMS that meets the requirements in Sec.  422.60(c)(1). \* \* \* \* \* 0 14. Section 422.68 is amended by revising paragraphs (a), (c), and (f) to read as follows:

Sec.  422.68  Effective dates of coverage and change of coverage.

\* \* \* \* \*     (a) Initial coverage election period. An election made during an initial coverage election period as described in Sec.  422.62(a)(1) is effective as follows:     (1) If made prior to the month of entitlement to both Part A and Part B, it is effective as of the first day of the month of entitlement to both Part A and Part B.     (2) If made during or after the month of entitlement to both Part A and Part B, it is effective the first day of the calendar month following the month in which the election is made. \* \* \* \* \*     (c) Open enrollment periods. For an election, or change in election, made during an open enrollment period, as described in Sec.   422.62(a)(3) through (5), coverage is effective as of the first day

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of the first calendar month following the month in which the election is made. \* \* \* \* \*     (f) Annual 45-day period for disenrollment from MA plans to Original Medicare. Through 2018, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in Sec.  422.62(a)(5), is effective the first day of the first month following the month in which the election is made. 0 15. Section 422.100 is amended-- 0 a. In paragraph (f)(2), by removing the phrase ``to services. and'' and adding in its place the phrase ``to services.''; and 0 b. By revising paragraphs (f)(4), (f)(5) introductory text, (f)(5)(ii), and (f)(6).     The revisions read as follows:

Sec.  422.100  General requirements.

\* \* \* \* \*     (f) \* \* \*     (4) Except as provided in paragraph (f)(5) of this section, MA local plans (as defined in Sec.  422.2) must have an out-of pocket maximum for Medicare Parts A and B services that is no greater than the annual limit set by CMS using Medicare Fee-for-Service data. CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.     (5) With respect to a local PPO plan, the limit specified under paragraph (f)(4) of this section applies only to use of network providers. Such local PPO plans must include a total catastrophic limit annually determined by CMS using Medicare Fee-for-Service and to establish appropriate beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services that is-- \* \* \* \* \*     (ii) Not greater than the annual limit set by CMS using Medicare Fee-for-Service data to establish appropriate beneficiary out-of-pocket expenditures. CMS will set the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.     (6) Cost sharing for Medicare Part A and B services specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. CMS may use Medicare Fee-for-Service data to evaluate the possibility of discrimination and to establish non-discriminatory out-of-pocket limits and also use MA encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory. \* \* \* \* \* 0 16. Section 422.101 is amended by revising paragraphs (d)(2) and (3) to read as follows:

Sec.  422.101  Requirements relating to basic benefits.

\* \* \* \* \*     (d) \* \* \*     (2) Catastrophic limit. MA regional plans are required to establish a catastrophic limit on beneficiary out-of-pocket expenditures for in- network benefits under the Medicare Fee-for-Service program (Part A and Part B benefits) that is no greater than the annual limit set by CMS using Medicare Fee-for-Service data to establish appropriate out-of- pocket limits. CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.     (3) Total catastrophic limit. MA regional plans are required to establish a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the Medicare Fee-for-Service program (Part A and Part B benefits).     (i) This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under Medicare Fee-for- Service, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section and may be no greater than the annual limit set by CMS using Medicare Fee-for-Service data.     (ii) CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. \* \* \* \* \* 0 17. Section 422.102 is amended by revising paragraph (d) to read as follows:

Sec.  422.102  Supplemental benefits.

\* \* \* \* \*     (d) Supplemental benefits packaging. MA organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services. \* \* \* \* \* 0 18. Section 422.111 is amended by revising paragraphs (a) introductory text, (a)(3), and (h)(2)(ii) to read as follows:

Sec.  422.111  Disclosure requirements.

    (a) Detailed description. An MA organization must disclose the information specified in paragraph (b) of this section in the manner specified by CMS-- \* \* \* \* \*     (3) At the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period. \* \* \* \* \*     (h) \* \* \*     (2) \* \* \*     (ii) Copies of its evidence of coverage, summary of benefits, and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies to enrollees upon request. \* \* \* \* \*

Sec.  422.152  [Amended]

0 19. Section 422.152 is amended by removing and reserving paragraphs (a)(3) and (d). 0 20. Sections 422.160, 422.162, 422.164 and 422.166 are added to Subpart D to read as follows:

Subpart D-Quality Improvement

\* \* \* \* \* Sec. 422.160 Basis and scope of the Medicare Advantage Quality Rating System. 422.162 Medicare Advantage Quality Rating System. 422.164 Adding, updating, and removing measures. 422.166 Calculation of Star Ratings.

Sec.  422.160  Basis and scope of the Medicare Advantage Quality Rating System.

    (a) Basis. This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part C.     (b) Purpose. Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:     (1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

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    (2) To provide quality ratings on a 5-star rating system to be used in determining quality bonus payment (QBP) status and in determining rebate retention allowances.     (3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by MA plans, where appropriate and possible to use data of the type described in Sec.  422.162(c).     (c) Applicability. The regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year and used to assign QBP ratings for the 2022 payment year.

Sec.  422.162  Medicare Advantage Quality Rating System.

    (a) Definitions. In this subpart the following terms have the meanings:     CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.     Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.     Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).     Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that scores in the same Star Rating level are as similar as possible and scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.     Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.     Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.     Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.     Domain rating means the rating that groups measures together by dimensions of care.     Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.     HEDIS is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.     Highest rating means the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.     Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).     HOS means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.     Low income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see Sec.  423.34 of this chapter for definition of a low-income subsidy eligible individual).     Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.     Measure score means the numeric value of the measure or an assigned `missing data' message.     Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1-5 star scale.     Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.     Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.     Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.     Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.     Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (``signal'') rather than random variation (``noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).     Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.

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    Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.     Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.     Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3, or 4, then the value should be rounded down by ***deleting*** the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place ***deleted***.     (b) Contract ratings--(1) General. CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA-PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with Sec.  422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with Sec.  422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with Sec.  422.166(c). Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with Sec.  422.166(d) with both the reward factor and CAI applied as applicable, as described in Sec.  422.166(f).     (2) Plan benefit packages. All plan benefit packages (PBPs) offered under an MA contract have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization. Data from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract except for Special Needs Plan (SNP)-specific measures collected at the PBP level. A contract level score is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.     (3) Contract consolidations. (i) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(iv) of this section. Paragraph (b)(3)(iii) of this section is applied to subsequent years that are not addressed in paragraph (b)(3)(ii) of this section for assigning the QBP rating.     (ii) For the first year after a consolidation, CMS will determine the QBP status of a contract using the enrollment-weighted means (using traditional rounding rules) of what would have been the QBP Ratings of the surviving and consumed contracts based on the contract enrollment in November of the year the preliminary QBP ratings were released in the Health Plan Management System (HPMS).     (iii) In subsequent years following the first year after the consolidation, CMS will determine QBP status based on the consolidated entity's Star Ratings displayed on Medicare Plan Finder.     (iv) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:     (A) For the first year after consolidation, CMS will use enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based and call center measures. The survey- based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.     (B) For the second year after consolidation, CMS will use the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except those from the following data sources: HEDIS, CAHPS, and HOS. HEDIS and HOS measure data will be scored as reported. CMS will ensure that the CAHPS survey sample will include enrollees in the sample frame from both the surviving and consumed contracts.     (c) Data sources. (1) CMS bases Part C Star Ratings on the type of data specified in section 1852(e) of the Act and on CMS administrative data. Part C Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Clinical data, beneficiary experiences, changes in physical and mental health, benefit administration information and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of MA plans' compliance with MA requirements and data submitted by plans.     (2) MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. MA organizations must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) of this section to CMS on a timely basis as requested by CMS.

Sec.  422.164  Adding, updating, and removing measures.

    (a) General. CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.     (b) Review of data quality. CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.     (c) Adding measures. (1) CMS will continue to review measures that are in alignment with the private sector, such as measures developed by NCQA and the Pharmacy Quality Alliance (PQA), or endorsed by the National Quality Forum for adoption and use in the Part C and Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.     (2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.     (3) New measures added to the Part C Star Ratings program will be on the display page on [*www.cms.gov*](http://www.cms.gov) for a minimum of 2 years prior to becoming a Star Ratings measure.     (4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.     (d) Updating measures--(1) Non-substantive updates. For measures that are already used for Star Ratings, CMS will update measures so long as the

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changes in a measure are not substantive. CMS will announce non- substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that--     (i) Narrow the denominator or population covered by the measure;     (ii) Do not meaningfully impact the numerator or denominator of the measure;     (iii) Update the clinical codes with no change in the target population or the intent of the measure;     (iv) Provide additional clarifications:     (A) Adding additional tests that would meet the numerator requirements;     (B) Clarifying documentation requirements;     (C) Adding additional instructions to identify services or procedures; or     (v) Add alternative data sources.     (2) Substantive updates. For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1) of this section, CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.     (e) Removing measures. (1) CMS will remove a measure from the Star Ratings program as follows:     (i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes; or     (ii) A measure shows low statistical reliability.     (2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.     (f) Improvement measure. CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph; the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.     (1) Identifying eligible measures. Annually, the subset of measures to be included in the Part C and Part D improvement measures will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measures if the measures meet all of the following:     (i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.     (ii) CMS will exclude any measure for which there was a substantive specification change from the previous year.     (iii) CMS will exclude any measures that are already focused on improvement in MA organization performance from year to year.     (iv) The Part C improvement measure will include only Part C measure scores; the Part D improvement measure will include only Part D measure scores.     (2) Determining eligible contracts. CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iv) of this section.     (3) Special rules for calculation of the improvement score. For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).     (4) Calculation of the improvement score. The improvement measure will be calculated as follows:     (i) The improvement change score (the difference in the measure scores in the two year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.     (ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05     (iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.     (iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.     (v) The improvement measure score will be converted to a measure- level Star Rating using hierarchical clustering algorithms.     (vi) The Part D improvement measure scores for MA-PDs and PDPs will be determined using cluster algorithms in accordance with Sec. Sec.   422.166(a)(2)(ii) through (iv) and 423.186(a)(2)(ii) through (iv) of this chapter. The Part D improvement measure thresholds for MA-PDs and PDPs would be reported separately.     (g) Data integrity. (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measure(s).     (i) CMS will reduce HEDIS measures to 1 star when audited data are submitted to NCQA with a designation of ``biased rate'' or BR based on an auditor's review of the data or a designation of ``nonreport'' or NR.     (ii) CMS will reduce measures based on data that an MA organization must submit to CMS under Sec.  422.516 to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation

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standards for data directly used to calculate the associated measure.     (iii) For the appeals measures, CMS will use statistical criteria to estimate the percentage of missing data for each contract using data from multiple sources such as a timeliness monitoring study or audit information to scale the star reductions to determine whether the data at the independent review entity (IRE) are complete. The criteria would allow CMS to use scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.     (A) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period will be used to determine the scaled reduction.     (B) The determination of the Part C appeals measure IRE data reduction is done independently of the Part D appeals measure IRE data reduction.     (C) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data would be a four-star reduction.     (D) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:     (1) 20 percent, 1 star reduction.     (2) 40 percent, 2 star reduction.     (3) 60 percent, 3 star reduction.     (4) 80 percent, 4 star reduction.     (E) If a contract receives a reduction due to missing Part C IRE data, the reduction is applied to both of the contract's Part C appeals measures.     (F) If a contract receives a reduction due to missing Part D IRE data, the reduction is applied to both of the contract's Part D appeals measures.     (G) The scaled reduction is applied after the calculation for the appeals measure-level Star Ratings. If the application of the scaled reduction results in a measure-level star rating less than 1 star, the contract will be assigned 1 star for the appeals measure.     (H) The Part C Calculated Error is determined using the quotient of number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. (The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during the data collection or data sample period and the number of cases not forwarded to the IRE during the same period.)     (I) The Part D Calculated Error is determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.     (J) The projected number of cases not forwarded to the IRE in a 3- month period is calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the data collection or data sample time period. The value of the constant will be 1.0 for contracts that submitted 3 months of data; 1.5 for contracts that submitted 2 months of data; and 3.0 for contracts that submitted 1 month of data.     (K) Contracts would be subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:     (1) The calculated error rate is 20 percent or more.     (2) The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.     (L) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.     (M) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.     (N) The reduction is identified by the highest threshold that a contract's lower bound exceeds.     (2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) through (iii) of this section, including a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements.

Sec.  422.166  Calculation of Star Ratings.

    (a) Measure Star Ratings--(1) Cut points. CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, CMS will determine MA-PD and PDP cut points separately.     (2) Clustering algorithm for all measures except CAHPS measures. (i) The method minimizes differences within star categories and maximizes differences across star categories using the hierarchical clustering method.     (ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.     (iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.     (A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.     (B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.     (3) Relative distribution and significance testing for CAHPS measures. The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60 Low reliability scores are defined as those with at least 11 respondents and reliability greater than or equal to 0.60 but less than 0.75 and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:     (i) A contract is assigned 1 star if both of the following criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(i)(C) or (D) of this section is met:     (A) Its average CAHPS measure score is lower than the 15th percentile; and     (B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score;     (C) The reliability is not low; or     (D) Its average CAHPS measure score is more than one standard error below the 15th percentile.     (ii) A contract is assigned 2 stars if it does not meet the 1 star criteria and meets at least one of the following criteria:     (A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; or     (B) Criterion (b) its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; or     (C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.     (iii) A contract is assigned 3 stars if it meets at least one of the following criteria:     (A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different

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from the national average CAHPS measure score; or     (B)(1) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile;     (2) The reliability is low; and     (3) The score is not statistically significantly lower than the national average CAHPS measure score.     (C)(1) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile;     (2) The reliability is low; and     (3) The score is not statistically significantly higher than the national average CAHPS measure score.     (iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of the following criteria:     (A) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability.     (B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability.     (C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.     (v) A contract is assigned five stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(v)(C) or (D) of this section is met:     (A) Its average CAHPS measure score is at or above the 80th percentile.     (B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score.     (C) The reliability is not low.     (D) Its average CAHPS measure score is more than one standard error above the 80th percentile.     (4) Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.     (b) Domain Star Ratings. (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.     (ii) The 5 domains for the MA Star Ratings are: Staying Healthy: Screenings, Tests and Vaccines; Managing Chronic (Long Term) Conditions; Member Experience with Health Plan; Member Complaints and Changes in the Health Plan's Performance; and Health Plan Customer Service. The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.     (2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.     (i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.     (ii) The domain ratings are on a 1- to 5- star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.     (c) Part C summary ratings. (1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section with an adjustment to reward consistently high performance and the application of the CAI under paragraph (f) of this section.     (2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated.     (ii) The Part C improvement measure is not included in the count of the minimum number of rated measures.     (3) The summary ratings are on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.     (d) Overall MA-PD rating. (1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with an adjustment to reward consistently high performance and the application of the CAI, under paragraph (f) of this section.     (2)(i) An MA-PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.     (ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.     (iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.     (iv) The overall rating is on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.     (v) Low enrollment contracts (as defined in Sec.  422.252) and new MA plans (as defined in Sec.  422.252) do not receive an overall and/or summary rating. They are treated as qualifying plans for the purposes of QBPs as described in Sec.  422.258(d)(7) and as announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853 (b) of the Act.     (e) Measure weights--(1) General rules. Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.     (i) Improvement measures receive the highest weight of 5.     (ii) Outcome and Intermediate outcome measures receive a weight of 3.     (iii) Patient experience and complaint measures receive a weight of 1.5     (iv) Access measures receive a weight of 1.5     (v) Process measures receive a weight of 1.     (2) Rules for new measures. New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. In subsequent years, the measure will be assigned the weight associated with its category.     (3) Special rule for Puerto Rico. Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.     (f) Completing the Part C summary and overall rating calculations. CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph.     (1) Reward factor. This rating-specific factor is added to the both the summary and overall ratings of contracts that qualify for the reward factor based on both high and stable relative performance for the rating level.     (i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA-PDs; Part C summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA-PDs; Part C

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summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs). The weighted mean and weighted variance are compared separately for MA-PD and standalone Part D contracts. The measure weights are specified in Sec.  422.166(e). Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean are calculated both with and without the improvement measures. For an MA- PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure.     (ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).     (iii) The combination of the relative variance and relative mean is used to determine the value of the reward factor to be added to the contract's summary and overall ratings as follows:     (A) A contract with low variance and a high mean will have a reward factor equal to 0.4     (B) A contract with medium variance and a high mean will have a reward factor equal to 0.3     (C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2     (D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1     (E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0     (iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.     (2) Categorical Adjustment Index. CMS applies the categorical adjustment index (CAI) as provided in this paragraph to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part C, Part D for MA-PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.     (i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment (if applicable).     (A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.     (B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year. The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period. Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.     (C) MA-PD contracts may have up to three rating-specific CAI adjustments: One for the overall Star Rating and one for each of the summary ratings (Part C and Part D).     (D) An MA-only contract may be adjusted only once for the CAI for the Part C summary rating.     (E) The CAI values are rounded and displayed with 6 decimal places.     (ii) In determining the CAI values, a measure will be excluded as a candidate for inclusion for adjustment if the measure meets any of the following:     (A) The measure is already case-mix adjusted for socioeconomic status.     (B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.     (C) The measure is scheduled to be retired or revised.     (D) The measure is applicable only to SNPs.     (iii) CMS will announce the measures identified for inclusion in the calculations of the CAI under this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. The measures for inclusion in the calculations of the CAI values will be selected based on the analysis of the dispersion of the LIS/DE within-contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. CMS calculates the results of each contract's estimated difference between the LIS/DE and non-LIS/DE performance rates per contract using logistic mixed effects models that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non- LIS/DE beneficiaries would be estimated separately. The following decision criteria is used to determine the measures for adjustment:     (A) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more.     (B) The LIS/DE subgroup performed better or worse than the non-LIS/ DE subgroup in all contracts.     (C) The Part D measures for MA-PDs and PDPs will be analyzed independently, but the Part D measures selected for adjustment will include measures that meet the selection criteria for either delivery system.     (iv) The adjusted measures score for the selected measures are determined using the results from regression models of beneficiary- level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts.     (A) A logistic regression model with contract fixed effects and beneficiary-level indicators of LIS/DE and disability status is used for the adjustment.     (B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.     (v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part C summary, Part D summary for MA-PDs and Part D summary for PDPs) in each final adjustment category.     (A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).     (B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

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    (C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).     (D) The mean difference within each final adjustment category by rating-type (Part C, Part D for MA-PD, Part D for PDPs or overall) would be the CAI values for the next Star Ratings year.     (vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:     (A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.     (B) The Medicare enrollment data from the same measurement period as the Star Ratings' year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states.     (vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.     (A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.     (B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.     (C) The model's coefficient and intercept are updated annually and published in the Technical Notes.     (g) Applying the improvement measure scores. (1) CMS runs the calculations twice for each highest level rating for each contract-type (overall rating for MA-PD contracts and Part C summary rating for MA- only contracts), with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:     (i) Contracts with 2 or fewer stars for their highest rating when calculated without improvement and with all applicable adjustments (CAI and the reward factor) will not have their rating calculated with the improvement measure(s).     (ii) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.     (iii) If the highest rating is between 2 stars and 4 stars with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).     (2) The Part C summary rating for MA-PDs will include the Part C improvement measure and the Part D summary rating for MA-PDs will include the Part D improvement measure.     (h) Posting and display of ratings. For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag ``Not enough data available.'' If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag ``Plan too new to be measured''.     (1) Medicare Plan Finder Performance icons. Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph (h):     (i) High-performing icon. The high performing icon is assigned to an MA-only contract for achieving a 5-star Part C summary rating and an MA-PD contract for a 5-star overall rating.     (ii) Low-performing icon. (A) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.     (B) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.     (2) Plan preview of the Star Ratings. CMS will have plan preview periods before each Star Ratings release during which MA organizations can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder. 0 21. Section 422.204 is amended by removing paragraph (b)(5) and adding paragraph (c).     The addition reads as follows:

Sec.  422.204  Provider selection and credentialing.

\* \* \* \* \*     (c) An MA organization must follow a documented process that ensures compliance with the preclusion list provisions in Sec.   422.222 0 22. Amend Sec.  422.206 by revising paragraph (b)(2)(i) to read as follows:

Sec.  422.206  Interference with health care professionals' advice to enrollees prohibited.

    (b) \* \* \*     (2) \* \* \*     (i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with all applicable requirements under subpart V of this part. \* \* \* \* \* 0 23. Section 422.208 is amended by revising paragraph (f)(2)(iii) and adding paragraphs (f)(2)(iv) through (vii) and (f)(3) to read as follows:

Sec.  422.208  Physician incentive plans: requirements and limitations.

\* \* \* \* \*     (f) \* \* \*     (2) \* \* \*     (iii)(A) Stop-loss protection must cover 90 percent of costs above the deductible or an actuarial equivalent amount of the costs of referral services that exceed the per-patient deductible limit. The single combined deductible, for policies that pay 90 percent of costs above the deductible or an actuarial equivalent amount, for stop-loss insurance for the various panel sizes for contract years beginning on or after January 1, 2019 is determined using the table published by CMS that is developed using the methodology in paragraph (f)(2)(iv) of this section. For panel sizes not shown in the table, use linear interpolation between the table values.     (B) To apply this table, a physician or physician group may use linear interpolation to compute the deductible

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for the globally capitated patients (DGCP) as well as the deductible for globally capitated patients plus NPEs (DGCPNPE). The deductible for the stop-loss insurance required to be provided for the physician or physician group is then based on the lesser of DGCP+100,000 and DGCPNPE.     (iv) The table referenced in paragraph (f)(2)(iii) of this section will be created, updated, and published by CMS in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act), as necessary, using the following methodology:     (A) The table and the methodology in this paragraph (f)(2)(iv) only address capitation arrangements in the PIP and that other stop-loss insurance needs to be used for non-capitated arrangements.     (B) If it is not a global capitation arrangement or is a different stop/loss arrangement, the tables developed using this methodology do not apply. The table is calculated using the following methodology and assumptions:     (1) CMS used the population of all Fee For Service (FFS) Part A and Part B claims for the most available recent year and assumed a multi- specialty practice since all physician claims were allowed.     (2) CMS's estimate of medical group income was derived from CMS claims files, which include payments for all Part A and Part B services.     (3) The central limit theorem was used to obtain the distribution of claim means for a multi-specialty group of any given panel size.     (4) The distribution was used to obtain, with 98 percent confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose more than 25 percent of the net income derived from services that the physicians personally rendered.     (i) This point is set as the deductible in the table described in paragraph (f)(2)(iii) of this section.     (ii) The `net benefit premium' (NBP) column in that table is not used for computation of combined insurance but is used to determine the separate deductibles for physician/professional services and institutional services.     (iii) The NBP is computed by dividing the total amount of stop loss claims (90 percent of claims above the deductible) for that panel size by the panel size.     (v)(A) Insurance using separate deductibles for professional and institutional claims is permissible for contract years beginning on or after January 1, 2019 so long as the separate deductibles for institutional services and professional services are consistent with the table published by CMS using the methodology and assumptions in paragraphs (f)(2)(vi) and (vii) of this section. For deductible amounts not shown in the table use linear interpolation between the table values. The tables and methodology in paragraph (f)(2)(iv) of this section only address capitation arrangements in the PIP and that other stop-loss insurance needs to be used for non-capitated arrangements. If it is not a global capitation arrangement or a different stop/loss arrangement, these tables do not apply.     (B) The maximum deductibles for each category of services (institutional and professional claims) are identified by using the net benefit premium (NBP) for the patient panel size from the table described in paragraph (f)(2)(iii) of this section. If the NBP is identified using interpolation from the values in the table described in paragraph (f)(2)(iii) of this section, interpolation is also used from the NBP values in the table described in paragraph (f)(2)(v)(A) of this section that are closest to the NBP identified by using the table described in paragraph (f)(2)(iii) of this section. TAs with combined stop-loss insurance, panel size may include non-risk patients. As with combined stop-loss insurance, the deductible for separate insurance that must be provided for the physician or physician group is the lesser of DGCP+100,000 and DGCPNPE.     (vi) The table described in (f)(2)(v) of this section is calculated using a methodology similar to the calculation of the table described in paragraph (f)(2)(iii) of this section.     (A) The population of all Part A and Part B claims was obtained.     (B) The source for our estimate of medical group income and institutional income is derived from CMS claims files which includes payments for all Part A and Part B services.     (C) The central limit theorem is used to obtain the distribution of claim means and deductibles are obtained at the 98 percent confidence level.     (vii) In determining the number of global risk patients for the types of services covered under Parts A and B of Medicare, commercial and Medicaid patients who are at global risk and in the same stop-loss risk pool may be included.     (A) The number of non-risk patient equivalents (NPEs) is equal to the projected annual aggregate payments to the physician or physician group for non-global risk patients, divided by an estimate of the average capitation per member per year (PMPY) for all non-global risk patients, whether or not they are capitated. Both numerator and denominator are for physician services that are rendered by the physician or physician group.     (B) The lowest deductible shown in the tables described in paragraphs (f)(2)(iii) and (v) of this section would generally not be available for sale from an insurance company. The number of risk patients and the net premiums are shown for the case where the MA plan might directly insure a contracted physician or physician group with protection at these lower deductibles.     (3) Special insurance. If there is a different type of stop-loss policy obtained by the physician group, it must be actuarially equivalent to the coverage shown in the tables described in paragraphs (f)(2)(iii) and (v) of this section. Actuarially equivalent deductibles are acceptable if the insurance is actuarially certified by an attesting actuary who fulfills all of the following requirements.     (i) Develops the deductibles to be actuarially equivalent to those coverages in the tables.     (ii) Makes the computations in accordance with generally accepted actuarial principles and practices.     (iii) Is certified as meeting the requirements in paragraphs (f)(3)(i) and (ii) of this section by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board. \* \* \* \* \* 0 24. Section 422.222 is revised to read as follows:

Sec.  422.222  Preclusion list.

    (a)(1) An MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in Sec.  422.2     (2) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in Sec.  422.2, in accordance with part 498 of this chapter.     (b) An MA organization that does not comply with paragraph (a) of this section may be subject to sanctions under Sec.  422.750 and termination under Sec.  422.510 0 25. Section 422.224 is revised to read as follows:

Sec.  422.224  Payment to individuals and entities excluded by the OIG or included on the preclusion list.

    (a) An MA organization may not pay, directly or indirectly, on any basis, for

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items or services (other than emergency or urgently needed services as defined in Sec.  422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in Sec.  422.2     (b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in Sec.  422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

Sec.  422.254  [Amended]

0 26. Section 422.254 is amended by removing paragraph (a)(4) and redesignating paragraph (a)(5) as paragraph (a)(4).

Sec.  422.256   [Amended]

0 27. Section 422.256 is amended by removing paragraph (b)(4).

Sec.  422.258   [Amended]

0 28. Section 422.258 is amended in paragraph (d)(7) introductory text by removing the phrase ``section 1852(e) of the Act)'' and adding in its place the phrase ``section 1852(e) of the Act) specified in subpart 166 of this part 422''. 0 29. Section 422.260 is amended by revising paragraph (a) and revising the definition of ``Quality bonus payment (QBP) determination methodology'' in paragraph (b) to read as follows:

Sec.  422.260  Appeals of quality bonus payment determinations.

    (a) Scope. The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA-PDs and Part C summary rating for MA-only contracts for the contract assigned under subpart D of this part     (b) \* \* \*     Quality bonus payment (QBP) determination methodology means the quality ratings system specified in subpart 166 of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP. (Low enrollment contracts and new MA plans are defined in Sec.  422.252 ) \* \* \* \* \* 0 30. Section 422.310 by adding paragraph (d)(5) to read as follows:

Sec.  422.310  Risk adjustment data.

\* \* \* \* \*     (d) \* \* \*     (5) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data, MA organizations must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance. \* \* \* \* \* 0 31. Section 422.501 is amended by revising paragraphs (c)(1)(iv) and (2) to read as follows:

Sec.  422.501  Application requirements.

\* \* \* \* \*     (c) \* \* \*     (1) \* \* \*     (iv) Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2     (2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in Sec.  422.2 \* \* \* \* \*

Sec.  422.502  [Amended]

0 32. Section 422.502 is amended in paragraphs (b)(1) and (2) by removing the phrase ``14 months'' and adding in its place ``12 months'' each time it appears. 0 33. Section 422.503 is amended-- 0 a. In paragraph (b)(4)(ii), by removing the phrase ``financial and marketing activities'' and adding in its place ``financial and communication activities''; and 0 b. Revising paragraph (b)(4)(vi)(C).     The revision reads as follows:

Sec.  422.503  General provisions.

\* \* \* \* \*     (b) \* \* \*     (4) \* \* \*     (vi) \* \* \*     (C)(1) Each MA organization must establish and implement effective training and education for its compliance officer and organization employees, the MA organization's chief executive and other senior administrators, managers and governing body members.     (2) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee and new appointment to a chief executive, manager, or governing body member. \* \* \* \* \* 0 34. Section 422.504 is amended by-- 0 a. Revising paragraphs (a) introductory text and (a)(6). 0 b. Removing paragraph (a)(16). 0 c. Redesignating paragraphs (a)(17) and (18) as paragraphs (a)(16) and (17), respectively; and 0 d. Revising newly redesignated paragraph (a)(17). 0 e. Revising paragraph (i)(2)(v).     The revisions read as follows:

Sec.  422.504  Contract provisions.

\* \* \* \* \*     (a) Agreement to comply with regulations and instructions. The MA organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. Compliance with the terms of this paragraph is material to the performance of the MA contract. The MA organization agrees-- \* \* \* \* \*     (6) To comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and the preclusion list requirements in Sec. Sec.  422.222 and 422.224 \* \* \* \* \*     (17) To maintain a Part C summary plan rating score of at least 3 stars under the 5-star rating system specified in part 422 subpart D. A Part C summary plan rating is calculated as provided in Sec.  422.166 \* \* \* \* \*     (i) \* \* \*     (2) \* \* \*     (v) They will ensure that payments are not made to individuals and entities included on the preclusion list, defined in Sec.  422.2 \* \* \* \* \*

Sec.  422.506  [Amended]

0 35. Section 422.506 is amended by-- 0 a. Removing paragraph (a)(3); 0 b. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(3) and (4); and 0 c. Removing and reserving paragraph (b).

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0 36. Section 422.508 is amended by adding paragraph (a)(3) to read as follows:

Sec.  422.508  Modification or termination of contract by mutual consent.

    (a) \* \* \*     (3) If the organization submits a request to end the term of its contract after the deadline provided in Sec.  422.506(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (a) through (d) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare program. \* \* \* \* \* 0 37. Section 422.510 is amended by revising paragraphs (a)(4)(viii) and (xiii) and adding paragraphs (a)(4)(xiv) and (xv) and (b)(2)(v) to read as follows:

Sec.  422.510  Termination of contract by CMS.

    (a) \* \* \*     (4) \* \* \*     (viii) Substantially fails to comply with the requirements in subpart V of this part. \* \* \* \* \*     (xiii) Fails to meet the preclusion list requirements in accordance with Sec.  422.222 and 422.224     (xiv) The MA organization has committed any of the acts in Sec.   422.752(a) that support the imposition of intermediate sanctions or civil money penalties under Subpart O of this part.     (xv) Following the issuance of a notice to the MA organization no later than August 1, CMS must terminate, effective December 31 of the same year, an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.     (b) \* \* \*     (2) \* \* \*     (v) In the event that CMS issues a termination notice to an MA organization on or before August 1 with an effective date of the following December 31, the MA organization must issue notification to its Medicare enrollees at least 90 days before to the effective date of the termination. \* \* \* \* \* 0 38. Section 422.514 is amended by revising paragraph (b) to read as follows:

Sec.  422.514  Minimum enrollment requirements.

\* \* \* \* \*     (b) Minimum enrollment waiver. For a contract applicant that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract, CMS may waive the minimum enrollment requirement for the first 3 years of the contract. To receive a waiver, a contract applicant must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract during the first 3 years of the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which--     (1)(i) The contract applicant management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section; or     (ii) The contract applicant has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in this paragraph (b)(1) and stop-loss insurance that is adequate and acceptable to CMS; and     (2) The contract applicant is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year. \* \* \* \* \*

Sec.  422.590  [Amended]

0 39. Section 422.590 is amended by removing paragraph (f) and redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively.

Sec.  422.664  [Amended]

0 40. Section 422.664 is amended in paragraph (b)(1) by removing the phrase ``July 15'' and adding in its place ``September 1''. 0 41. Section 422.750 is amended by revising paragraph (a)(3) to read as follows:

Sec.  422.750  Types of intermediate sanctions and civil money penalties.

    (a) \* \* \*     (3) Suspension of communication activities to Medicare beneficiaries by an MA organization, as defined by CMS. \* \* \* \* \* 0 42. Section 422.752 is amended by revising paragraphs (a)(11) and (13) and (b) to read as follows:

Sec.  422.752  Basis for imposing intermediate sanctions and civil money penalties.

    (a) \* \* \*     (11) Fails to comply with communication restrictions described in subpart V of this part or applicable implementing guidance. \* \* \* \* \*     (13) Fails to comply with Sec. Sec.  422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities on the preclusion list, defined in Sec.  422.2     (b) Suspension of enrollment and communications. If CMS makes a determination that could lead to a contract termination under Sec.   422.510(a), CMS may impose the intermediate sanctions at Sec.   422.750(a)(1) and (3). \* \* \* \* \*

Subpart V--Medicare Advantage Communication Requirements

0 43. The subpart heading for Subpart V is revised to read as set forth above. 0 44. Section 422.2260 is revised to read as follows:

Sec.  422.2260  Definitions.

    For the purposes of this section--     Communications means activities and use of materials to provide information to current and prospective enrollees.     Communication materials means all information provided to current and prospective enrollees. Marketing materials are a subset of communication material.     Marketing means the use of materials or activities that meet the following:     (1) By the MA organization or downstream entities.     (2) Intended to draw a beneficiary's attention to a MA plan or plans.     (3) Influence a beneficiary's decision-making process when making a MA plan selection or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).     Marketing materials include, but are not limited to the following:     (1) Materials such as brochures; posters; advertisements in media such as newspapers, magazines, television, radio, billboards, or the Internet; and social media content.     (2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.     (3) Presentation materials such as slides and charts.     Marketing materials exclude materials that--     (1) Do not include information about the plan's benefit structure or cost sharing;     (2) Do not include information about measuring or ranking standards (for example, star ratings);     (3) Mention benefits or cost sharing, but do not meet the definition of marketing in this section; or

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    (4) Unless otherwise specified by CMS because of their use or purpose, are required under Sec.  422.111 0 45. Section 422.2262 is amended by revising paragraph (d) to read as follows:

Sec.  422.2262  Review and distribution of marketing materials.

\* \* \* \* \*     (d) Enrollee communication materials. Enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used. 0 46. Section 422.2264 is revised to read as follows:

Sec.  422.2264   Guidelines for CMS review.

    In reviewing marketing material or election forms under Sec.   422.2262, CMS determines that the materials--     (a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:     (1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.     (2) Adequate written description of any supplemental benefits and services.     (b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area and if applicable, continuation areas.     (c) Include in written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non- renewal may result in termination of the beneficiary's enrollment in the plan.     (d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations. 0 47. Section 422.2268 is amended by: 0 a. Removing the introductory text; and 0 b. Revising paragraphs (a) and (b).     The revisions read as follows:

Sec.  422.2268  Standards for MA organization communications and marketing.

    (a) In conducting communication activities, MA organizations may not do any of the following:     (1) Provide information that is inaccurate or misleading.     (2) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.     (3) Claim the MA organization is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the MA plan. It may explain that the organization is approved for participation in Medicare.     (4) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition must not apply to MA plan names in effect on July 31, 2000.     (5) Display the names and/or logos of co-branded network providers on the organization's member identification card, unless the provider names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals).     (6) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.     (7) For markets with a significant non-English speaking population, provide materials, as defined by CMS, unless in the language of these individuals. Specifically, MA organizations must translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.     (b) In marketing, MA organizations may not do any of the following:     (1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.     (2) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.     (3) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.     (4) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.     (5) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.     (6) Distribute marketing materials for which, before expiration of the 45-day period, the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.     (7) Conduct sales presentations or distribute and accept MA plan enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.     (8) Conduct sales presentations or distribute and accept plan applications at educational events.     (9) Display the names and/or logos of provider co-branding partners on marketing materials, unless the materials clearly indicate that other providers are available in the network.     (10) Knowingly target or send marketing materials to any MA enrollee during the Open Enrollment Period.     (11) Engage in any other marketing activity prohibited by CMS in its marketing guidance.     (12) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.     (13) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.     (14) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.     (15) Provide meals to potential enrollees, which is prohibited, regardless of value. \* \* \* \* \*

Sec.  422.2272  [Amended]

0 48. Section Sec.  422.2272 is amended by removing paragraph (e).

Sec.  422.2274   [Amended]

0 49. Section 422.2274 is amended by-- 0 a. Redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(iv). 0 b. Redesignating paragraph (b)(2)(iii) as paragraph (b)(1)(iii). 0 c. Removing paragraph (b)(2); and 0 d. Redesignating paragraph (b)(3) as paragraph (b)(2).

Sec.  422.2410   [Amended]

0 50. Section 422.2410 is amended in paragraph (a) by removing the phrase

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``an MLR'' and adding in its place the phrase ``the information required under Sec.  422.2460''.

Sec.  422.2420   [Amended]

0 51. Section 422.2420 is amended-- 0 a. By removing and reserving paragraph (b)(2)(ix); and 0 b. In paragraph (d)(2)(i), removing the phrase ``in Sec.  422.2420(b) or (c)'' and adding in its place the phrase ``in paragraph (b) or (c) of this section''. 0 52. Section 422.2430 is amended by-- 0 a. Redesignating paragraph (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively; 0 b. Adding a paragraph (a) subject heading and revising newly redesignated paragraph (a)(1); 0 c. Adding paragraph (a)(4); and 0 d. Removing and reserving paragraph (b)(8).     The revision and addition read as follows:

Sec.  422.2430  Activities that improve health care quality.

    (a) Activity requirements. (1) Activities conducted by an MA organization to improve quality must either--     (i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or     (ii) Be listed in paragraph (a)(4). \* \* \* \* \*     (4)(i) For an MA contract that includes MA-PD plans (described in Sec.  422.2420(a)(2)), Medication Therapy Management Programs meeting the requirements of Sec.  423.153(d) of this chapter.     (ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. \* \* \* \* \* 0 53. Section 422.2460 is revised to read as follows:

Sec.  422.2460  Reporting requirements.

    (a) For each contract year, from 2014 through 2017, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes but is not limited to the data needed by the MA organization to calculate and verify the MLR and remittance amount, if any, for each contract, under this part, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under Sec.  422.2410     (b) For contract year 2018 and for each subsequent contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:     (1) Fully credible and partially credible contracts. For each contract under this part that has fully credible or partially credible experience, as determined in accordance with Sec.  422.2440(d), the MA organization must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under Sec.  422.2410     (2) Non-credible contracts. For each contract under this part that has non-credible experience, as determined in accordance with Sec.   422.2440(d), the MA organization must report to CMS that the contract is non-credible.     (c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.     (d) The MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

Sec.  422.2480   [Amended]

0 54. Section 422.2480 is amended-- 0 a. In the introductory text by removing the phrase ``reviews of reports submitted'' and adding in its place ``review of data submitted''. 0 b. In paragraph (d) introductory text by removing the phrase ``Reports submitted '' and adding in its place the phrase ``Data submitted''.

Sec.  422.2490   [Amended]

0 55. Section 422.2490 is amended in paragraph (a) by removing the phrase ``information contained in reports submitted'' and adding in its place the phrase ``information submitted''.

PART 423--MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

0 56. The authority citation for part 423 continues to read as follows:

    Authority:  Secs. 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act (42 U.S.C 1302, 1395w-101 through 1395w- 152, and 1395hh).

0 57. Amend Sec.  423.4 by revising the definition of ``Generic drug'' to read as follows:

Sec.  423.4  Definitions.

\* \* \* \* \*     Generic drug means--     (1) A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)) is approved; and     (2) For purposes of cost sharing under sections 1860D-2(b)(4) and 1860D-14(a)(1)(D) of the Act only, a biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C 262(k)) is approved. \* \* \* \* \* 0 58. Amend Sec.  423.32 by revising paragraph (b) introductory text and redesignating paragraphs (b)(i) and (ii) as (b)(1) and (2).     The revision reads as follows:

Sec.  423.32  Enrollment process.

\* \* \* \* \*     (b) Enrollment form or CMS-approved enrollment mechanism. The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in Sec.  423.2262 \* \* \* \* \* 0 59. Section 423.38 is amended by-- 0 a. Revising paragraph paragraphs (c) introductory text, (c)(4), and (c)(8)(i)(C); 0 b. Adding paragraph (c)(9); 0 c. Revising paragraph (d); and 0 d. Adding paragraph (e).     The revisions and additions read as follows:

Sec.  423.38  Enrollment periods.

\* \* \* \* \*     (c) Special enrollment periods. A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA-PD plan (as provided at Sec.  422.62(b) of this chapter), as applicable, under any of the following circumstances: \* \* \* \* \*     (4) The individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in Sec.  423.772, who has not been identified as a ``potential at-risk beneficiary'' or ``at-risk beneficiary'' as defined in Sec.  423.100 and--     (i) Making an allowable onetime-per-calendar-year election; or     (ii) Making an election after notification of a CMS or State- initiated enrollment action or within 2 months of that enrollment action's effective date. \* \* \* \* \*     (8) \* \* \*     (i) \* \* \*     (C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communication materials as outlined in subpart V. \* \* \* \* \*     (9) The individual is making an election within 2 months of a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later.     (d) Enrollment period to coordinate with MA annual 45-day disenrollment

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period. Through 2018, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in Sec.  422.62(a)(5), may also elect a PDP during this time.     (e) Enrollment period to coordinate with MA open enrollment period. For 2019 and subsequent years, an individual who makes an election as described in Sec.  422.62(a)(3), may make an election to enroll in or disenroll from Part D coverage. An individual who elects Original Medicare during the MA open enrollment period may elect to enroll in a PDP during this time. 0 60. Section 423.40 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

Sec.  423.40  Effective dates.

\* \* \* \* \*     (d) PDP enrollment period to coordinate with the MA annual disenrollment period. Through 2018, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in Sec.  422.62(a)(5) will be effective the first day of the month following the month in which the enrollment in the PDP is made.     (e) PDP enrollment period to coordinate with the MA annual disenrollment period. For 2019 and subsequent years, an enrollment made by an individual who elects Original Medicare during the MA open enrollment period as described in Sec.  422.62(a)(3), will be effective the first day of the month following the month in which the election is made. 0 61. Section Sec.  423.100 is amended-- 0 a. By revising the definition of ``Affected enrollee''; 0 b. By adding in alphabetical order definitions for ``At risk beneficiary'', ``Clinical guidelines'', ``Exempted beneficiary'', ``Frequently abused drug'', and ``Mail-Order pharmacy''; 0 c. By removing the definition of ``Other authorized prescriber''; 0 d. By adding in alphabetical order definitions for ``Potential at-risk beneficiary'', ``Preclusion List'', and ``Program size''; and 0 e. By revising the definition of ``Retail pharmacy''.     The revisions and additions read as follows:

Sec.  423.100  Definitions.

\* \* \* \* \*     Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing and such drug removal or cost-sharing change affects the Part D enrollee's access to the drug during the current plan year. \* \* \* \* \*     At-risk beneficiary means a Part D eligible individual--     (1) Who is--     (i) Identified using clinical guidelines (as defined in Sec.   423.100);     (ii) Not an exempted beneficiary; and     (iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program in accordance with the requirements of Sec.  423.153(f); or     (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. \* \* \* \* \*     Clinical guidelines, for the purposes of a drug management program under Sec.  423.153(f), are criteria--     (1) To identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs; and     (2) That are developed in accordance with Sec.  423.153(f)(16) and published in guidance annually. \* \* \* \* \*     Exempted beneficiary means with respect to a drug management program, an enrollee who--     (1) Has elected to receive hospice care;     (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or     (3) Has a cancer diagnosis.     Frequently abused drug means a controlled substance under the Federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account all of the following factors:     (1) The drug's schedule designation by the Drug Enforcement Administration.     (2) Government or professional guidelines that address that a drug is frequently abused or misused.     (3) An analysis of Medicare or other drug utilization or scientific data. \* \* \* \* \*     Mail-order pharmacy means a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing. \* \* \* \* \*     Potential at-risk beneficiary means a Part D eligible individual--     (1) Who is identified using clinical guidelines (as defined in Sec.  423.100); or     (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification.     Preclusion list means a CMS compiled list of prescribers who--     (1) Meet all of the following requirements:     (i) The prescriber is currently revoked from the Medicare program under Sec.  424.535     (ii) The prescriber is currently under a reenrollment bar under Sec.  424.535(c).     (iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:     (A) The seriousness of the conduct underlying the prescriber's revocation;     (B) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and     (C) Any other evidence that CMS deems relevant to its determination; or.     (2) Meet both of the following requirements:     (i) The prescriber has engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare.     (ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the all of the following factors:     (A) The seriousness of the conduct involved.     (B) The degree to which the prescriber's conduct could affect the integrity of the Part D program.     (C) Any other evidence that CMS deems relevant to its determination. \* \* \* \* \*     Program size means the estimated population of potential at-risk beneficiaries in drug management

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programs (described in Sec.  423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines. \* \* \* \* \*     Retail pharmacy means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy. \* \* \* \* \* 0 62. Section 423.120 is amended by-- 0 a. Redesignating paragraph (b)(3)(i) introductory text and paragraphs (b)(3)(i)(A) through (D) as paragraphs (b)(3)(i)(A) introductory text and (b)(3)(i)(A)(1) through (4); 0 b. Adding a new paragraph (b)(3)(i)(B); 0 c. Revising paragraph (b)(3)(iii); 0 d. In paragraph (b)(5)(i) introductory text, by removing the figure ``60'' and adding in its place the figure ``30'' and by adding the phrase ``(for purposes of this paragraph (b)(5) these entities are referred to as ``CMS and other specified entities'') after the word ``pharmacists''; 0 e. In paragraph (b)(5)(i)(A), by removing the phrase ``60 days'' and adding in its place the phrase ``2 months''; 0 f. In paragraph (b)(5)(i)(B), by removing the figure ``60'' and adding in its place the figure ``30''; 0 g. In paragraph (b)(5)(iii), by removing the phrase ``, CMS, State Pharmaceutical Assistance Programs (as defined in Sec.  423.454), entities providing other prescription drug coverage (as described in Sec.  423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists'' and adding in its place the phrase ``and CMS and other specified entities''; 0 h. Adding paragraph (b)(5)(iv); 0 i. In paragraph (b)(6), by removing the phrase ``under paragraphs (b)(5)(iii) of this section'' and adding in its place the phrase ``under paragraphs (b)(5)(iii) and (iv) of this section''; and 0 j. Revising paragraphs (c)(5) and (6).     The additions and revisions read as follows:

Sec.  423.120  Access to covered Part D drugs.

\* \* \* \* \*     (b) \* \* \*     (3) \* \* \*     (B) Not apply in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as permitted under paragraphs (b)(5)(iv) and (b)(6) of this section. \* \* \* \* \*     (iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least a month's supply of medication, unless the prescription is written by a prescriber for less than a month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of a month's supply of medication. \* \* \* \* \*     (5) \* \* \*     (iv) A Part D sponsor may immediately remove a brand name drug (as defined in Sec.  423.4) from its Part D formulary or change the brand name drug's preferred or tiered cost-sharing without meeting the deadlines and refill requirements of paragraph (b)(5)(i) of this section provided that the Part D sponsor does all of the following:     (A) At the same time that it removes such brand name drug or changes its preferred or tiered cost-sharing, it adds a therapeutically equivalent (as defined in Sec.  423.100) generic drug (as defined in Sec.  423.4) to its formulary with the same or lower cost-sharing and the same or less restrictive utilization management criteria.     (B) The Part D sponsor previously could not have included such therapeutically equivalent generic drug on its formulary when it requested CMS formulary approval consistent with Sec.  423.120(b)(2) because such generic drug was not yet available on the market.     (C) Before making any permitted generic substitutions, the Part D sponsor provides general notice to all current and prospective enrollees in its formulary and other applicable beneficiary communication materials advising them that--     (1) Such changes may be made at any time when a new generic is added in place of a brand name drug, and there may be no advance direct notice to the affected enrollees;     (2) If such a substitution should occur, affected enrollees will receive direct notice including information on the specific drugs involved and steps they may take to request coverage determinations and exceptions under Sec. Sec.  423.566 and 423.578; and     (D) Before making any permitted generic substitutions, the Part D sponsor provides advance general notice to CMS and other specified entities.     (E) The Part D sponsor provides notice of any such formulary changes to affected enrollees and CMS and other specified entities consistent with the requirements of paragraphs (b)(5)(i) (as applicable) and (ii) of this section. This would include direct notice to the affected enrollees. \* \* \* \* \*     (c) \* \* \*     (5)(i) A Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug.     (ii) The sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).     (A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to--     (1) Confirm that the NPI is active and valid; or     (2) Correct the NPI.     (B) If the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.     (iii) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor--     (A) Has complied with paragraph (ii) of this section;     (B) Has verified that a submitted NPI was not in fact active and valid; and     (C) The agreement between the parties explicitly permits such recoupment.     (iv) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.     (6)(i) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in Sec.  423.100     (ii) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its

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PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in Sec.  423.100     (iii) A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in Sec.   423.100, for the date of service.     (iv)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) of this section or deny a request for reimbursement under paragraph (c)(6)(ii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.     (B) Upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraph (c)(6)(i) or (ii) of this section, a Part D sponsor or its PBM must do the following:     (1) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:     (i) A provisional supply coverage period during which the sponsor must cover all drugs dispensed to the beneficiary in accordance with prescriptions written by the individual on the preclusion list. The provisional supply period begins on the date-of-service the first drug is dispensed in accordance with a prescription written by the individual on the preclusion list.     (ii) Written notice within 3 business days after adjudication of the first claim or request for the drug in a form and manner specified by CMS.     (2) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(B)(1)(ii) of this section.     (v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights.     (B) A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with 42 CFR part 498.     (vi) CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS takes into account--     (A) The degree to which beneficiary access to Part D drugs would be impaired; and     (B) Any other evidence that CMS deems relevant to its determination. \* \* \* \* \* 0 63. Section 423.128 is amended by revising paragraph (d)(2)(iii) to reads as follows:

Sec.  423.128  Dissemination of Part D plan information.

\* \* \* \* \*     (d) \* \* \*     (2) \* \* \*     (iii) Provides current and prospective Part D enrollees with notice that is timely under Sec.  423.120(b)(5) regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. \* \* \* \* \* 0 64. Section 423.153 is amended by adding a sentence at the end of paragraph (a) and adding paragraph (f) to read as follows:

Sec.  423.153  Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

    (a) \* \* \*     A Part D plan sponsor may establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section. \* \* \* \* \*     (f) Drug management programs. A drug management program must meet all the following requirements:     (1) Written policies and procedures. A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. These policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following:     (i) The appropriate credentials of the personnel conducting case management required under paragraph (f)(2) of this section.     (ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2) of this section.     (iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary and a potential at- risk beneficiary in Sec.  423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at- risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plan.     (2) Case management/clinical contact/prescriber verification--(i) General rule. The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following:     (A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at risk beneficiary.     (B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary.     (C) In cases where the prescribers have not responded to the inquiry described in paragraph (f)(2)(i)(B) of this section, make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.     (ii) Exception for identification by prior plan. If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is clinically adequate and up to date.     (3) Limitation on access to coverage for frequently abused drugs. Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following:     (i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary.     (ii) In accordance with paragraphs (f)(10) and (11) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are--     (A) Prescribed for the beneficiary by one or more prescribers;

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    (B) Dispensed to the beneficiary by one or more network pharmacies; or     (C) Specified in both paragraphs (f)(3)(ii)(A) and (C) of this section.     (iii)(A) If the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal.     (B) If the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) or prescriber(s) or both, as applicable--     (1) In accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal; and     (2) Except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section.     (4) Requirements for limiting access to coverage for frequently abused drugs. (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following:     (A) Conducted case management as required by paragraph (f)(2) of this section and updated it, if necessary.     (B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate.     (C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section.     (ii) If the sponsor has complied with the requirement of paragraph (f)(2)(i)(C) of this section, and the prescribers were not responsive after 3 attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section.     (iii) The sponsor has met the case management requirement in paragraph (f)(2)(i) of this section if--     (A) The beneficiary meets paragraph (2) of the definition of a potential at-risk beneficiary or an at-risk beneficiary; and     (B) The sponsor has obtained the applicable case management information from the sponsor of the beneficiary's most recent plan and updated it as appropriate.     (iv) A Part D sponsor must not limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers under paragraph (f)(3)(ii)(A) of this section unless--     (A) At least 6 months has passed from the date the beneficiary was first identified as a potential at-risk beneficiary from the date of the applicable CMS identification report; and     (B) The beneficiary meets the clinical guidelines and was reported by the most recent CMS identification report.     (5) Initial notice to a beneficiary. (i) A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary.     (ii) The notice must do all of the following:     (A) Use language approved by the Secretary.     (B) Be in a readable and understandable form.     (C) Provide all of the following information:     (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary.     (2) A description, of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits).     (3) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at- risk beneficiary and the standard and expedited redetermination processes described at Sec.  423.580 et seq.     (4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under paragraph (f)(3)(ii) of this section.     (5) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including the following:     (i) An explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program.     (ii) The timeframe for the sponsor's decision     (iii) If applicable, any limitation on the availability of the special enrollment period described in Sec.  423.38     (6) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(4) of this section.     (7) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program.     (8) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     (iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i) of this section.     (6) Second notice. (i) Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary.     (ii) The second notice must do all of the following:     (A) Use language approved by the Secretary.     (B) Be in a readable and understandable form.     (C) Provide all of the following information:     (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary.     (2) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including--     (i) The limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and     (ii) If applicable, any limitation on the availability of the special enrollment period described in Sec.  423.38     (3) The prescriber(s) or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor.

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    (4) An explanation of the beneficiary's right to a redetermination under Sec.  423.580 et seq., including--     (i) A description of both the standard and expedited redetermination processes; and     (ii) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.     (5) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs.     (6) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(5) of this section.     (7) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     (iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(6)(i) of this section.     (7) Alternate second notice. (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary.     (ii) The alternate second notice must do all of the following:     (A) Use language approved by the Secretary.     (B) Be in a readable and understandable form.     (C) Provide all of the following information:     (1) The sponsor has determined that the beneficiary is not an at- risk beneficiary.     (2) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs.     (3) If applicable, the SEP limitation no longer applies.     (4) Clear instructions that explain how the beneficiary may contact the sponsor.     (5) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     (ii) The Part D sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required in accordance with paragraph (f)(7)(i) of this section.     (8) Timing of notices. (i) Subject to paragraph (f)(8)(ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days and not more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice described in paragraph (f)(5) of this section.     (ii) Immediately upon the beneficiary's enrollment in the gaining plan, the gaining plan sponsor may immediately provide a second notice described in paragraph (f)(6) of this section to a beneficiary for whom the gaining sponsor received a notice that the beneficiary was identified as an at-risk beneficiary by his or her most recent prior plan, and such identification had not been terminated in accordance with paragraph (f)(14) of this section, if the sponsor is implementing either of the following:     (A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i) of this section.     (B) A limitation on access to coverage as described in paragraph (f)(3(ii) of this section, if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under paragraph (f)(9) of this section.     (9) Beneficiary preferences. Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following:     (i) Review such preferences.     (ii) If the beneficiary is--     (A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s).     (B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s).     (iii) The sponsor must inform the beneficiary of the selection in--     (A) The second notice; or     (B) If the second notice is not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission.     (10) Exception to beneficiary preferences. (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary.     (ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with--     (A) At least 30 days advance written notice of the change; and     (B) A rationale for the change.     (11) Reasonable access. In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure both of the following:     (i) That the beneficiary continues to have reasonable access to frequently abused drugs, taking into account--     (1) Geographic location;     (2) Beneficiary preference;     (3) The beneficiary's predominant usage of a prescriber or pharmacy or both;     (4) The impact on cost-sharing; and     (5) Reasonable travel time.     (ii) Reasonable access to frequently abused drugs in the case of--     (A) Individuals with multiple residences;     (B) Natural disasters and similar situations; and     (C) The provision of emergency services.     (12) Selection of prescribers and pharmacies. (i) A Part D plan sponsor must select, as applicable--     (A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP and the selection involves a prescriber(s), in which case, the prescriber need not be a network prescriber; and     (B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary.     (ii)(A) For purposes of this paragraph (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy must collectively be treated as one pharmacy.

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    (B) For purposes of this paragraph (f)(12) of this section, in the case of a group practice, all prescribers of the group practice must be treated as one prescriber.     (13) Confirmation of selections(s). (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is (are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs.     (ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both that the selection is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the prescriber or pharmacy will be notified by the sponsor of its selection.     (14) Termination of identification as an at-risk beneficiary. The identification of an at-risk beneficiary as such must terminate as of the earlier of the following:     (i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary.     (ii) The end of a 12-calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section.     (15) Data disclosure. (i) CMS identifies each potential at-risk beneficiary to the sponsor of the prescription drug plan in which the beneficiary is enrolled.     (ii) A Part D sponsor that operates a drug management program must disclose any data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner specified by CMS. The data and information disclosures must do all of the following:     (A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS.     (B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries;     (C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs.     (D) Transfer case management information upon request of a gaining sponsor as soon as possible but not later than 2 weeks from the gaining sponsor's request when--     (1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and     (2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.     (16) Clinical guidelines. Potential at-risk beneficiaries and at- risk beneficiaries are identified by CMS or the Part D sponsor using clinical guidelines that--     (i) Are developed with stakeholder consultation;     (ii) Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of this factors;     (iii) Are derived from expert opinion and an analysis of Medicare data; and     (iv) Include a program size estimate. 0 65. Section 423.160 is amended by 0 a. Revising paragraph (b)(1)(iv); 0  b. Adding paragraph (b)(1)(v); 0 c. Revising paragraph (b)(2)(iii); 0 d. Adding paragraph (b)(2)(iv); 0 e. Revising paragraph (b)(4); and 0 f. Adding paragraph (c)(1)(vii).     The revisions and additions read as follows:

Sec.  423.160  Standards for electronic prescribing.

\* \* \* \* \*     (b) \* \* \*     (1) \* \* \*     (iv) From March 1, 2015 until January 1, 2019, the standards specified in paragraphs (b)(2)(iii), (b)(3), (b)(4)(i), (b)(5)(iii), and (b)(6).     (v) On or after January 1, 2019, the standards specified in paragraphs (b)(2)(iii) and (b)(3), (b)(4)(ii), (b)(5)(iii), and (b)(6) of this section.     (2) \* \* \*     (iii) National Council for Prescription Drug Programs Prescriber/ Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 10, Release 6 (Version 10.6), November 12, 2008 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:     (A) Get message transaction.     (B) Status response transaction.     (C) Error response transaction.     (D) New prescription transaction.     (E) Prescription change request transaction.     (F) Prescription change response transaction.     (G) Refill/Resupply prescription request transaction.     (H) Refill/Resupply prescription response transaction.     (I) Verification transaction.     (J) Password change transaction.     (K) Cancel prescription request transaction.     (L) Cancel prescription response transaction.     (M) Fill status notification.     (iv) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or related prescription-related information between prescribers and dispensers for the following:     (A) Get message transaction.     (B) Status response transaction.     (C) Error response transaction.     (D) New prescription transaction.     (E) Prescription change request transaction.     (F) Prescription change response transaction.     (G) Refill/Resupply prescription request transaction.     (H) Refill/Resupply prescription response transaction.     (I) Verification transaction.     (J) Password change transaction.     (K) Cancel prescription request transaction.     (L) Cancel prescription response transaction.     (M) Fill status notification.     (N) Prescription drug administration message.     (O) New prescription requests.     (P) New prescription response denials.     (Q) Prescription transfer message.     (R) Prescription fill indicator change.     (S) Prescription recertification.     (T) REMS initiation request.     (U) REMS initiation response.     (V) REMS request.     (W) REMS response. \* \* \* \* \*     (4) Medication history. Medication history to provide for the

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communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers and dispensers:     (i) Until January 1, 2017, Either the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005 (incorporate by reference in paragraph (c)(1)(v) of this section, or the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(vi) of this section.     (ii) On or after January 1, 2019, the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section). \* \* \* \* \*     (c) \* \* \*     (1) \* \* \*     (vii) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017. \* \* \* \* \* 0 66. Sections 423.180, 423.182, 423.184 and 423.186 are added Subpart D to read as follows:

Subpart D--Cost Control and Quality Improvement Requirements

\* \* \* \* \* Sec. 423.180 Basis and scope of the Part D Quality Rating System. 423.182 Part D Quality Rating System. 423.184 Adding, updating, and removing measures. 423.186 Calculation of star ratings.

Sec.  423.180  Basis and scope of the Part D Quality Rating System.

    (a) Basis. This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part D.     (b) Purpose. Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:     (1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.     (2) To provide quality ratings on a 5-star rating system.     (3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by Part D plans, where appropriate and possible to use data of the type described in Sec.  423.182(c).     (c) Applicability. The regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year.

Sec.  423.182  Part D Quality Rating System.

    (a) Definitions. In this subpart the following terms have the meanings:     CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.     Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.     Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).     Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that scores in the same Star Rating level are as similar as possible and scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.     Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.     Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.     Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.     Domain rating means the rating that groups measures together by dimensions of care.     Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.     Highest rating means the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.     Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).     Low-income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see Sec.  423.34 for definition of a low-income subsidy eligible individual).     Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.     Measure score means the numeric value of the measure or an assigned `missing data' message.     Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1-5 star scale.

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    Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.     Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.     Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.     Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.     Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (``signal'') rather than random variation (``noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).     Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.     Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.     Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.     Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by ***deleting*** the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place ***deleted***.     (b) Contract ratings--(1) General. CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA-PD contract and a Part D summary rating for each PDP contract using the 5- star rating system described in this subpart. For PDP contracts, the Part D summary rating is the highest rating. Measures are assigned stars at the contract level and weighted in accordance with Sec.   423.186(a). Domain ratings are the average of the individual measure ratings under the topic area in accordance with Sec.  423.186(b). Summary ratings are the weighted average of the individual measure ratings for Part C or Part D in accordance with Sec.  423.186(c). Overall Star Ratings are calculated by using the weighted average of the individual measure ratings in accordance with Sec.  423.186(d) with both the reward factor and CAI applied as applicable, as described in Sec.  423.186(f).     (2) Plan benefit packages. All plan benefit packages (PBPs) offered under an MA contract or PDP plan sponsor have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization or PDP plan sponsor. Data from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract. A contract level score is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.     (3) Contract consolidations. (i) In the case of contract consolidations involving two or more contracts for health and/or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(ii) of this section.     (ii) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:     (A) For the first year after consolidation, CMS will use enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based and call center measures. The survey- based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.     (B) For the second year after consolidation, CMS will use the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except those from CAHPS. CMS will ensure that the CAHPS survey sample will include enrollees in the sample frame from both the surviving and consumed contracts.     (c) Data sources. (1) Part D Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Beneficiary experiences, benefit administration information, clinical data, and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of Part D plans' compliance with contract requirements, data submitted by plans, and CMS administrative data.     (2) Part D sponsors are required to collect, analyze, and report data that permit measurement of indices of quality. Part D sponsors must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) to CMS on a timely basis as requested by CMS.

Sec.  423.184  Adding, updating, and removing measures.

    (a) General. CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.     (b) Review of data quality. CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.     (c) Adding measures. (1) CMS will continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance and the Pharmacy Quality Alliance or endorsed by the National Quality Forum for adoption and use in the Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.     (2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

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    (3) New measures added to the Part D Star Ratings program will be on the display page on [*www.cms.gov*](http://www.cms.gov) for a minimum of 2 years prior to becoming a Star Ratings measure.     (4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.     (d) Updating measures--(1) Non-substantive updates. For measures that are already used for Star Ratings, CMS will update measures so long as the changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that--     (i) Narrow the denominator or population covered by the measure;     (ii) Do not meaningfully impact the numerator or denominator of the measure;     (iii) Update the clinical codes with no change in the target population or the intent of the measure;     (iv) Provide additional clarifications:     (A) Adding additional qualifiers that would meet the numerator requirements;     (B) Clarifying documentation requirements;     (C) Adding additional instructions; or     (v) Add alternative data sources.     (2) Substantive updates. For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1), CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of the performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.     (e) Removing measures. (1) CMS will remove a measure from the Star Ratings program as follows:     (i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes, or     (ii) A measure shows low statistical reliability.     (2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.     (f) Improvement measure. CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph; the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.     (1) Identifying eligible measures. Annually, the subset of measures to be included in the Part D improvement measure will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measure if the measures meet all the following:     (i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.     (ii) CMS will exclude any measure for which there was a substantive specification change, from the previous year.     (iii) The Part D improvement measure will include only Part D measure scores.     (2) Determining eligible contracts. CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iii) of this section.     (3) Special rules for calculation of the improvement score. For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).     (4) Calculation of the improvement score. The improvement measure will be calculated as follows:     (i) The improvement change score (the difference in the measure scores in the 2-year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.     (ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05     (iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.     (iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.     (v) The improvement measure score will be converted to a measure- level Star Rating using hierarchical clustering algorithms.     (vi) The Part D improvement measure scores for MA-PDs and PDPs will be determined using cluster algorithms in accordance with Sec.   423.186(a)(2)(ii). The Part D improvement measure thresholds for MA-PDs and PDPs would be reported separately.     (g) Data integrity. (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measures.     (i) CMS will reduce measures based on Part D reporting requirements data to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation standards/sub-standards for data directly used to calculate the associated measure.

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    (ii) For the appeals measures, CMS will use statistical criteria to estimate the percentage of missing data for each contract using data from multiple sources such as a timeliness monitoring study or audit information to scale the star reductions to determine whether the data at the independent review entity (IRE) are complete.     (A) The criteria would allow CMS to use scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.     (B) The data submitted for the timeliness monitoring project (TMP) or audit that aligns with the Star Ratings year measurement period will be used to determine the scaled reduction.     (C) The determination of the Part C appeals measure IRE data reduction is done independently of the Part D appeals measure IRE data reduction.     (D) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data would be a four-star reduction.     (E) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:     (1) 20 percent, 1 star reduction.     (2) 40 percent, 2 star reduction.     (3) 60 percent, 3 star reduction.     (4) 80 percent, 4 star reduction.     (F) If a contract receives a reduction due to missing Part D IRE data, the reduction is applied to both of the contract's Part D appeals measures.     (G) The scaled reduction is applied after the calculation for the appeals measure-level star ratings. If the application of the scaled reduction results in a measure-level star rating less than one-star, the contract will be assigned one-star for the appeals measure.     (H) The Part D Calculated Error is determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.     (I) The projected number of cases not forwarded to the IRE in a 3- month period is calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the data collection or data sample time period. The value of the constant will be 1.0 for contracts that submitted 3 months of data; 1.5 for contracts that submitted 2 months of data; and 3.0 for contracts that submitted 1 month of data.     (J) Contracts would be subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:     (1) The calculated error rate is 20 percent or more; and     (2) The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.     (K) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.     (1) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.     (2) The reduction is identified by the highest threshold that a contract's lower bound exceeds.     (2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) and (ii) of this section, including a contract's failure to adhere to CAHPS reporting requirements.

Sec.  423.186  Calculation of Star Ratings.

    (a) Measure Star Ratings--(1) Cut points. CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, we propose to determine MA-PD and PDP cut points separately.     (2) Clustering algorithm for all measures except CAHPS measures. (i) The method minimizes differences within star categories and maximize differences across star categories using the hierarchical clustering method.     (ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.     (iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.     (A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.     (B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.     (3) Relative distribution and significance testing for CAHPS measures. The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60 Low reliability scores are those with at least 11 respondents, reliability greater than or equal to 0.60 but less than 0.75, and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:     (i) A contract is assigned 1 star if both of the following criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(i)(C) or (D) of this section is met:     (A) Its average CAHPS measure score is lower than the 15th percentile; and     (B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score.     (C) The reliability is not low.     (D) Its average CAHPS measure score is more than one standard error below the 15th percentile.     (ii) A contract is assigned two stars if it does not meet the 1 star criteria and meets at least one of the following criteria:     (A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability.     (B) Its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability.     (C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.     (iii) A contract is assigned three stars if it meets at least one of the following criteria:     (A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different from the national average CAHPS measure score.     (B)(1) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile;     (2) The reliability is low; and     (3) The score is not statistically significantly lower than the national average CAHPS measure score.     (C)(1) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile;     (2) The reliability is low; and     (3) The score is not statistically significantly higher than the national average CAHPS measure score.     (iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of the following criteria:     (A) Its average CAHPS measure score is at or above the 60th percentile and

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the measure does not have low reliability.     (B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability.     (C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.     (v) A contract is assigned five stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(v)(C) or (D) of this section is met:     (A) Its average CAHPS measure score is at or above the 80th percentile.     (B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score.     (C) The reliability is not low.     (D) Its average CAHPS measure score is more than one standard error above the 80th percentile.     (4) Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.     (b) Domain Star Ratings. (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.     (ii) The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.     (2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.     (i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.     (ii) The domain ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.     (c) Part D summary ratings. (1) CMS will calculate the Part D summary ratings using the weighted mean of the measure-level Star Ratings for Part D, weighted in accordance with paragraph (e) with an adjustment to reward consistently high performance described and the application of the CAI, under paragraph (f) of this section.     (2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have a summary rating calculated.     (ii) The Part D improvement measure is not included in the count of the minimum number of rated measures.     (3) The summary ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.     (d) Overall MA-PD rating. (1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with an adjustment to reward consistently high performance described and the application of the CAI, under paragraph (f).     (2)(i) An MA-PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.     (ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.     (iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.     (iv) The overall rating is on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.     (e) Measure weights--(1) General rules. Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.     (i) Improvement measures receive the highest weight of 5.     (ii) Outcome and Intermediate outcome measures receive a weight of 3.     (iii) Patient experience and complaint measures receive a weight of 1.5     (iv) Access measures receive a weight of 1.5     (v) Process measures receive a weight of 1.     (2) Rules for new measures. New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. In subsequent years, the measure will be assigned the weight associated with its category.     (3) Special rule for Puerto Rico. Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.     (f) Completing the Part D summary and overall rating calculations. CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph.     (1) Reward factor. This rating-specific factor is added to both the summary and overall ratings of contracts that qualify for the reward factor based on both high and stable relative performance for the rating level.     (i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA-PDs and Part D summary for MA-PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA-PDs and Part D summary for MA-PDs and PDPs). The weighted mean and weighted variance are compared separately for MA-PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean will be calculated both with and without the improvement measures. For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure.     (ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).     (iii) The combination of the relative variance and relative mean is used to determine the reward factor to be added to the contract's summary and overall ratings as follows:     (A) A contract with low variance and a high mean will have a reward factor equal to 0.4

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    (B) A contract with medium variance and a high mean will have a reward factor equal to 0.3     (C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2     (D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1     (E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0     (iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.     (2) Categorical adjustment index. CMS applies the categorical adjustment index (CAI) as provided in this paragraph to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE)/or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part D for MA-PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.     (i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment (if applicable).     (A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.     (B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year. The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period. Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.     (C) A MA-PD contract may be adjusted up to three times with the CAI: one for the overall Star Rating and one for each of the summary ratings (Part C and Part D).     (D) A PDP contract may be adjusted only once for the CAI: For the Part D summary rating.     (E) The CAI values are rounded and displayed with 6 decimal places.     (ii) In determining the CAI values, a measure will be excluded as a candidate for inclusion for adjustment if the measure meets any of the following:     (A) The measure is already case-mix adjusted for socioeconomic status.     (B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.     (C) The measure is scheduled to be retired or revised.     (D) The measure is applicable only to SNPs.     (iii) CMS will announce the measures identified for inclusion in the calculations of the CAI in accordance with this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. The measures for inclusion in the calculations of the CAI values will be selected based on the analysis of the dispersion of the LIS/DE within contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. CMS calculates the results of each contract's estimated difference between the LIS/DE and non-LIS/DE performance rates per contract using logistic mixed effects model that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately. The following decision criteria is used to determine the measures for adjustment:     (A) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more.     (B) The LIS/DE subgroup performed better or worse than the non-LIS/ DE subgroup in all contracts.     (C) The Part D measures for MA-PDs and PDPs will be analyzed independently, but the Part D measures selected for adjustment will include measures that meet the selection criteria for either delivery system.     (iv) The adjusted measures scores for the selected measures are determined using the results from regression models of beneficiary level measure scores that adjust for the average within contract difference in measure scores for MA or PDP contracts.     (A) A logistic regression model with contract fixed effects and beneficiary level indicators of LIS/DE and disability status is used for the adjustment.     (B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.     (v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part D summary for MA-PDs and Part D summary for PDPs) in each final adjustment category.     (A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled (using the enrollment data that parallels the previous Star Ratings year's data) would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).     (B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.     (C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).     (D) The mean difference within each final adjustment category by rating-type (Part D for MA-PD, Part D for PDPs or overall) would be the CAI values for the next Star Ratings year.     (vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:     (A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.     (B) The Medicare enrollment data from the same measurement period as the Star Rating's year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries

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with mailing addresses in the 10 highest poverty states.     (vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.     (A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.     (B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.     (C) The model's coefficient and intercept are updated annually and published in the Technical Notes.     (g) Applying the improvement measure scores. (1) CMS runs the calculations twice for each highest rating for each contract-type (overall rating for MA-PD contracts and Part D summary rating for PDPs), with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest rating, CMS applies the following rules:     (i) Contracts with 2 or fewer stars for their highest rating when calculated without improvement and with all applicable adjustments (CAI and the reward factor) will not have their rating calculated with the improvement measure(s).     (ii) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.     (iii) If the highest rating is between 2 stars and 4 stars with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).     (2) The Part D summary rating for MA-PDs will include the Part D improvement measure.     (h) Posting and display of ratings. For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag ``Not enough data available.'' If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag ``Plan too new to be measured''.     (i) Medicare Plan Finder performance icons. Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph:     (1) High-performing icon. The high performing icon is assigned to a Part D plan sponsor for achieving a 5-star Part D summary rating and an MA-PD contract for a 5-star overall rating.     (2) Low-performing icon. (i) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.     (ii) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.     (3) Plan preview of the Star Ratings. CMS will have plan preview periods before each Star Ratings release during which Part D plan sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder. 0 67. Section 423.265 is amended by revising paragraph (b)(2) to read as follows.

Sec.  423.265  Submission of bids and related information.

\* \* \* \* \*     (b) \* \* \*     (2) Substantial differences between bids--(i) General rule. Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered ``substantially different,'' each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.     (ii) Exception. A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions. \* \* \* \* \*

Sec.  423.503   [Amended]

0 68. Section 423.503 is amended in paragraphs (b)(1) and (2) by removing the phrase ``14 months'' and adding in its place ``12 months'' each time it appears. 0 69. Section 423.504 is amended by revising paragraphs (b)(4)(ii) and (b)(4)(vi)(C) to read as follows.

Sec.  423.504  General provisions.

\* \* \* \* \*     (b) \* \* \*     (4) \* \* \*     (ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and communication activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization. \* \* \* \* \*     (vi) \* \* \*     (C)(1) Each Part D plan sponsor must establish and implement effective training and education for its compliance officer and organization employees, the Part D sponsor's chief executive and other senior administrators, managers and governing body members.     (2) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, and new appointment to a chief executive, manager, or governing body member. \* \* \* \* \* 0 70. Section 423.505 is amended-- 0 a. By revising paragraph (b)(18); 0 b. In paragraph (b)(25), by removing the word ``marketing'' and adding in its place the word ``communication''; and 0 c. By revising paragraph (b)(26).     The revisions read as follows:

Sec.  423.505  Contract provisions.

\* \* \* \* \*     (b) \* \* \*     (18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy including all of the following:     (i) Making standard contracts available upon request from interested pharmacies no later than September 15 of each year for contracts effective January 1 of the following year.     (ii) Providing a copy of a standard contract to a requesting pharmacy within 2 business days after receiving such a request from the pharmacy. \* \* \* \* \*

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    (26) Maintain a Part D summary plan rating score of at least 3 stars under the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in Sec.  423.186 \* \* \* \* \*

Sec.  423.507  [Amended]

0 71. Section 423.507 is amended by removing and reserving paragraph (b). 0 72. Section 423.508 is amended by revising paragraph (a) to read as follows:

Sec.  423.508  Modification or termination of contract by mutual consent.

    (a) General rule. A contract may be modified or terminated at any time by written mutual consent. If the PDP sponsor submits a request to end the term of its contract after the deadline provided in Sec.   423.507(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (b) through (f) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare Part D program. \* \* \* \* \* 0 73. Section 423.509 is amended by revising paragraph (a)(4)(v)(A) and adding paragraphs (a)(4)(xiii) and (xiv) and (b)(2)(v) to read as follows:

Sec.  423.509  Termination of contract by CMS.

    (a) \* \* \*     (4) \* \* \*     (v) \* \* \*     (A) Requirements in subpart V of this part. \* \* \* \* \*     (xiii) The Part D plan sponsor has committed any of the acts in Sec.  423.752 that support the imposition of intermediate sanctions or civil money penalties under Sec.  423.750     (xiv) Following the issuance of a notice to the sponsor no later than August 1, CMS must terminate, effective December 31 of the same year, an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.     (b) \* \* \*     (2) \* \* \*     (v) In the event that CMS issues a termination notice to a Part D plan sponsor on or before August 1 with an effective date of the following December 31, the Part D plan sponsor must issue notification to its Medicare enrollees at least 90 days prior to the effective date of the termination. \* \* \* \* \* 0 74. Section 423.558 is amended by adding paragraph (a)(4) to read as follows:

Sec.  423.558  Scope.

    (a) \* \* \*     (4) Review of at-risk determinations made under a drug management program in accordance with Sec.  423.153(f). \* \* \* \* \* 0 75. Section 423.560 is amended by revising the definitions of ``Appeal'', ``Grievance'', ``Reconsideration'', and ``Redetermination'' and adding in alphabetical order a definition for ``Specialty tier'' to read as follows:

Sec.  423.560  Definitions.

\* \* \* \* \*     Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in Sec.  423.566(b). Appeal also includes the review of at-risk determinations made under a drug management program in accordance with Sec.  423.153(f). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (Council), and judicial reviews. \* \* \* \* \*     Grievance means any complaint or dispute, other than one that involves a coverage determination or at-risk determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested. \* \* \* \* \*     Reconsideration means a review of an adverse coverage determination or at-risk determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.     Redetermination means a review of an adverse coverage determination or at-risk determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.     Specialty tier means a formulary cost-sharing tier dedicated to very high cost Part D drugs and biological products that exceed a cost threshold established by the Secretary. 0 76. Section 423.562 is amended by revising paragraph (a)(1)(ii), adding paragraph (a)(1)(v), and revising paragraph (b)(4) to read as follows:

Sec.  423.562  General provisions.

    (a) \* \* \*     (1) \* \* \*     (ii) Use a single, uniform exceptions and appeals process which includes procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with Sec.  423.128(b)(7) and (d)(1)(iv). \* \* \* \* \*     (v) If the Part D plan sponsor has established a drug management program under Sec.  423.153(f), appeal procedures that meet the requirements of this subpart for issues that involve at-risk determinations. \* \* \* \* \*     (b) \* \* \*     (4) If dissatisfied with any part of a coverage determination or an at-risk determination under a drug management program in accordance with Sec.  423.153(f), all of the following appeal rights:     (i) The right to a redetermination of the adverse coverage determination or at-risk determination by the Part D plan sponsor, as specified in Sec.  423.580     (ii) The right to request an expedited redetermination, as provided under Sec.  423.584     (iii) If, as a result of the redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination or at- risk determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in Sec.  423.600     (iv) If the IRE affirms the plan's adverse coverage determination or at-risk determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in Sec.   423.1970     (v) If the ALJ or attorney adjudicator affirms the IRE's adverse coverage determination or at-risk determination, in whole or in part, the right to request Council review of the ALJ's or attorney adjudicator's decision, as specified in Sec.  423.1974     (vi) If the Council affirms the ALJ's or attorney adjudicator's adverse coverage determination or at-risk determination, in whole or in part, the right to judicial review of the decision if the amount in

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controversy meets the requirements in Sec.  423.1976 \* \* \* \* \* 0 77. Section 423.564 is amended by revising paragraph (b) to read as follows:

Sec.  423.564  Grievance procedures.

\* \* \* \* \*     (b) Distinguished from appeals. Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in Sec.  423.566(b) and at-risk determinations made under a drug management program in accordance with Sec.  423.153(f). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures. \* \* \* \* \* 0 78. Section 423.578 is amended by-- 0 a. Revising paragraphs (a) introductory text, (a)(1) and (2), (a)(4) introductory text, and (a)(5) and (6); 0 b. Removing paragraph (a)(7); and 0 c. Revising paragraph (c)(3).     The revisions read as follows:

Sec.  423.578  Exceptions process.

    (a) Requests for exceptions to a plan's tiered cost-sharing structure. Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the requested non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section.     (1) The tiering exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.     (2) Part D plan sponsors must establish criteria that provide for a tiering exception, consistent with paragraphs (a)(3) through (6) of this section. \* \* \* \* \*     (4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug(s) for the treatment of the enrollee's condition-- \* \* \* \* \*     (5) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.     (6) Limitations on tiering exceptions: A Part D plan sponsor is permitted to design its tiering exceptions procedures such that an exception is not approvable in the following circumstances:     (i) To cover a brand name drug, as defined in Sec.  423.4, at a preferred cost-sharing level that applies only to alternative drugs that are--     (A) Generic drugs, for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or     (B) Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act.     (ii) To cover a biological product licensed under section 351 of the Public Health Service Act at a preferred cost-sharing level that does not contain any alternative drug(s) that are biological products.     (iii) If a Part D plan sponsor maintains a specialty tier, as defined in Sec.  423.560, the sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception. \* \* \* \* \*     (c) \* \* \*     (3) When a tiering exceptions request is approved. Whenever an exceptions request made under paragraph (a) of this section is approved--     (i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as--     (A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;     (B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and     (C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.     (ii) The Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies to preferred alternative drugs. If the plan's formulary contains alternative drugs on multiple tiers, cost-sharing must be assigned at the lowest applicable tier, under the requirements in paragraph (a) of this section. \* \* \* \* \* 0 79. Section 423.580 is revised to read as follows:

Sec.  423.580  Right to a redetermination.

    An enrollee who has received a coverage determination (including one that is reopened and revised as described in Sec.  423.1978) or an at-risk determination under a drug management program in accordance with Sec.  423.153(f) may request that it be redetermined under the procedures described in Sec.  423.582, which address requests for a standard redetermination. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request a standard redetermination under the procedures described in Sec.  423.582 An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee) may request an expedited redetermination as specified in Sec.  423.584 0 80. Section 423.582 is amended by revising paragraphs (a) and (b) to read as follows:

Sec.  423.582  Request for a standard redetermination.

    (a) Method and place for filing a request. An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination or the at-risk determination under a drug management program in accordance with Sec.  423.153(f). The Part D plan sponsor may adopt a policy for accepting oral requests.     (b) Timeframe for filing a request. Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days from the date of the notice of the coverage determination or the at-risk determination under a drug management program in accordance with Sec.  423.153(f). \* \* \* \* \* 0 81. Section 423.584 is amended by revising paragraph (a) to read as follows:

Sec.  423.584  Expediting certain redeterminations.

    (a) Who may request an expedited redetermination. An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in

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Sec.  423.566(b) or an at-risk determination made under a drug management program in accordance with Sec.  423.153(f). (This does not include requests for payment of drugs already furnished.) \* \* \* \* \* 0 82. Section 423.590 is amended by revising paragraphs (a), (b)(1) and (2), the paragraph (f) subject heading, and paragraphs (f)(1) and (g)(3)(i) to read as follows:

Sec.  423.590  Timeframes and responsibility for making redeterminations.

    (a) Standard redetermination--request for covered drug benefits or review of an at-risk determination. (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with Sec.   423.636(a)(1) or (3) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.     (2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination or at- risk determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.     (b) \* \* \*     (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with Sec.   423.636(a)(2)) no later than 14 calendar days from the date it receives the request for redetermination.     (2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 14 calendar days from the date it receives the request for redetermination. \* \* \* \* \*     (f) Who must conduct the review of an adverse coverage determination or at-risk determination. (1) A person or persons who were not involved in making the coverage determination or an at-risk determination under a drug management program in accordance with Sec.   423.153(f) must conduct the redetermination. \* \* \* \* \*     (g) \* \* \*     (3) \* \* \*     (i) For adverse drug coverage redeterminations, or redeterminations related to a drug management program in accordance with Sec.   423.153(f), describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process; \* \* \* \* \* 0 83. Section 423.602 is amended by revising paragraph (b)(2) to read as follows:

Sec.  423.602  Notice of reconsideration determination by the independent review entity.

\* \* \* \* \*     (b) \* \* \*     (2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination or redetermination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under Sec.  423.1970; \* \* \* \* \* 0 84. Section 423.636 is amended by revising paragraph (a)(2) and adding paragraphs (a)(3) and (b)(3) to read as follows:.

Sec.  423.636  How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

    (a) \* \* \*     (2) Requests for payment. If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 14 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.     (3) Review of an at-risk determination. If, on redetermination of an at-risk determination made under a drug management program in accordance with Sec.  423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.     (b) \* \* \*     (3) Review of an at-risk determination. If, on appeal of an at-risk determination made under a drug management program in accordance with Sec.  423.153(f), the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must implement the change to the at-risk determination within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision. 0 85. Section 423.638 is revised to read as follows:

Sec.  423.638  How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

    (a) Reversals by the Part D plan sponsor--     (1) Requests for benefits. If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.     (2) Review of an at-risk determination. If, on an expedited redetermination of an at-risk determination made under a drug management program in accordance with Sec.  423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.     (b) Reversals other than by the Part D plan sponsor--     (1) Requests for benefits. If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.     (2) Review of an at-risk determination. If the expedited redetermination of an at-risk determination made under a drug management program in accordance with Sec.  423.153(f) by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan

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sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

Sec.  423.652   [Amended]

0 86. Section 423.652 is amended paragraph (b)(1) by removing the phrase ``July 15'' and adding in its place ``September 1''. 0 87. Section 423.750 is amended by revising paragraph (a)(3) to read as follows:

Sec.  423.750  Types of intermediate sanctions and civil money penalties.

    (a) \* \* \*     (3) Suspension of communication activities to Medicare beneficiaries by a Part D plan sponsor, as defined by CMS. \* \* \* \* \* 0 88. Section 423.752 is amended by revising paragraphs (a)(9) and (b) to read as follows:

Sec.  423.752  Basis for imposing intermediate sanctions and civil money penalties.

    (a) \* \* \*     (9) Fails to comply with communication restrictions described in subpart V or applicable implementing guidance. \* \* \* \* \*     (b) Suspension of enrollment and communications. If CMS makes a determination that could lead to a contract termination under Sec.   423.509(a), CMS may impose the intermediate sanctions at Sec.   423.750(a)(1) and (3). \* \* \* \* \* 0 89. Section 423.756 is amended by revising paragraph (c)(3)(ii) introductory text to read as follows:

Sec.  423.756  Procedures for imposing intermediate sanctions and civil money penalties.

    (c) \* \* \*     (3) \* \* \*     (ii) In instances where intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. \* \* \* \* \* 0 90. Section 423.1970 is amended by revising paragraph (b) to read as follows:

Sec.  423.1970  Right to an ALJ hearing.

\* \* \* \* \*     (b) Calculating the amount in controversy in specific circumstances. (1) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs must include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.     (2) If the basis for the appeal is an at-risk determination made under a drug management program in accordance with Sec.  423.153(f), CMS uses the projected value of the drugs subject to the drug management program to compute the amount remaining in controversy. The projected value of the drugs subject to the drug management program shall include the value of any refills prescribed for the drug(s) in dispute during the plan year. \* \* \* \* \*

Sec.  423.2018   [Amended]

0 91. Section 423.2018 is amended-- 0 a. In paragraph (a)(1), by removing the phrase ``appealed coverage determination was made'' and adding in its place the phrase ``appealed coverage determination or at-risk determination was made''; and 0 b. In paragraph (a)(2), by removing the phrase ``after the coverage determination to be considered'' and adding in its place the phrase ``after the coverage determination or at-risk determination to be considered''.

Sec.  423.2020   [Amended]

0 92. Section 423.2020 is amended in paragraph (c)(1) by removing the phrase ``the coverage determination, and'' and adding in its place the phrase ``the coverage determination or at-risk determination, and''.

Sec.  423.2022   [Amended]

0 93. Section 423.2022 is amended by-- 0 a. Removing the first appearance of paragraph the (b) subject heading and paragraph (b)(1) introductory text; and. 0 b. In paragraph (b)(1)(i) by removing the phrase ``the coverage determination, redetermination,'' and adding in its place the phrase ``the coverage determination or at-risk determination, redetermination,''.

Sec.  423.2032   [Amended]

0 94. Section 423.2032 is amended in paragraph (a) by removing the phrase ``the coverage determination, redetermination,'' and adding in its place the phrase ``the coverage determination or at-risk determination, redetermination,''.

Sec.  423.2036   [Amended]

0 95. Section 423.2036 is amended in paragraph (e) by removing the phrase ``a coverage determination'' and adding in its place the phrase ``a coverage determination or at-risk determination''.

Sec.  423.2038   [Amended]

0 96. Section 423.2038 is amended in paragraph (c) by removing the phrase ``may be made, and'' and adding in its place the phrase ``may be made, or an enrollee's at-risk determination should be reversed, and''.

Sec.  423.2046   [Amended]

0 97. Section 423.2046 is amended in paragraph (a)(1)(iii) by removing the phrase ``the coverage determination.'' and adding in its place the phrase ``the coverage determination or at-risk determination.

Sec.  423.2056   [Amended]

0 98. Section 423.2056 is amended-- 0 a. In paragraph (a)(1) by removing the phrase ``appealed coverage determination'' and adding in its place the phrase ``appealed coverage determination or at-risk determination'', and 0 b. In paragraph (e) by removing the phrase ``the coverage determination to be considered in the appeal.'' and adding in its place ``the coverage determination or at-risk determination to be considered in the appeal.''

Sec.  423.2062   [Amended]

0 99. Section 423.2062 is amended in paragraph (b) by removing the phrase ``coverage determination being considered and does not have precedential effect'' and adding in its place the phrase ``coverage determination or at-risk determination being considered and does not have precedential effect''.

Sec.  423.2122   [Amended]

0 100. Section 423.2122 is amended-- 0 a. In paragraph (a)(1) by removing the phrase ``the coverage determination.'' and adding in its place the phrase ``the coverage determination or at-risk determination''; 0 b. In paragraph (a)(3) by removing the phrase ``a coverage determination is made'' and adding in its place ``a coverage determination or at-risk determination is made'' and by removing the phrase ``after the coverage determination considered'' and adding in its place ``after the coverage determination or at-risk determination considered''.

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Sec.  423.2126   [Amended]

0 101. Section 423.2126 is amended in paragraph (b) by removing the phrase ``coverage determination to be considered in the appeal.'' and adding in its place the phrase ``coverage determination or at-risk determination to be considered in the appeal.''

Subpart V--Part D Communication Requirements

0 102. The subpart V heading is amended to read as set forth above. 0 103. Section 423.2260 is amended by-- 0 a. Revising the section heading; 0 b. Adding in alphabetical order definitions for ``Communications'', ``Communications materials'', and ``Marketing''; and 0 c. Revising the definition of ``Marketing materials''.     The revisions and additions read as follows:

Sec.  423.2260  Definitions.

\* \* \* \* \*     Communications means activities and use of materials to provide information to current and prospective enrollees.     Communication materials means all information provided to current and prospective enrollees. Marketing materials are a subset of communication materials.     Marketing means the use of materials or activities that meet the following:     (1) By the Part D sponsor or downstream entities.     (2) Intended to draw a beneficiary's attention to a Part D plan or plans.     (3) Influence a beneficiary's decision making process when making a Part D plan selection or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).     Marketing materials--     (1) Include, but are not limited to following:     (i) Materials such as brochures; posters; advertisements in media such as newspapers, magazines, television, radio, billboards, or the Internet; and social media content.     (ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.     (iii) Presentation materials such as slides and charts.     (2) Exclude the following materials:     (i) Information about the plan's benefit structure or cost sharing;     (ii) Information about measuring or ranking standards (for example, star ratings);     (iii) Mention benefits or cost sharing, but do not meet the definition of marketing in this section; or     (3) Unless otherwise specified by CMS because of their use or purpose, are required under Sec.  423.128 0 104. Section 422.2262 is amended by revising paragraph (d) to read as follows:

Sec.  422.2262  Review and distribution of marketing materials.

\* \* \* \* \*     (d) Enrollee communication materials. Enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used. 0 105. Section 423.2264 is revised to read as follows:

Sec.  423.2264  Guidelines for CMS review.

    In reviewing marketing material or election forms under Sec.   423.2262 of this part, CMS determines that the materials--     (a) Provide to Medicare beneficiaries interested in enrolling, adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges in a format (and, where appropriate, print size) and using standard terminology that may be specified by CMS.     (b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.     (c) Include in written materials notice that the Part D sponsor is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non- renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.     (d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations. 0 106. Section 423.2268 is revised to read as follows:

Sec.  423.2268  Standards for Part D Sponsor communications and marketing.

    (a) In conducting communication activities, Part D sponsors may not do any of the following:     (1) Provide information that is inaccurate or misleading.     (2) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.     (3) Claim the Part D sponsor is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the Part D plan. It may explain that the organization is approved for participation in Medicare.     (4) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.     (5) Display the names and/or logos of co-branded network providers or pharmacies on the sponsor's member identification card, unless the names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals).     (6) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.     (7) For markets with a significant non-English speaking population, provide materials, as defined by CMS, unless in the language of these individuals. Specifically, MA organizations must translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.     (b) In marketing, Part D sponsors may not do any of the following:     (1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.     (2) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.     (3) Market non-health care/non-prescription drug plan related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.     (4) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.     (5) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.     (6) Distribute marketing materials for which, before expiration of the 45-day period, the Part D sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the Part D sponsor, its marketing representatives, or CMS.

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    (7) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.     (8) Conduct sales presentations or distribute and accept plan applications at educational events.     (9) Display the names and/or logos of provider co-branding partners on marketing materials, unless the materials clearly indicate that other providers are available in the network.     (10) Knowingly target or send marketing materials to any Part D enrollee, whose prior year enrollment was in an MA plan, during the Open Enrollment Period.     (11) Engage in any other marketing activity prohibited by CMS in its marketing guidance.     (12) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.     (13) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.     (14) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.     (15) Provide meals to potential enrollees, which is prohibited, regardless of value.

Sec.  423.2272   [Amended]

0 107. Section 423.2272 is amended by removing paragraph (e).

Sec.  423.2274   [Amended]

0 108. Section 423.2274 is amended-- 0 a. By redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(iv); 0 b. By redesignating paragraph (b)(2)(iii) as paragraph (b)(1)(iii); 0 c. By removing paragraph (b)(2); 0 d. By redesignating paragraph (b)(3) as paragraph (b)(2); and 0 e. In newly redesignated paragraph (b)(2)(iii), by removing the phrase ``from an MA plan,'' and adding the phrase ``from a Part D sponsor,'' in its place.

Sec.  423.2410   [Amended]

0 109. Section 423.2410 is amended in paragraph (a) by removing the phrase ``an MLR'' and adding in its place the phrase ``the information required under Sec.  423.2460''.

Sec.  423.2420   [Amended]

0 110. Section 423.2420 is amended by-- 0 a. Removing and reserving paragraph (b)(2)(viii); 0 b. Revising paragraph (d)(2)(i); and 0 c. Removing the first paragraph designated as (d)(2)(ii).     The revision reads as follows:

Sec.  423.2420   Calculation of medical loss ratio.

\* \* \* \* \*     (d) \* \* \*     (2)     (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories in paragraph (b) or (c) of this section will generally be the most accurate method. \* \* \* \* \* 0 111. Section 423.2430 is amended by-- 0 a. Redesignating paragraphs (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively; 0 b. Revising newly redesignated paragraph (a)(1); 0 c. Adding paragraph (a)(4); and 0 d. Removing and reserving paragraph (b)(8).     The revisions and additions read as follows:

Sec.  423.2430  Activities that improve health care quality.

    (a) Activity requirements. (1) Activities conducted by a Part D sponsor to improve quality must either--     (i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or     (ii) Be listed in paragraph (a)(4) of this section. \* \* \* \* \*     (4)(i) Medication Therapy Management Programs meeting the requirements of Sec.  423.153(d).     (ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. \* \* \* \* \* 0 112. Section 423.2460 is revised to read as follows:

Sec.  423.2460  Reporting requirements.

    (a) For each contract year, from 2014 through 2017, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes but is not limited to the data needed by the Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract, under this part, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under Sec.  423.2410     (b) For contract year 2018 and for each subsequent contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, the following information:     (1) Fully credible and partially credible contracts. For each contract under this part that has fully credible or partially credible experience, as determined in accordance with Sec.  423.2440(d), the Part D sponsor must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under Sec.  423.2410     (2) Non-credible contracts. For each contract under this part that has non-credible experience, as determined in accordance with Sec.   423.2440(d), the Part D sponsor must report to CMS that the contract is non-credible.     (c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.     (d) The MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

Sec.  423.2480   [Amended]

0 113. Section 423.2480 is amended-- 0 a. In the introductory text by removing the phrase ``reviews of reports submitted'' and adding in its place ``review of data submitted''; and 0 b. In paragraph (d) introductory text by removing the phrase ``Reports submitted under'' and adding in its place the phrase ``Data submitted under''.

Sec.  423.2490   [Amended]

0 114. Section 423.2490 is amended in paragraph (a) by removing the phrase ``information contained in reports submitted'' and adding in its place the phrase ``information submitted''.

PART 460--PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

0 115. The authority citation for part 460 continues to read as follows:

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    Authority:  Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C 1302, 1395, 1395eee(f), and 1396u-4(f)).

0 116. Section 460.40 is amended by revising paragraph (j) to read as follows:

Sec.  460.40  Violations for which CMS may impose sanctions.

\* \* \* \* \*     (j) Makes payment to any individual or entity that is included on the preclusion list, defined in Sec.  422.2 of this chapter. 0 117. Section 460.50 is amended by revising paragraph (b)(1)(ii) to read as follows:

Sec.  460.50  Termination of PACE program agreement.

\* \* \* \* \*     (b) \* \* \*     (1) \* \* \*     (ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including making payment to an individual or entity that is included on the preclusion list, defined in Sec.  422.2 of this chapter. \* \* \* \* \*

Sec.  460.68   [Amended]

0 118. Section 460.68 is amended by removing paragraph (a)(4).

Sec.  460.70   [Amended]

0 119. Section 460.70 is amended by removing paragraph (b)(1)(iv).

Sec.  460.71   [Amended]

0 120. Section 460.71 is amended by removing paragraph (b)(7). 0 121. Section 460.86 is revised to read as follows:

Sec.  460.86  Payment to individuals and entities excluded by the OIG or included on the preclusion list.

    (a) A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in Sec.  460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in Sec.  422.2 of this chapter.     (b) If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in Sec.  422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

PART 498--APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

0 122. The authority for part 498 continues to read as follows:

    Authority:  Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C 1302, 1320a-7j, and 1395hh).

0 123. Section 498.3 is amended by adding paragraph (b)(20) to read as follows:

Sec.  498.3  Scope and applicability.

\* \* \* \* \*     (b) \* \* \*     (20) An individual or entity is to be included on the preclusion list as defined in Sec.  422.2 or Sec.  423.100 of this chapter. \* \* \* \* \* 0 124. Section 498.5 is amended by adding paragraph (n) to read as follows:

Sec.  498.5  Appeal rights.

\* \* \* \* \*     (n) Appeal rights of individuals and entities on preclusion list. (1) Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in Sec.  422.2 or Sec.   423.100 of this chapter) may request a reconsideration in accordance with Sec.  498.22(a).     (2) If CMS or the individual or entity under paragraph (n)(1) of this section is dissatisfied with a reconsidered determination under paragraph (n)(1) of this section, or a revised reconsidered determination under Sec.  498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.     (3) If CMS or the individual or entity under paragraph (n)(2) of this section is dissatisfied with a hearing decision as described in paragraph (n)(2) of this section, CMS or the individual or entity may request Board review and the individual or entity has a right to seek judicial review of the Board's decision.

    Dated: October 27, 2017. Seema Verma, Administrator, Centers for Medicare & Medicaid Services.     Dated: October 30, 2017. Eric D. Hargan, Acting Secretary, Department of Health and Human Services. [FR Doc. 2017-25068 Filed 11-16-17; 4:15 pm]  BILLING CODE 4120-01-P

**Load-Date:** November 29, 2017

**End of Document**



[***Tower Hamlets final council to declare - as it happened; Electoral Reform Society releases figure as local elections in England bring mixed results for main partiesLocal council election results 2018 - in fullEarly morning summaryHow the night unfolded in key races***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5S7P-GBT1-F021-63DD-00000-00&context=1516831)

The Guardian(London)

May 3, 2018 Thursday 10:09 PM GMT

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**Section:** POLITICS; Version:47

**Length:** 41585 words

**Byline:** Jamie Grierson, Andrew Sparrow and Kevin Rawlinson

**Body**

block-time published-time 11.20pm BST

Labour has gained control of Tower Hamlets council, over which no party previously had overall control, the Press Association reports. The party has won 23 of the 45 available seats, though some wards are still to declare.

With that, we're going to close this live blog. Thanks for reading.

block-time published-time 9.56pm BST

According to the Press Association, 149 of the 150 councils have now declared, with only Tower Hamlets' results to come. Here's how the main parties stand:

Labour

Councils: 73 (-1)

Seats: 2,308 (+77)

Conservatives

Councils: 46 (-2)

Seats: 1,230 (-93)

Lib Dems

Councils: 9 (+4)

Seats: 536 (+77)

Greens

Seats: 39 (+8)

Ukip

Seats: 3 (-57)

block-time published-time 7.33pm BST

The former cabinet minister, Justine Greening, has hit out at her party colleagues in the Eurosceptic European Research Group (ERG), accusing them of behaving a "little bit like Russia... vetoing things that they don't like" during the Brexit deliberations.

The rightwing group, led by the Tory MP Jacob Rees-Mogg, must understand that "no one is going to quite get their perfect outcome", the former education secretary told Sky News.

The sooner they all realise that and then work through the give and take and find a sustainable long-term solution on Brexit, the sooner we'll be able to get on with the implementation planning around that which is urgent, and the sooner we'll be able to get on with running the country and get on with the domestic agenda - for me the equality of opportunity - and the issues that are really at the heart of what I think people want tackled.

Asked if the ERG was being given too much attention, Greening said:

Well look, I think what we can't have is a group of MPs who behave a little bit like Russia does on the Security Council - vetoing things that they don't like.

We have got to go forward on Brexit as a country together. That will mean give and take and people need to understand that, whatever wing of my party they are on, and whatever elements of the Leave/Remain debate they are on. I'm afraid no one is going to quite get their perfect outcome.

She also told the broadcaster she was concerned the Brexit war cabinet would find itself out of step with the Tory party when it discusses what sort of customs arrangement it wants with the European Union post-Brexit.

I think it's time for the moderates in the party like myself to work with the prime minister on a sensible approach to the customs policy and a broader package and then make sure this is something we can get through Parliament.

block-time published-time 6.38pm BST

Here's an update on the 146 councils out of 150 that have declared so far:

Labour

Councils: 70 (-1)

Seats: 2,133 (+72)

Conservatives

Councils: 46 (-2)

Seats: 1,295 (-85)

Lib Dems

Councils: 9 (+4)

Seats: 528 (+79)

Greens

Seats: 33 (+3)

Ukip

Seats: 3 (-57)

There is no overall control in 21 councils (-1)

block-time updated-timeUpdated at 8.01pm BST

block-time published-time 6.14pm BST

Labour retains Hounslow, winning 33 of the available 60 seats. The Conservatives have won six seats so far, with 21 still to declare.

block-time published-time 5.57pm BST

Here are some analysis articles about the local elections that are worth reading.

* Rafael Behr at the Guardian says the political pendulum is stuck.

The pendulum is stuck. The traditional laws of political gravity predict a swing away from the party of national government in local elections, but it has been a while since British politics followed the obvious arc of precedent.

If [*last night's council election results*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) conform to any pattern, it is the laudable habit that voters have acquired of giving party leaders cause to scratch their heads and wonder what the hell is going on. There is no big national winner. Since the Tories were braced for a mauling and escaped without one,   [*Theresa May will be feeling relatively relaxed*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) today. Labour needed to demonstrate that last year's general election gains were a staging post on the road to national power; that   [*destiny was calling Jeremy Corbyn*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections). Destiny didn't hang up the phone, but it has put the ***opposition*** on hold. Labour had ambitious targets - Tory bastions in London such as Westminster and Wandsworth - that did not fall.

* Gary Gibbon at Channel 4 News says the election results will encourage Tory Brexiters.

One pro-remain Conservative told me last night's results were "a bit of a disaster for our side." He said they would encourage Tories to see Brexit supporters as their core demographic and prioritise pleasing them. At the same time, he worried, Labour would now feel it has to go hunting lost Brexit support to make up vital electoral ground outside London.

The more hardline amongst the Brexit-supporting Tory MPs might be emboldened by the overnight results in some pro-leave areas of England. Those who have been waving around letters to Graham Brady, the chairman of the 1922 committee, calling for a vote of no confidence in Theresa May, could in the tense weeks and months ahead feel that throwing the pieces in the air and seeing where they land, even if it heightens the risk of a general election, is not such a risk as some have suggested and preferable to what they see as a heavily diluted Brexit.

* Owen Jones at the Guardian says Labour had its best result in London since 1971.

When is a victory a defeat? Labour won its best local election results in London - and the Tories their worst results - since 1971. Although the Tories largely benefited nationally from the implosion of Ukip, as things stand, Labour have dozens of net gains. That doesn't mean Labour doesn't need to learn lessons and act on them (it does) or that these results are good enough (they're not). But the surreal triumphalism of Tories and pundits - who are desperate to return to a world before Jeremy Corbyn's [*Labour*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) won 40% of the vote and ended a generation-old political consensus - is almost pitiful.

* Faisal Islam at Sky News suggests the results show that both Theresa May and Jeremy Corbyn have passed their moment of peak appeal.

1. Katy Balls at the Guardian says "Corbyn's messiah status has taken a knock".
2. Stephen Fisher, an academic who works with Prof John Curtice on BBC election analysis, says in a Prospect article that Brexit helped to explain voting patterns in the elections - except in areas with Jewish populations.

The Conservatives have so far made 163 seat gains and suffered 165 losses. As a result they will likely end the day with a similar overall tally as the one they started with. Most, 89, of the Conservative losses were in London, and most, 132, of their gains were outside London. This differential in the Tory performance is part of a broader pattern whereby the Conservatives won more votes and seats in places which were more supportive of Brexit. As a result, the councils the party has won (Basildon, Peterborough, Redditch) are all places that voted to leave the EU at a rate of 61 per cent or more in 2016.

The exception to this rule tells an important story linked to the row over anti-Semitism in the Labour Party. Of the wards across the country where the BBC collected the votes, Labour is up by just 3 points where more than 4 per cent of the population is Jewish, but the party is up by 7 points on average elsewhere. This correlation had a particular impact in both Barnet and Bury where the Jewish population is relatively large. That Labour not only failed to take its (notionally) easiest target in London, but the Conservatives actually managed to gain six seats and take control of Barnet (where 38 per cent voted Remain) is quite remarkable.

* Stephen Bush at the New Statesman floats the idea that local elections are becoming less useful as a means of predicting general election results because Labour may be increasingly reliant on voters who are inclined not to vote in the locals.

I [*first advanced the theory*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) that Labour's electoral coalition might simply be becoming less likely to turn up in off-years under Ed Miliband as a possible explanation for why Labour were underperforming relative to the opinion polls. Of course, that wasn't true in 2015, but it doesn't mean it won't turn out to be true in the future. Labour's coalition has been getting younger, more likely to live in a city and more diverse pretty steadily since 2001 and it took a big leap forward in that direction in 2017. My feeling is that at some point that is going to mean that the predictive value of local election performances at general elections is going to change and change big. We may have reached that point already, but then again it may not.

* Bagehot at the Economist says the results show Corbynmania is dead.

Mr Corbyn has a proud history of leaving commentators with egg all over their faces. He can summon up charisma when he needs it and has an extraordinary ability to keep battling on regardless of circumstances. He also has some huge advantages on his side. A Tory party that is deeply divided over the most important issue facing the country; an establishment that thinks that Brexit is a Tory-made disaster; a generational divide that has left people under 40 struggling to get their feet on the property ladder; and a widespread sense that the country's infrastructure, from the NHS to the transport system, is on the verge of collapse. Even so, Corbynmania is now officially dead.

That's all from me for today.

My colleague Kevin Rawlinson is now taking over.

block-time published-time 5.39pm BST

Almost 4,000 people may have been denied vote by voter ID pilots, says Electoral Reform Society

The Electoral Reform Society has warned of what it calls a "dark day for politics" after saying that almost 4,000 would-be voters were turned away from polling stations for not having the necessary ID in the five boroughs which tested out voter ID schemes on Thursday.

The tally - carried out by the Democracy Volunteers group - estimated that 3,981 people were denied a ballot paper in all, 1.67% of the total number of votes cast.

The scheme, which could be extended nationwide in future elections, saw varying ID requirements in Bromley, Woking, Gosport, Watford and Swindon.

Critics had warned the trail was targeting a tiny problem of voter impersonation at polling booths, and risked putting off more vulnerable voters who might not hold the necessary documents, for example older people and the homeless.

The total was reached by extrapolation of observations in the five areas, which saw 1.67% of voters turned away, and does not take into account those who might have come back later with the correct ID. Darren Hughes, chief executive of the Electoral Reform Society, said:

Britain prides itself on being a leading democracy - but it is a dark day for politics when thousands of blameless people turn out to vote only to be refused.

Our estimates, based on evidence gathered by electoral observers, reveal the shocking scale of the problem. These trials have been shown up to be the chaotic, undemocratic mess many predicted.

* Update: To clarify, while Democracy Volunteers provided the 1.67% figure, the extrapolation was done by the Electoral Reform Society; of it is independent.

block-time updated-timeUpdated at 8.59pm BST

block-time published-time 5.35pm BST

[*According to the BBC,*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) the Conservative party has reinstated a candidate who won a seat in Sunderland who had been suspended over offensive social media posts, including one about Diane Abbott from several years ago.

Abbott has posted a message on Twitter suggesting this shows the Tories are not taking the problem seriously.

enltrIs this how seriously the Conservatives are taking online abuse?.. [*https://t.co/7plcRJFGJc*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Diane Abbott (@HackneyAbbott) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 5.21pm BST

Here are some results that have come in in the last hour or so.

Hackney Lab No change Lab gain 2, C gain 1, LD lose 3 New council: Lab 52, C 5

Lewisham Lab No change Lab gain 1, Green lose 1 New council: Lab 54

Haringey Lab No change LD gain 7, Lab lose 7 New council: Lab 42, LD 15

Newcastle-under-Lyme NOC No change Boundary change Ind down 6, C down 5, Lab down 5 New council: Lab 20, C 18, Ind 3, LD 3

Cherwell C No change C 12, Lab 3, LD 1, Vacant 1 Boundary change Lab up 1, LD up 1, C down 1, Ind down 1 New council: C 36, Lab 9, Ind 1, LD 1, Vacant 1

Manchester Lab No change Boundary change LD up 1, Lab down 1 New council: Lab 94, LD 2

block-time published-time 5.07pm BST

Tories gain control of Pendle council by reinstating racist joke councillor

A former mayor whose reinstatement gave the Conservatives control of a council by one seat has "sincerely apologised" over a racial Facebook joke which saw her suspended from the party, the Press Association reports. Rosemary Carroll, who made a post comparing an Asian with a dog last June, rejoined "as the votes were being counted" on Friday, giving the Tories narrow control of Pendle council in Lancashire.

Conservative group leader Paul White said:

The post was shared in error but Rosemary fully accepted the potential upset caused and sincerely apologised. Having served her suspension period she rejoined the party and completed additional diversity training.

Carroll, a former mayor of Pendle who represents the Earby ward, previously said she meant to ***delete*** the post but accidentally published it in error.

Leader of the Labour group, Mohammed Iqbal, said the situation was an "appalling state of affairs". He said:

Here's a councillor who brought shame on the borough on an international level and was welcomed back into the fold with open arms simply to grab control to the council. She turned up with a Conservative rosette literally as the votes were being counted.

block-time published-time 4.54pm BST

Dan Jarvis used his victory after being elected as Sheffield city region's mayor to call for a wider devolution deal for Yorkshire. The post has only just been established, and the job does not yet come with agreed powers, an agreed budget, or even an agreed salary. He said:

I understood that the exceptional nature of my candidacy [ie, remaining an MP] would raise some eyebrows and it has. But I believed then, as I know now, that the exceptional circumstances of this mayoralty and the importance of devolution for the future of the UK meant that I couldn't stand on the sidelines and that I had to step forward.

I say this because I believe that the issue of devolution goes to the heart of two of the most important ***strategic*** issues that our country faces - how we respond to the causes of Brexit and how we prepare for a post-Brexit Britain.

If we are to find the right answer to these questions we must be prepared to reform every aspect of our political system.

Dan Jarvis making a speech after being elected as the Sheffield city region's mayor Photograph: Danny Lawson/PA

block-time published-time 4.37pm BST

Labour hold Birmingham

Labour has retained control of Birmingham council, the Press Association reports. It has got 51 of the 101 seats, with 14 two-councillor wards yet to declare.

Birmingham, which is the largest council in Britain, is one of the areas that has had all-out council elections (with all seats being up for grabs, not just the usual one third) following boundary changes.

These are from the BBC's Kathryn Stanczyszyn.

enltrRevising numbers - now [*#Labour*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) sources saying expected to get between 57-63 seats out of 101 in   [*#Birmingham*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) which would be much closer to the status quo   [*#localelection2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Kathryn Stanczyszyn (@stanchers) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrWe're getting to the business end now and I'm hearing it's likely to be status quo - Labour around 64, Con around 29, Lib Dem 8, Green 1. And yet there has been churn in percentage and some key people. [*#BrumVotes18*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*#localelection2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Kathryn Stanczyszyn (@stanchers) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrIt's been a bit of a rollercoaster so far - some big individual upsets like loss of [*#Conservative*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) deputy leader Randal Brew and   [*#Labour*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) Lord Mayor-elect Lynda Clinton. And yet it's looking increasingly like something pretty close to the existing percentages.   [*#BrumVotes18*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Kathryn Stanczyszyn (@stanchers) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 4.21pm BST

Lord Heseltine, the Conservative former deputy prime minister, has told Sky News that he thinks the election results amount to a "stalemate". He says he thinks Labour under Jeremy Corbyn has hit a "glass ceiling".

block-time published-time 4.19pm BST

Lib Dems gain South Cambridgeshire from Tories

The Lib Dems have gained South Cambridgeshire from the Conservatives. Here are the figures.

South Cambridgeshire LD gain from C Boundary change LD up 16, Lab up 1, C down 25, Ind down 4 New council: LD 30, C 11, Lab 2, Ind 2

block-time published-time 4.16pm BST

Burnham says Labour must take 'much firmer grip' on antisemitism problem

Labour's two most senior mayors have both within the last few minutes said that party must do more to address its antisemitism problem.

Andy Burnham, the mayor of Greater Manchester, told Sky News that Labour had to take a "much firmer grip" on the issue because the anger against the party was "painfully real". He said:

It is clear that antisemitism was a very real issue in this campaign, not everywhere, but in areas where particularly there is a large Jewish community. That is true here in Greater Manchester. If you look at the Kersal ward in Salford, I was out there myself and it was a pretty sobering experience, to be honest, because the hurt and the anger is painfully real in those places.

So what I would say back to Ken Livingstone and others how have made this argument that it's all a smear designed to just undermine Jeremy Corbyn, let's hope that these elections draw a very firm line under these arguments and basically knock it out, because the truth of the matter is there is a very real sense of rawness in the Jewish community. And the Labour party needs now to reach out in a much more convincing way to those communities and take a much firmer grip on this issue of antisemitism, and come to a resolution on some of the outstanding issues on it.

Andy Burnham Photograph: Sky News

And Sadiq Khan, the mayor of London, said Jewish people in the capital did not fee comfortable voting for Labour. He told the BBC.

I think there are lots of voters, Jewish people in London, who don't feel comfortable voting Labour. That can't be right. It can't be right that anybody feels that the Labour party is a safe place for anyone who is an antisemitic person. Antisemitism is racism. We should have no truck with that. We need to make sure that we investigate any allegations made against anybody.

I'm really please Jeremy Corbyn has now tasked the new general secretary, Jennie Formby, to investigate speedily those members of our party against whom allegations have been made. They should be kicked out if those allegations are upheld.

block-time published-time 3.45pm BST

Dan Jarvis elected mayor of Sheffield city region

The Labour MP Dan Jarvis has been elected mayor of Sheffield city region on the second count.

Here are the second round voting figures.

Dan Jarvis (Lab) 144,154 Ian Walker (C) 50,619

block-time published-time 3.41pm BST

Boris Johnson claims Tory customs union policy helped deliver electoral success

Boris Johnson, the foreign secretary, is arguing that the local election results show why the government should remain committed to taking the UK out of the customs union.

enltrFantastic effort by [*@BrandonLewis*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) ,   [*@JamesCleverly*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) and all Conservative activists who worked tirelessly and delivered results beyond expectations 1/3

- Boris Johnson (@BorisJohnson) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrI would also like to pay personal tribute to Ray Puddifoot and all the incredible [*@Hillingdon\_Tory*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) team for holding and increasing the majority despite everything that Labour threw at them 2/3

- Boris Johnson (@BorisJohnson) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrJeremy Corbyn has been abandoned in many leave areas - his pledge to stay in the customs union means he is not trusted to deliver Brexit. PM's clear Mansion House vision for leaving the single market and customs union a key part of Tory electoral success 3/3

- Boris Johnson (@BorisJohnson) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

Jacob Rees-Mogg, the Conservative MP and chair of the European Research Group, which is pushing for a harder Brexit, is saying the same thing. Commenting on this Tweet...

enltrBBC polling expert John Curtice: Conservatives have been reminded that "the electorate that it now has is disproportionately a Leave electorate... 70% of the Conservative vote are people that voted Leave... it has to deliver Brexit." [*pic.twitter.com/DxKhlzhC8Q*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Darren Grimes (@darrengrimes\_) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

Rees-Mogg responded with this:

enltrSir John Curtice's view that the local election result means the government must deliver on Brexit is surely right, he usually is. [*https://t.co/xTHNzUlaAa*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Jacob Rees-Mogg (@Jacob\_Rees\_Mogg) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 3.33pm BST

Here are some more results that have come in over the last hour or so.

Islington Lab No change New council: Lab 47, Green 1

Woking C No change C 5, LD 3, Lab 1, Ind 1 LD gain 1, C lose 1 New council: C 16, LD 8, Lab 3, Ind 3

Blackburn with Darwen Lab No change Boundary change Lab down 7, C down 4, LD down 2 New council: Lab 37, C 13, LD 1

Camden Lab No change Lab gain 4, LD gain 1, C lose 4, Ind lose 1 New council: Lab 43, C 7, LD 3, Green 1

Elmbridge NOC No change C 10, LD 3, R 3 C gain 3, LD gain 1, R lose 4 New council: C 24, R 15, LD 9

Watford LD No change LD 9, Lab 3 LD gain 1, Lab lose 1 New council: LD 26, Lab 10

Crawley Lab No change Lab 8, C 4 New council: Lab 20, C 17

block-time published-time 3.27pm BST

According to the Press Association, 133 out of 150 councils have now declared. Here are the latest figures.

Conservatives

Councils: 44 (no change)

Seats: 1,142 (-44)

Labour

Councils: 63 (-1)

Seats: 1,741 (+75)

Lib Dems

Councils: 6 (+2)

Seats: 408 (+39)

Greens

Seats: 33 (+4)

Ukip

Seats: 3 (-55)

block-time published-time 3.21pm BST

And here is the BBC's estimate of what the House of Commons would look like if there were to be a general election with people voting in the same way as they did at the local elections.

enltrWhat would the House of Commons look like based on [*#elections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) voting patterns?   [*pic.twitter.com/VxoYhlN0cO*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- BBC Daily Politics and Sunday Politics (@daily\_politics) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

The BBC projection, like the Sky projection (see [*2.18pm)*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections), anticipates a hung parliament. But the BBC has Labour on course to gain 21 seats, and the Tories on course to lose 38 seats, while Sky just anticipates more modest Tory losses.

There's a different between the two projections because the BBC and Sky use [*different methods*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) to calculate how the local election results can be converted into a national share.

block-time published-time 3.12pm BST

The Liberal Democrats have gained Three Rivers, south-west Hertfordshire, from no overall control, the Press Association reports. They had eight councillors elected last night compared to four for the Conservatives and one for Labour.

Here are the figures.

Three Rivers LD gain from NOC LD 8, C 4, Lab 1 LD gain 1, Ind lose 1 New council: LD 20, C 16, Lab 3

block-time updated-timeUpdated at 3.21pm BST

block-time published-time 3.08pm BST

The Labour MP Chuka Ummuna told the World at One that he wanted the party's national executive committee to conduct a proper inquiry into why it did not do better at the elections. He said:

From a Labour point of view there needs to be a proper post-mortem - I think the national executive committee should appoint somebody to do that - on this result.

We haven't gone forwards and if we are looking to form an election-winning majority, we cannot be confident of that happening based on the results yesterday.

block-time published-time 3.03pm BST

The sole Green councillor in Islington, Caroline Russell, has held her seat in Highbury East.

This is from Caroline Lucas, the Green party co-leader.

enltrGreat result from [*@CarolineRussell*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) - thank goodness there's still a bold Green voice on Camden council, holding Labour to account & standing up for what matters   [*https://t.co/uTgc1CPGNv*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Caroline Lucas (@CarolineLucas) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 2.57pm BST

Tories and Labour level pegging on 35% of projected national share - Analysis

What do these projected national share (PNS) figures (see [*2.31pm)*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) actually mean? As usual, it depends.

How it's good for Labour

* Labour is getting the same of the vote as the Conservative party. They did not at the 2017 general election, and so in that respect they are moving forwards.

1. Labour is also doing much better relative to the Tories than it was in the 2017 local elections (which were held a few weeks before the general election). In that contest the Tories had an 11-point lead on PNS.
2. At 35%, Labour's local election share of the PNS is the highest it has been since 2012 (when it was 38%). That was a year when the Lib Dem vote had collapsed, because of Nick Clegg going into the coalition, but the big Ukip rise had not fully materialised.

How it's bad for Labour

* ***Opposition*** parties almost always have to be ahead in mid-term local elections if they are going to go on and ***win*** the subsequent general election. Labour is not ahead.

1. Labour is doing worse relative to the Tories on this measure than it was in 2014, when most of these seats were last fought. Four years ago Labour came out two points ahead on PNS. (The figures are here.) It is also doing worse than it did relative to the Tories in 2016, when on a relatively disappointing local elections night Jeremy Corbyn's Labour was still one point ahead of the Tories on PNS.
2. Excluding general election years, this is the first year since 1988 when Labour has been in ***opposition*** and it has not been ahead of the Conservatives on PNS at the local elections.

There is a table with all the PNS figures going back to 1982 [*here.*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 2.31pm BST

Tories and Labour both on 35% of projected national share of vote, BBC reports

The BBC has now produced its projected national share figure. This is not the share of the vote figure in the actual elections (a fairly meaningless figure, because the councils where elections took place were not representative of Britain as a whole.) It is a calculation as to what the vote share would have been if all wards in Britain had voted in the same way as people voted yesterday. (More on how this works [*here.)*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

These are the figures:

Conservatives: 35%

Labour: 35%

Lib Dems: 16%

Others: 14%

block-time published-time 2.20pm BST

Labour has retained Crawley after winning seven of the 12 seats being contested, the Press Association reports. The Conservatives won four, with one result to come.

And the Tories are on course to retain control of Woking council in Surrey.

block-time published-time 2.18pm BST

According to Sky News, if there were a general election and people voted as they did in the local elections yesterday, there would be a hung parliament. Here are their figures.

Projection for how local elections would translate into general election result Photograph: Sky News

The only party that would celebrate a result like this would be the Lib Dems. They won 12 seats at the 2017 election, and so on the basis of this notional result, they would be up 14.

Theresa May won 317 seats last year. On the basis of this result, she would be down 12. And Jeremy Corbyn, who won 262 seats at the general election, would be down one seat too.

block-time published-time 2.08pm BST

The Labour MP Dan Jarvis is on course to be elected mayor of the new Sheffield city region, but he did not ***win*** on the first round (ie, he did not get more than 50% of first preference votes.) Here are the first round results.

Dan Jarvis (Lab) 122,635 (47.99%) Ian Walker (C) 37,738 (14.77%) Hannah Kitching (LD) 27,146 (10.62%) Mick Bower (Yorkshire) 22,318 (8.73%) Rob Murphy (Green) 20,339 (7.96%) David Allen (Eng Dem) 14,547 (5.69%) Naveen Judah (Save NHS) 10,837 (4.24%) The last four candidates have been eliminated, and their second-preference votes are being counted.

Turnout was just 25.36%.

block-time published-time 2.02pm BST

Turning away from the local elections for a moment, my colleague Rajeev Syal has some good news for the Unite general secretary Len McCluskey.

enltrSources saying that [*@LenMcCluskey*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) has survived an attempt to force a rerun of his leadership election by   [*@gerard\_coyne*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections). Union watchdog will continue to hear other allegations next month, but these won't oust Unite leader from office. Huge relief for Corbynites.

- rajeev syal (@syalrajeev) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 2.01pm BST

From my colleague Heather Stewart

enltrHearing the LibDems could be in for a really good result in Kingston, which they've been targeting heavily. Rumours the Tories could even go down to single figures.

- Heather Stewart (@GuardianHeather) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 2.00pm BST

Here's [*a BBC video clip*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) with Prof John Curtice explaining what he thinks the election results means. His main takeaway is that, apart from the collapse of the Ukip vote, not a huge amount changed since 2014.

block-time published-time 1.57pm BST

Conservatives have lost Mole Valley, Surrey, to no overall control after losing one seat to the Liberal Democrats, the Press Association reports.

block-time updated-timeUpdated at 2.00pm BST

block-time published-time 1.52pm BST

The first results of the day are in from Manchester, with Labour holding on to all three seats in the Woodhouse Park ward, on a turnout of 18.04%, the Press Association reports. Manchester is holding "whole council" elections rather than the usual thirds, due to boundary changes; 32 wards will elect 96 councillors. Turnout ranges from 17% in Fallowfield to 46% in Chorlton.

block-time published-time 1.47pm BST

Good afternoon. I'm Andrew Sparrow, taking over from Jamie Grierson.

Last week my colleagues Jessica Elgot and Heather Stewart reported that the Labour MP Heidi Alexander - a centrist, in Labour terminology, not a Corbynite - was thinking of standing down as an MP to take up a post working for Sadiq Khan at City Hall.

Related: [*Heidi Alexander thought to be considering role at London City Hall*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

According to Channel 4 News' Michael Crick, we may get the announcement this afternoon.

enltrI hear Heidi Alexander may make an announcement in this later today [*https://t.co/EUE8br6S1Y*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Michael Crick (@MichaelLCrick) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrShe has a 21,000+ majority, so a by-election shouldn't be a problem for a Labour, though it's very inconvenient and costly for the party [*https://t.co/Z0bigQx8ON*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Michael Crick (@MichaelLCrick) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 1.15pm BST

Rokhsana Fiaz was comfortably elected as mayor of Newham, east London with the Labour candidate achieving 73% share of the vote, Dan Sabbagh writes.

She said she would use her mayoralty to "put people at the heart of what we do" and suggested that a Labour party rocked by the antisemitism crisis needed to do the same.

"In this borough I will make sure we work closely with Muslim, Jewish and other communities to build bridges. I'm desperately sorry Labour lost in Barnet and I'm sure the party will reflect closely on what has happened in Barnet and elsewhere," she said, speaking to the Guardian a few minutes after she was elected.

Fiaz takes over the former Olympic borough after 23 years of rule by Sir Robin Wales, who she defeated in a primary contest earlier this year.

The new mayor's share of the vote was 12 percentage points higher than Wales achieved in 2014. One of her first steps will be to introduce a consultative youth citizen assembly in the borough; she also plans to review the finances in a borough that had to write off £52m in loans for the repurposing of the Olympic stadium for football in December.

block-time published-time 1.14pm BST

Liberal Democrat former cabinet minister, Ed Davey, said it had been a "brilliant night" for his party.

Speaking at the Kingston-upon-Thames count, Davey said: "We've won councils like Richmond, we might well ***win*** here in Kingston, and there are one or two other counts coming later elsewhere in the country where we might well ***win*** control of the council.

"So we might end up winning more councils net from the previous position than any other party."

Davey, who said the party had focused on local issues rather than simply Brexit in its campaigning, added: "Across the country this looks like a real fightback for the Liberal Democrats."

block-time published-time 1.05pm BST

Labour sources at the count in Birmingham say it doesn't look like a good performance for them, reports political editor Heather Stewart.

All of the seats are up for grabs, and they're being fought on new boundaries - but reports suggest Labour is struggling in white, working-class wards; while advancing in the inner city.

Birmingham is hosting the Conservative party conference this year, as the party celebrates the success of Andy Street in winning the metropolitan mayorality.

With the balance of power on the city council before yesterday's poll 79 Labour seats to 29 Tories, there is no danger of Labour losing control, say those on the ground - but the party's majority could be significantly reduced. The count is ongoing.

block-time published-time 1.03pm BST

In the West Midlands, Conservatives gained control of Redditch, taking two seats from Labour and one from Ukip.

They have 16 seats out of 29, with two results to go.

block-time published-time 12.47pm BST

Latest tally from the Press Association:

State of parties after 101 of 150 councils

Conservatives: 31 councils; 892 seats (-26)

Labour: 52 councils (-1); 1,444 seats (+59)

LibDems: 4 councils (+1); 327 seats (+40)

Green: 22 seats (+7)

UKIP: 3 seats (-47)

Independent: 58 seats (-57)

Liberal: 1 seat (-1)

Ratepayers and Residents: 41 seats

No overall control: 14 councils

block-time published-time 12.46pm BST

There is mounting interest in the result in Birmingham, where there are suggestions Labour could lose, in what would be significant blow to the party.

The Conservatives have already made gains in West Midlands, in Dudley and Walsall.

enltrHearing Labour could lose Birmingham. Conservatives have already made gains in the West Mids, in Dudley and Walsall [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Frances Perraudin (@fperraudin) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrCounting well under way in the biggest council area, Birmingham. A generally low turnout suggests final result may come before the projected 5-6 pm

- Patrick Burns (@PatrickBurnsBBC) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.20pm BST

Labour's [*failure to take Barnet council from the Conservatives*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) is directly related to   [*the antisemitism scandal*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) that has plagued the national party, say local activists and councillors.

The north-west London council was Labour's prime target in the capital. The party hoped to seize control from the Conservative-led administration whose focus on outsourcing earned them the nickname "Easycouncil".

Sadiq Khan, the mayor of London, said Barnet was [*a Conservative "crown jewel"*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) Labour could ***win***, but overnight the Tories took back the council from no overall control.

Barry Rawlings, Barnet's Labour leader, laid the blame directly on the party's antisemitism crisis, which has led to Jewish leaders and members of the community protesting against Jeremy Corbyn in Westminster:

I want to speak directly to our Jewish brothers and sisters. I am extremely grateful to members of the Jewish community who cast votes for Labour. But too many didn't.

It wasn't because they disagreed with our manifesto, but because they felt the Labour party has failed to deal with antisemitism on a national level. They are right.

Related: [*Labour antisemitism scandal blamed for Tory* ***win*** *in Barnet*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 11.37am BST

The prime minister has visited Wandsworth in south London to congratulate Conservatives on seeing off a challenge from Labour to hold on to control despite losing six seats.

Theresa May said: "Labour thought they could take control, this was one of their top targets and they threw everything at it, but they failed.

"The people of Wandsworth re-elected a Conservative council, and that's for a simple reason. You charge the second lowest council tax in the country, you provide excellent local services like the weekly bin collection.

"That's the message of these elections across the country - that Conservative councils deliver great local services at lower taxes."

To cheers from activists waving Conservative banners, May added: "We've seen other success in London. We've held Hillingdon, Barnet, Westminster.

"And outside of London, we've made progress in places like Dudley and Walsall. We've taken control in Basildon and Peterborough. And that's all the result of the really hard work of our councillors, our activists, our supporters and our revitalised campaign machine.

"But we won't take anything for granted. We will continue to work hard for local people and we will build on this success for the future."

block-time published-time 11.26am BST

Labour's deputy leader Tom Watson told the BBC: "We have consolidated the base we made after the General Election. If you looked at the national polls, it showed the parties were neck-and-neck and we have done rather better than that in some areas."

Mr Watson said Labour now has more councillors in London than at any time since the 1970s.

"You can always do better, but we think we have consolidated our base and we are quietly satisfied with the result," he said.

block-time published-time 11.14am BST

The Conservatives became the biggest political party in the Black Country town of Walsall today, and are expected to form a minority administration.

The Tories ended up with 30 seats, while Labour lost two to be left with 26, with the remaining four seats split between the Liberal Democrats and independents.

They also made gains from UKIP, who lost all three of their councillors in Walsall.

Previously Labour was in control with 28 seats to the Tories' 24.

Walsall Conservative leader Mike Bird is confident of getting the support he requires to run a minority administration.

Labour was expected to hang on to power, with some activists claiming they would take an overall majority.

It follows the Conservatives' Eddie Hughes unexpected victory in the general election last year in Walsall North.

block-time updated-timeUpdated at 11.15am BST

block-time published-time 11.14am BST

Labour has called on the Government to scrap voter ID as a matter of urgency after a trial saw people in England turned away from polling booths for not carrying the necessary documents.

Cat Smith MP, shadow minister for voter engagement and youth, said:

There was absolutely no case for introducing voter ID in the first place but after yesterday's fiasco, it is impossible for the Government to justify rolling it out.

After completely ignoring a number of serious warning signs, the Government decided to pilot discriminatory measures which denied people their right to vote.

We cannot allow the Conservative Party to undermine our democracy, which is why Labour is calling on the Government to scrap their voter ID plans as a matter of urgency.

block-time published-time 11.07am BST

Ken Livingstone has been on Sky News talking about the local election results and the impact of allegations of antisemitism on the Labour party, from which he is currently suspended.

Livingstone, who has been accused of antisemitism himself, denied previously labelling Adolf Hitler as a Zionist. He said:

If you go on Jerusalem's Holocaust memorial website, one of the documents you can download is about the deal that the Zionists did with Hitler did with the Zionists in the thirties.

Hitler wanted to get all the Jews out of journey, and the Zionists wanted to move them all and create a Jewish state in Palestine. They collaborated, they didn't like each other but they collaborated together to do that."

The former Labour MP and London mayor accepted that claims that he was antisemitic had hit the result in Barnet, where the Tories gained control:

If anybody believes I said Hitler was a Zionist then yes, that is damaging. What's been so bad is that two years on this smear about me is still there unchallenged."

Sky News presenter Adam Boulton suggested that "the best advice might be not to bring Hitler into contemporary politics".

"I only do it when I ask a question like you've just done," Livingstone said. "I've never written a speech or article about Hitler.

"It always gets you into trouble if you tell the truth," he added.

Asked if he should just retire, Livingstone said: "I'm not going to my grave without this issue being resolved."

Livingstone said the antisemitism row was a "distraction" from discussing Labour policies and also blamed moderate Labour MPs for attacking the party leader, Jeremy Corbyn.

He said: "If we hadn't had two years of Labour MPs undermining Jeremy, if they'd been out there campaigning, we only needed to take another seven seats and Jeremy would be leading a minority government ... his policies connects with people."

He added: "Part of the problem is for the last month everything in the media about the Labour party has been about antisemitism. Any serious debate about our policies just hasn't happened."

Livingstone said he was optimistic that he will not be expelled from the party.

block-time updated-timeUpdated at 11.15am BST

block-time published-time 10.36am BST

The leader of the Barnet Labour Group, Barry Rawlings, has issued a statement, in which he addresses the group's "Jewish brothers and sisters". He said Labour has failed to deal with "anti-semitism". He said:

I want to thank all Labour members in Barnet for their support and hard work, not just over the past few weeks, but over the past four years, and our wonderful candidates who could not have done anything more.

We campaigned hard, we gave the Conservatives a tough time over their failure to run a fair, effective Council for the people of Barnet, and we have built, and will continue to build, good relationships with all of Barnet's communities.

That wasn't enough this time. I am confident we can bounce back from this but to do so we will need to work harder still.

I want to speak directly to our Jewish brothers and sisters.

I am extremely grateful to all members of the Jewish community who cast votes for Labour yesterday.

But too many didn't. It wasn't because they disagreed with our manifesto, but because they felt the Labour Party has failed to deal with anti-Semitism at a national level. They are right.

I pledge that Barnet Labour will be a beacon to the rest of the Labour Party in tackling and defeating this anti-Semitism virus that has infected our party. For me dealing with anti-Semitism, Islamophobia, and all forms of hate is not an electoral issue, ***win*** or lose, it's a moral responsibility that defines who we are as a Party.

I am so proud of the work we have done both within and across communities, faiths, backgrounds.

We either fix this or our values of equality, social justice and human rights die.

I pledge that Barnet Labour will be at the forefront of this collective effort by the Party we all love and wish to see succeed.

block-time published-time 10.21am BST

Labour now well placed to ***win*** general election - Corbyn

Jeremy Corbyn, leader of the Labour Party, has issued a statement on the local election results.

Labour achieved a solid set of results in the local elections. We have consolidated and built on the advances we made at last year's General Election, when we won the largest increase in Labour's share of the vote since 1945.

In these elections we have won seats across England in places we have never held before. We won Plymouth from the Tories, who lost control of Trafford, their flagship northern council. And Labour has won even more council seats than at our high watermark of 2014.

Last year Labour showed the difference we can make in a full national campaign. This year our members and supporters campaigned in impressive numbers. And their energy, talent and enthusiasm will continue to take Labour's message of real change to communities across the whole country.

In a sign of how worried they are about Labour's advance, the Tories talked up our chances to unrealistic levels, especially in London. The results show they're right to be worried - we came within a whisker of winning Wandsworth for the first time in over 40 years.

The Labour Party is now well placed to fight and ***win*** the next General Election - and form a government that will work for the many, not the few.

block-time updated-timeUpdated at 10.21am BST

block-time published-time 10.14am BST

Labour MP Lisa Nandy says last night's performance for Labour, losing ground in Wigan, Bolton and Dudley, underlines the fact that Labour's message is failing to appeal to voters in Britain's towns.

While Labour comfortably held her own local council of Wigan last night, the Conservatives got more votes there than at any time since 1979.

"For a lot of people who choose to forgo the fast pace and diversity and access to culture of cities, the reason they do that is because they value the sense of community you feel very strongly in places like mine," she says.

She says politicians, including Labour, have failed to address the decline in local jobs and opportunities that has eroded this sense of community.

"Towns like mine have really found themselves at the sharp end over the last 30 years. Demographic changes mean we have an ageing population - young people who used to go away to study and come back, have found there's nothing to come back to. Wages are low, which accounts for the decline of high streets and pubs."

"People have looked to politics for some time to solve this and seen us obsessed with a city-centric model which is reliant on the benefits trickling down."

She warns: "Unless Labour gets to grips with that, the next election is far from secure, with Labour piling up the votes in cities, and the Tories having a near-monopoly on the countryside".

"It's about jobs, jobs, jobs jobs," she says. "Politicians need to catch up. Whoever gets this towns argument will ***win*** the next general election and the one after that."

block-time published-time 10.06am BST

Theresa May has tweeted congratulations to a couple of councils, which saw holds and gains for her Conservative party in the local elections.

enltrCongratulations to [*@CllrCornelius*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) and the   [*@BarnetTories*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) team for their increased majority in Barnet - and successfully retaking the council!   [*pic.twitter.com/3fMFVFv98n*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Theresa May (@theresa\_may) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrThank you to Cllr John Holdich and the [*@PbConservatives*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) for campaigning hard for every vote across the city and gaining control of the council. A great result!   [*pic.twitter.com/QM1AYc62Nn*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Theresa May (@theresa\_may) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrCongratulations to [*@CllrDavidRenard*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) and the   [*@TorySwindon*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) team for a great result, ensuring residents will continue to receive excellent public services.

- Theresa May (@theresa\_may) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrCongratulations to [*@RaviGovindia1*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) and all the   [*@Wandsworth*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) team for holding control of the council. I know you will continue to keep council tax low and provide great local services.   [*pic.twitter.com/ErEkOssLbs*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Theresa May (@theresa\_may) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrCongratulations to Cllr Patrick Harley and the whole Conservative team in Dudley for making great progress. I visited Dudley recently and was so impressed at the support you are giving to businesses that create better, higher-paying jobs.

- Theresa May (@theresa\_may) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrHuge congratulations to Cllr Mike Bird and the Walsall Conservatives team for a great result, becoming the largest party on the council.

- Theresa May (@theresa\_may) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time updated-timeUpdated at 10.17am BST

block-time published-time 9.30am BST

State of parties after 98 of 150 councils:

Conservatives: 30 councils; 878 seats (-31)

Labour: 50 councils (-1); 1,424 seats (+57)

LibDems: 4 councils (+1); 324 seats (+41)

Green: 21 seats (+6)

UKIP: 2 seats (-44)

Independent: 61 seats (-49)

Liberal: 1 seat (-1)

Ratepayers and Residents: 37 seats (-4)

No overall control: 14 councils

block-time published-time 9.18am BST

Paul Oakley

Ukip general secretary Paul Oakley has insisted it was not "all over" for the party and has defended his party by comparing it favourably to the Black Death.

He said the plague had caused a lot of disruption in the Middle Ages before going "dormant".

"It's not all over at all," Oakley told BBC Radio 4's Today programme.

"Think of the Black Death in the Middle Ages. It comes along and it causes disruption and then it goes dormant, and that's exactly what we are going to do. Our time isn't finished because Brexit is being betrayed."

Challenged over whether he wanted to compare his party to a plague that killed millions of people, Oakley said: "Absolutely. What's wrong with that?"

He pointed to positive outcomes from the Black Death: "It also led to economic growth and the Renaissance. It got rid of the whole issue of servitude, basically, and allowed people to go into the towns and escape their landlords and create their own businesses."

block-time published-time 9.12am BST

Anti-racism group, Hope Not Hate, has hailed the demise of "far right and radical right" political parties in the local elections.

Hope Not Hate said it had been a "disastrous" night for Ukip, which it accused of plying anti-Muslim rhetoric under its leader Gerard Batten.

Far-right parties - such as the British National Party and Anne Marie Waters' For Britain Movement - also failed across the board, the group said.

Nick Lowles, chief executive of HOPE not hate, said: "We should take a moment to enjoy the decline of extremist parties. It's down to the hard work of thousands of anti-racist campaigners up and down the country, as well as incompetence and defections on the part of Ukip and the far right."

block-time published-time 8.48am BST

The Guardian's associate editor, Dan Sabbagh, has written an analysis of the local election results.

Labour made limited progress, but failed to produce the kind of surge that would allow the party to claim it is a government-in-waiting, he writes, while Theresa May can be modestly relieved, although the results do not necessarily point to her party winning an overall Westminster majority either.

Read the full piece here:

Related: [*A hazy night in English local elections: the key conclusions*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 8.45am BST

More from Jeremy Corbyn on the local election results.

Asked whether the night's results showed that Labour had passed the point of "peak Corbyn", Corbyn said: "No, no, there is much more to come and it's going to get even better."

The Labour leader told Sky News: "We were defending seats that were last won in 2014, which was a particularly good year for Labour in local government.

"Obviously, I am disappointed at any places where we lost a bit of ground, but if you look at the overall picture, Labour gained a lot of seats across the whole country, we gained a lot of votes in places we never had those votes before."

He added: "We are ready for a general election whenever it comes. A year ago, a general election was surprisingly called and we had the biggest swing to Labour for decades.

"We are absolutely ready for it. We have got members, we have got organisation, we have got enthusiasm."

block-time published-time 8.41am BST

The Jewish Labour Movement, the affiliated society for Jewish Labour supporters, say they will be holding an urgent meeting with Labour's new general secretary Jennie Formby to discuss the impact anti-semitism had on the party's local election results.

JLM's spokesman Ivor Caplin said: "For the second time within a year, England has seen the electoral impact of the Labour Party's problem with antisemitism.

"For the Party of anti-racism to lose seats because of antisemitism is a sad chapter in our proud history. JLM will be meeting with Jennie Formby next week and will be urgently raising this."

block-time updated-timeUpdated at 9.08am BST

block-time published-time 8.41am BST

Labour's Jess Phillips take on the local election results:

enltrUp and at em. I see everyone is claiming failure as victory.

- Jess Phillips (@jessphillips) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 8.36am BST

In other election news, Sinn Fein are celebrating in Northern Ireland with a by-election victory in West Tyrone.

Orfhlaith Begley, 26, declared herself a history maker as she became the first woman elected as MP for the West Tyrone constituency.

The solicitor from the Co Tyrone village of Carrickmore secured an almost 8,000 majority in the parliamentary by-election, ahead of second placed Democratic Unionist Thomas Buchanan, though Sinn Fein's percentage of the vote did drop from more than 50% in last year's general election to 47%.

The political newcomer comfortably held on to a seat relinquished by party colleague Barry McElduff when he quit amid a furore over a controversial social media post.

McElduff resigned as MP for the area in January, 10 days after a controversy flared when he posted a video of himself with a Kingsmill-branded loaf on his head on the anniversary of the notorious Kingsmill massacre.

block-time published-time 8.31am BST

Jeremy Corbyn at a polling station yesterday

Jeremy Corbyn made an early-morning visit to Plymouth to celebrate his party seizing control of the city's council.

Surrounded by cheering activists at Plymouth Hoe, the Labour leader said he was "delighted" by the result, adding: "The South West has the unenviable title of being the low-pay capital of Britain. That's got to change and a Labour government will offer that change.

"Today, winning Plymouth is a sign Labour is back in this part of Britain. Labour is back to gain parliamentary seats.

"The mission of Labour is always to stand for a decent society and stand up against poverty in Britain, and that means local government must be properly funded by central government, and local councils that want to deal with the housing crisis and the social care crisis, and want a cleaner, better environment, are the ones that they should be supporting."

block-time published-time 8.29am BST

Brandon Lewis

Brandon Lewis, the Conservative party chairman, said his party had a "reasonable night, a good night".

"We've seen interesting results across the country," he told BBC Radio 4 Today programme. "When we look at what Labour were predicting... that simply hasn't happened."

"When they were claiming the whole of London was going to turn red, they've not gained a single council."

Asked if the Tories have problem in urban areas, he said: "We're working hard all over the country.

We have to work and learn from that over the next few years as we go towards the next general election as we're delivering on those domestic agendas on issues that matter to people in their lives every day.

block-time published-time 8.15am BST

Adam Langleben, a Labour councillor who lost his seat in Barnet, told the Guardian:

We knew this was a possibility since last night, that this was worse than the general election in 2017. Things have definitely shifted since June. Every Jewish Labour household we visited, people said, "not this time." Activists were being told, "this is a racist party, an anti-Semitic party", doors were slammed in their faces. We as Jewish Labour activists were told we were endorsing anti-semitism. The reason we have lost here is the inability to deal with this issue and to tackle anti-semitism.

Jeremy Corbyn was supposed to come here tomorrow for a victory speech. We want him to come to Barnet anyway, to apologise to Jewish Labour activists, to Barnet Labour and to the Jewish community here so we can start the healing process. We won this election on ideas, the Tories just ran a relentlessly negative campaign. But just look at the wards with high Jewish populations where we lost, East Barnet, Brunswick Park, West Hendon. The seats with even higher Jewish populations, where Labour didn't target as hard, the Tories have huge landslides.

The Labour leadership and people around them have seen the signs for a long time and they have not acted.

I'm not quitting, this is about the health of our democracy. We have two parties of government in this country and one has a sickness that it needs to deal with. People need to join the party; they need to educate people and those who are anti-Semitic need to be immediately expelled. But first of all, the party can start by listening to Jewish activists and the community.

block-time updated-timeUpdated at 8.20am BST

block-time published-time 7.57am BST

enltrBarnet Labour leader Barry Rawlings has admitted there is an issue with anti-Semitism and inaction in the Labour party [*pic.twitter.com/zxfjhrJtPn*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Sky News (@SkyNews) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 7.51am BST

enltrLabour group leader in Barnet [*@BarryJohnRawlin*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) tells me antisemitism played "the biggest part" in Labour's "defeat". He says Labour leadership acted too late "If it had of happened a couple of years ago Barnet would now be a Labour council"   [*@BBCRadioLondon*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*#Londonelection2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/eBpSMUvKdP*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Susana Mendonça (@susana\_mendonca) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 7.45am BST

Andrew Gwynne campaigning in 2017

Andrew Gwynne, Labour's national campaign coordinator and a shadow communities minister, admitted the anti-semitism row had led to the Conservative victory in Barnet.

"It disappoints me," he said on BBC Radio 4's Today Programme.

We have got a job to do to rebuild trust and confidence with the Jewish community across the country. I'm sure that is the case. I see it as my job to help rebuild that trust with the Jewish community. There are so many Jewish people who do share Labour's values.

Looking at the overall picture, Gwynne said "there was always going to be a limited number of gains we could make".

"It was an election of consolidation," he said. He cited Labour victory in Trafford as a significant achievement but admitted there had been some "disappointing results in other parts of the country".

Asked about Labour's performance in London, Gwynne said: "We did pick up seats in those areas."

"What we've seen is that politics is very polarised," he said. "All published opinion polls show Labour and Tories pretty much neck and neck."

block-time updated-timeUpdated at 7.46am BST

block-time published-time 7.33am BST

Here's some reaction from the Twitter commentariat to the result in Barnet, which saw the Conservative ***win*** control, taking it back from "no overall control".

enltrAnd there it is: Barnet remains Conservative. All three of Labour's big targets in the capital - the "crown jewels" for the taking according to Sadiq Khan - have stayed blue. Momentum misfire. [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Sebastian Payne (@SebastianEPayne) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrCrucial point about Barnet is its not just Jewish Labour voters who have been disgusted by the party's handling of its antisemites - it's non Jews too.

- Stephen Pollard (@stephenpollard) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrTories take Barnet, which I think we can attribute pretty directly to the Labour anti-Semitism scandal [*https://t.co/6piUAOFhXx*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- James Forsyth (@JGForsyth) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrConservative gain in Barnet from overall control. Needed a tiny swing to Labour for them to ***win*** it. No doubt anti-Semitism hugely influential- in some wards turnout over 70%. Now looks certain there will be no Labour council gains in London (but overall seat numbers will go up).

- Lewis Goodall (@lewis\_goodall) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrPeople screamed at me for saying this. But I am not surprised at all that Barnet has stayed in Conservative control. I have never found such clear and consistent strength of feeling about an issue. [*https://t.co/ZnIhlEGux*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Paul Brand (@PaulBrandITV) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrBased on Tories holding Barnet and Hillingdon, there's a real possibility of Labour actually going backwards in London when the result in Harrow is announced at circa 5pm.

- Theo Usherwood (@theousherwood) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrI feel sorry for the defeated Labour councillors, but Labour had to be defeated in Barnet. A victory would have been taken as an endorsement of antiSemitism [*https://t.co/fuAIFS6uJe*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Nick Cohen (@NickCohen4) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrHow Labour has fared against those targets: Swindon ? Trafford ? Amber Valley ? Westminster ? Carlisle ? Plymouth ?? Wandsworth ? Dudley ? Barnet ? Walsall ? Kirklees - still to come Tower Hamlets - still to come [*#Election2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Ian Jones (@ian\_a\_jones) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time updated-timeUpdated at 7.47am BST

block-time published-time 7.26am BST

Conservatives ***win*** key Labour target of Barnet

The Conservatives have won control of Barnet Council, taking it back from no overall control.

The seat was a Labour target and political commentators on Twitter are already putting the result down to the anti-semitism row engulfing the Labour party. Barnet has a significant Jewish population, according to census data, with the second largest religious group being Jewish.

Earlier, a defeated Labour councillor in West Hendon tweeted an apparent reference to the party's anti-Semitism row, saying "we must NEVER have another election like this" after the Conservatives took all three seats from the party in the ward.

Outgoing councillor Adam Langleben, who also sits on the national executive committee of Jewish Labour, tweeted: "No community group should have their vote dictated by their safety. That should shame us UKLabour."

block-time published-time 7.21am BST

The results are now in from 94 of the 150 councils holding elections. Here are the latest figures.

Conservatives

Councils: 28 (-1)

Seats: 776 (-11)

Labour

Councils: 48 (-1)

Seats: 1,291 (+44)

Lib Dems

Councils: 4 (+1)

Seats: 324 (+45)

Greens

Seats: 21 (+6)

Ukip

Seats: 2 (-41)

That's all from me. My colleague Jamie Grierson is taking over now.

block-time published-time 7.05am BST

Here are the latest results from London.

Conservatives

Councils: 4 (-1 - Richmond)

Seats: 271 (-46)

Labour

Councils: 8 (no change)

Seats: 434 (+29)

Lib Dems

Councils: 2 (+1 - Richmond)

Seats: 94 (+18)

block-time published-time 7.01am BST

On the Today programme Caroline Lucas, the Green party's co-leader, said the Greens had had "a really good night". She said that they were now the official ***opposition*** in Richmond, that they had seats on four new councils and that some of the best results they were expecting were yet to come in, in places like Islington and Lambeth.

Martha Kearney, the presenter, said the BBC's analysis was that the Greens were only getting 6.5% in the wards they were fighting, a drop of 1.5% compared with 2014.

block-time published-time 6.57am BST

In their morning email, the New Statesman's Stephen Bush and Dulcie Lee reckon that the biggest winner of election night was the Lib Dems. Here's an excerpt.

Much to everyone's surprise, the winner of the local elections is.... Vince Cable.

The Liberal Democrats harvested local discontent effectively in Sunderland, gave Labour a fright in Hull, won back Richmond at a clip, held onto Sutton, Eastleigh and Cheltenham and are at time of writing the biggest gainers as far as seat gains go

It will silence - at least for a while - the noises off about Cable and his leadership.

block-time published-time 6.52am BST

I'm finally leaving Kensington town hall following a disappointing night for Labour.

The party had hoped to make gains in the west London borough, which is still dealing with the aftermath of the Grenfell Tower disaster, amid speculation that it had an outside chance of taking control of the council.

Instead Labour gained just one councillor as the Conservatives won another overwhelming majority, maintaining their control of a borough they have run since 1964.

Labour even failed to take wards such as Chelsea Riverside, which it had been confident of winning from the Tories, as some local party activists suggested Grenfell had not been the deciding issue for most voters in the election, especially in the wealthier south of the borough.

The final results left the Tories with 36 seats, and Labour on 13.

"We all recognise we still need to rebuild trust," said Conservative leader Elizabeth Campbell. "We must be and we will be open to all voices of our communities."

"We all live in the shadow of Grenfell. Grenfell was, Grenfell is, and Grenfell will be our first priority."

There were few signs of a revival for the Lib Dems, who clung on to their single councillor while showing few signs of progress elsewhere, even in a borough that voted 69% in favour of remain at the EU Referendum.

It was even worse for the new Advance Together political party, which had been compared to French President Emmanuel Macron's En Marche movement. It ran candidates in most wards, declaring that the "narrow demands of party politics has ill-served the people of Kensington & Chelsea". The people of Kensington & Chelsea felt otherwise and the party came consistently last.

Kensington and Chelsea is London's smallest borough by population and just 37,000 ballots were returned in Thursday's election. Despite this the final results were only declared at 6.30am, hours after many other larger councils had finished counting and gone home. Bleary-eyed Labour activists were left wondering what went wrong.

block-time updated-timeUpdated at 6.58am BST

block-time published-time 6.45am BST

Richard Angell, director of Progress, the Blairite pressure group in the Labour party (which is much disliked by the Corbynites), says Labour would not ***win*** a general election on the basis of these results.

enltrI went to bed with Labour on course for big gains and have woke up with only one Labour council gained and losses in councils like Derby. Such a disappointing result is heartbreaking and some brilliant candidates have been failed [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- (((Richard Angell))) (@RichardAngell) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrConsidering Labour has such a small number of targets and a huge number of activists is it sad that on these results Labour would lose seats like Battersea in a general election and not make the kind of gains that are desperately needed in places like Nuneaton [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- (((Richard Angell))) (@RichardAngell) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrTo become the next government Labour needs to do more than tread water [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/1t53MeBYQ7*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- (((Richard Angell))) (@RichardAngell) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 6.40am BST

Nickie Aiken, the Conservative leader of Westminster city council, claimed her party's victory in the borough was partly a vote against Momentum. She said:

Labour thought they could take Westminster city council, and the people of Westminster sent a very clear message that Westminster would remain Conservative.

The Labour party threw everything they had at us today. We had hordes of Momentum supporters throughout Westminster, particularly in the south, and the people of Westminster sent them the message 'We do not like your politics'.

block-time published-time 6.38am BST

More from Prof John Curtice, the BBC's elections analyst, on Labour. He said:

There is very little in the way of Labour gains. Yes, they have denied the Tories control of Trafford but that's a very strong remain area. Beyond that, there isn't very much for the Labour party to celebrate.

block-time published-time 6.35am BST

In London, with only a few wards yet to declare results, the Conservatives have retained control of Kensington and Chelsea.

And Labour have retained control of Brent after winning 33 seats, with the Conservatives on three and 24 results still to come.

block-time updated-timeUpdated at 6.36am BST

block-time published-time 6.31am BST

The Tories have taken all three West Hendon seats from Labour in Barnet, the Press Association reports.

This is from the Independent's Benjamin Kentish.

enltrLabour source in Barnet says wards with the highest proportion of Jewish voters are looking like "a car crash" for them. Adds: "Vote down would be an understatement."

- Benjamin Kentish (@BenKentish) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 6.12am BST

Early morning summary

* Theresa May has emerged unscathed from her first major electoral test since the general election. In a night that saw all the major parties make some initial gains as the Ukip vote collapsed, preliminary analysis suggested that outside London there was a swing from Labour to the Conservatives. In London the trend was different, but Labour failed to secure some of the high-profile council gains that some in the party had been hoping might prove possible. Overall it was a mixed night, and very few councils have so far changed hands (see 4.02am), but that was a relief to the Conservatives who know that in local elections governing parties often do much worse.

1. With results in from 87 of the 150 councils in England holding elections, all three main parties had achieved net gains in numbers of seats. Labour was on 1,072 seats (+30), the Conservatives 642 (+16) and the Lib Dems 278 (+24). Labour had won 44 councils (-1), the Conservatives 27 (no change) and the Lib Dems 3 (no change).
2. Ukip were the biggest losers of the night. With results in from 87 councils, they had lost 35 seats, and won just 2.
3. The BBC said its analysis of voting suggested that the Conservatives and Labour were either level-pegging, or else one party was marginally ahead of the other. Prof John Curtice, who analyses the figures for the BBC, said an early analysis of the figures suggested there had been a 1% swing to the Conservatives outside London, compared with 2014, but a swing to Labour in the capital. But his team is still analysing the results and firm figures will be released later.
4. The Conservatives comfortably held off Labour challenges to some of their flagship councils in London. They have retained control of Wandsworth and Westminster, and Labour has conceded that the Tories will also hold Kensington and Chelsea. Governing parties expect to lose ground in mid-term local elections, but in some areas they were making progress. They gained control of Basildon and Peterborough, both from no overall control.
5. Labour claimed the results showed the party had consolidated its position. It did not achieve a dramatic breakthrough, and party figures admitted the results were "mixed", but it gained Plymouth from the Conservatives and won enough seats in Tory-led Trafford to tip it into no overall control. Curtice said, if Labour and the Conservatives ended the day roughly equal in terms of the national share of the vote, that would allow Labour to claim it had made progress since the general election, when the Tories were ahead. (See 5.37am.)
6. The Lib Dems have won back Richmond from the Conservatives and are confident of gaining back Kingston-upon-Thames too, when counting there concludes later today.

block-time updated-timeUpdated at 6.41am BST

block-time published-time 5.41am BST

This is from Sky's Lewis Goodall.

enltrResults confirm that the culture war is yielding two zombie parties.Labour strong in cities but struggling in small town Britain. Cons making gains in post industrial areas and semi-rural England. But inability to breakout means there's no clear path to a majority for either.

- Lewis Goodall (@lewis\_goodall) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 5.39am BST

On the BBC J onathan Ashworth has just said that Labour has been too slow to deal with some of the allegations of antisemitism against party members. He said that one problem was that, when cases got taken to the national executive committee for disciplinary action, some NEC members were too willing to give the offenders the benefit of the doubt.

block-time published-time 5.37am BST

Prof John Curtice and his team analyse the election results to produce an estimate for the national share of the vote. (See [*11.46pm.)*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) He said that there was a small swing to the Conservatives, compared with four years ago, outside London, but that London was different. He said, in terms of the share of the vote, they were not quite sure whether Labour and the Conservatives were "exactly even-stevens" or whether one party was slightly ahead.

He went on:

Although these results are not particularly good for Labour, they are better, relatively speaking, than they were in the general election last year. So you certainly can't argue that the Labour party has not made any progress as compared with last year's general election [where the Tories were ahead]. But, on the other hand, you can't necessarily argue the Labour party is in a stronger position than they were in the 2016 local elections as well as the 2014 local elections [in both of which Labour ended up ahead].

block-time published-time 5.25am BST

Jonathan Ashworth, the shadow health secretary, told BBC News that the results were "mixed" for Labour. But he said the party was making progress. And he claimed that Labour thought, on the basis of the way people voted tonight, it would ***win*** the Putney parliamentary seat, which is currently held by the Conservative Justine Greening with a a majority of 1,554.

On the same programme John Curtice disputed this. He said that he thought the Tories would hold Putney on the basis of these results. But he said his own analysis of the Wandworth result suggested the Conservatives would now be on course to ***win*** Battersea (a seat Labour gained from the Tories at the general election, with a majority of 2,416).

block-time published-time 5.17am BST

This is from Jonathan Carr-West, chief executive of the Local Government Information Unit, on the results so far.

We've only seen a few councils change hands at this stage in the results but at present it looks like a better night for the Conservatives than many would have anticipated, while Labour results have not quite lived up to expectations.

In London, Labour were targeting flagship Conservative councils like Wandsworth and Westminster but have fallen short despite increasing their number of seats.

Labour needed to talk up the possibility of gains to get their vote out, but now risk disappointment even though Wandsworth and Westminster (both Conservative for more than 40 years) were always going to be a long shot.

Outside London the picture is one of Conservative consolidation. In places like Swindon, Nuneaton, Basildon and Southend, Labour need to ***win*** if they are to ***win*** a general election but the Conservatives are tightening their grip.

Meanwhile, the Lib Dems made big strides in terms of numbers of councillors and swept away the Conservatives in Richmond presumably benefiting from being the only major party opposed to Brexit in the borough that recorded one of the highest remain votes in the country.

Overall though, we seem to be seeing an entrenchment of the status quo; a divided Britain in which big cities vote Labour and everywhere else votes Conservative.

block-time published-time 5.12am BST

A much-touted Labour attempt to wrestle control of Wandsworth - controlled by the Tories since 1978 - was foiled after the Conservatives successfully concentrated resources in key strongholds amid a significantly increased turnout.

However, Labour came close on a night when it gained seven seats on a flagship Tory council that has been known for its ultra low council tax and outsourcing of local services since 1978.

The final results left the Tories on 33 seats, Labour on 26 and one in the hands of Malcolm Grimston, a former Conservative-turned independent who had the largest personal vote of the night (4002).

Even before the results started to come in, London's Mayor Sadiq Khan had earlier sought to manage expectations when he arrived at the count in South London where his party had needed to take 12 Tory seats to ***win*** outright control.

"Of course we may not ***win*** councils but I think winning councillors who are Labour is a fantastic achievement," he said, when it was put to him by reporters that he and other Labour figures had "talked up" the possibility of winning Wandsworth.

While Labour did make gains at the expense of the Tories, the latter fended of the challenge by bringing home increased votes to retain control of all seats in wards such as Fairfield, Thamesfield and Southfields.

Ravi Govindia, the Tory leader of the council, said:

The strategy was to take the message to every household to every door to every resident and convince them that this was a council that had not run out of steam.

Bright spots for Labour included Queenstown, where it made a gain from the Tories, and where councillors included 25-year-old Aydin Emre Dikerdem, who won a by-election in 2016.

Another story of the night was the sheer irrelevance of explicitly anti Brexit parties in a part of London that recorded a 75% for Remain during the referendum on membership of the EU.

Both the Liberal Democrats and Renew, a new party seeking to carve out ground on the centre, failed to make any real threats to the Tories or Labour in what was entirely a two-horse race. Renew's founder, former Foreign Office anti-terrorist officer Chris Coghlan, said that he was "pretty happy" with Renew's performance in target wards such as Balham, where he finished ahead of the three Liberal Democrats.

block-time updated-timeUpdated at 6.26am BST

block-time published-time 5.08am BST

Here are the figures from Richmond. This is from OnLondon's Dave Hill, who says the electoral pact that the Lib Dems and the Greens were operating in the borough seems to have worked.

enltrStonking ***win*** for [*@LondonLibDems*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) in   [*#Richmond*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections), where the   [*@LonGreenParty*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) also won four seats. So the Lib-Green electoral agreement seems to have worked. Tories reduced to seven. Boy, did I call that one wrong.   [*pic.twitter.com/f6EN4xiN6z*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Dave Hill On London (@DaveHill) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 5.04am BST

And the Conservatives have held Westminster too.

Westminster C No change Lab gain 4, C lose 4 New council: C 41, Lab 19

block-time published-time 5.03am BST

enltrUkip has so far won two council seats - double the number the party won in last year's local elections. [*#Election2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Ian Jones (@ian\_a\_jones)

[*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 5.02am BST

According to the Press Association's Ian Jones, only 19 more councils will declare tonight.

enltrJust 19 more councils left to declare tonight. The rest start counting in the morning. [*#Election2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Ian Jones (@ian\_a\_jones) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 5.00am BST

Tories hold Wandsworth

The Conservatives have held Wandsworth. It is a flagship Tory low tax borough, quoted approvingly by Theresa May at PMQs on Wednesday, and Labour would loved to have won it, although that was always a very high ask. Labour hasn't won it since 1974.

Here are the figures.

Wandsworth C No change Lab gain 7, C lose 6, Ind lose 1 New council: C 33, Lab 26, Ind 1

block-time published-time 4.37am BST

Jonathan Ashworth, the shadow health secretary, has just told BBC News that he thinks the Ukip vote is going to different parties. In some areas it was going to the Lib Dems, he said. That sounded counter-intuitive, he accepted, but it was in some respects a protest vote.

block-time published-time 4.35am BST

Here are the latest figures for London.

Conservatives

Councils: 1

Seats: 76 (+10)

Labour

Councils: 2

Seats: 118 (+3)

Lib Dems

Councils: 1

Seats: 33 (-11)

block-time published-time 4.33am BST

enltrTories are only 2 away from keeping Wandsworth, sounds pretty much like it's gone for Labour

- Laura Kuenssberg (@bbclaurak)

[*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 4.29am BST

Here is another slug of results.

Welwyn Hatfield C No change C 8, LD 6, Lab 5 LD gain 3, C lose 2, Lab lose 1 New council: C 25, Lab 15, LD 8

Bradford Lab No change Lab 20, C 8, LD 2 Lab gain 3, C gain 1, Ind lose 2, LD lose 1, Green lose 1 New council: Lab 52, C 22, Ind 7, LD 7, Green 2

Winchester C No change LD 9, C 6 LD gain 2, C lose 1, Ind lose 1 New council: C 23, LD 22

Hillingdon C No change C gain 2, Lab lose 2 New council: C 44, Lab 21

Daventry C No change C 11, Lab 2 Lab gain 2, UKIP lose 2 New council: C 30, Lab 5, LD 1

North East Lincolnshire NOC No change C 10, Lab 5, LD 1 C gain 3, Lab gain 2, UKIP lose 3, LD lose 1, Ind lose 1 New council: Lab 19, C 18, LD 4, Ind 1

Sutton LD No change C gain 10, Ind gain 1, LD lose 11 New council: LD 33, C 18, Ind 3

Waltham Forest Lab No change Lab gain 3, C lose 2, Ind lose 1 New council: Lab 46, C 14

Eastleigh LD No change Boundary change C down 2, Ind down 2, LD down 1 New council: LD 32, C 4, Ind 3

Cheltenham LD No change LD 17, C 3, Ind 1 LD gain 3, Ind lose 2, C lose 1 New council: LD 32, C 6, Ind 2

block-time published-time 4.25am BST

The Lib Dems have gained Richmond and they are confident of gaining Kingston too, party sources says. They also held Sutton, Eastleigh and Cheltenham. They claim holding Sutton was significant because the Conservatives fought it hard.

block-time published-time 4.19am BST

On the BBC Jonathan Ashworth, the shadow health secretary, says the results are pretty good for Labour. "We are making gains in the sorts of constituencies that will decide the next election," he says, citing Chingford, Putney and Plymouth as examples.

block-time published-time 4.17am BST

The Conservative MP Johnny Mercer, a former soldier and MP for Plymouth Moor view, told the BBC that the government's approach to defence had contributed to the Conservatives losing the city's council. He said:

We've lost control of the council. I think across the country, clearly, it's not been a good night for Labour, but certainly challenging down here.

It's pretty clear to me the biggest factor in this city is defence. It always has been. I've made very public my concerns around the handling of defence at the moment and what the vision is.

block-time published-time 4.17am BST

On Sky News Sky's election expert Michael Thrasher was asked whether it was fair to say this was a bad night for Labour. He did not want to go that far. But it was "certainly not a good night", he said.

Liam Fox, the international trade secretary, told the programme the results were at the higher end of his party's expectations. He claimed that the results would lead to Labour party members wondering whether, under Jeremy Corbyn, the party was too London-centric.

block-time published-time 4.11am BST

More news snaps from the Press Association.

Labour looks set to retain control of its mayoral seat in Tower Hamlets with a party source saying they are "very confident" John Biggs will be returned

The Liberal Democrats have gained control of the London Borough of Richmond upon Thames after winning at least 38 of the 54 seats.

The Conservatives have retained control of Hillingdon, after winning 35 of the 65 seats.

The Conservatives have retained control of Winchester City Council despite losing one seat to the Liberal Democrats.

block-time published-time 4.06am BST

Labour loses Derby to no overall control

Here are the figures for Derby.

Derby Lab lose to NOC C 8, Lab 5, LD 2, UKIP 2 C gain 2, UKIP gain 1, Lab lose 3 New council: Lab 23, C 20, LD 5, UKIP 3

Carrie Symonds, the Conservative party's director of communications, has taken to Twitter to gloat.

enltrIf the results tonight in Derby North had been replicated in the last general election, Chris Williamson would have lost his seat. Let's remember what Chris Williamson said just last week: "It's the easiest period to campaign for Labour in my entire life"

- Carrie Symonds (@carriesymonds)

[*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 4.03am BST

Wandsworth might have voted remain by 75% in the referendum on membership of the EU, but another story of tonight was the sheer irrelevance of explicitly anti Brexit parties.

Both the Liberal Democrats and Renew, a new party seeking to carve out ground on the centre, failed to make any real threats to the Tories or Labour in what was entirely a two-horse race.

If there is a tiny 'civil war' among the remain parties however, it was members Renew who were patting themselves on the back.

Its founder, former Foreign Office anti-terrorist officer Chris Coghlan, said that he was "pretty happy" with Renew's performance in target wards such as Balham, where he finished ahead of the three Liberal Democrats.

The figures are small however: Coghlan polled 568 in a ward where three Tories romped home with more than 7,000 votes between them.

So what happened to the 75% remain vote? The answer may or may not be down to the fact that this was about bins rather than Brexit.

"The results will have been blurred by the fact that this was a local election," said Coghlan. "We are also a startup and it's about building ourselves as a party that is fundamentally about more than just being anti-Brexit."

block-time published-time 4.02am BST

According to the Press Association, results are now in from 71 of the 150 councils where elections have been taking place.

Here are the figures.

Conservatives

Councils: 20 (nc)

Seats: 412 (+27)

Labour

Councils: 37 (-1)

Seats: 743 (+9)

Lib Dems

Councils: 2 (nc)

Seats: 180 (+21)

Greens

Seats: 15 (+4)

Ukip

Seats: 2 (-29)

And here are the councils that have changed hands.

Conservative gains

Basildon (from no overall control)

Peterborough (from no overall control)

Conservative losses

Trafford (to no overall control)

Plymouth (to Labour)

Labour gains

Plymouth (from Conservative)

Labour losses

Nuneaton & Bedworth (to no overall control)

Derby (to no overall control)

block-time published-time 3.49am BST

Labour has become the biggest party in Trafford, winning four seats from the Tories to take their total to 30. After a surprise double ***win*** by the Green party in Altrincham, the Conservative party was left with 29 seats, down from 33.

"I'm absolutely ecstatic," said Andrew Western, leader of the Labour group on Trafford council. "This is far beyond our expectations. We hoped to tip the council into no overall control tonight, but to have become the largest party at the same time is a fantastic bonus. We could not be happier."

enltrLabour celebrating becoming the largest party in Trafford. Lab leader Andrew Western says result is an indictment of local Conservatives [*#LocalElection2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/7rKyMqvhZz*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Frances Perraudin (@fperraudin) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

Conservative council leader Sean Anstee said his party would have to reflect on the results. He said:

Elections in Trafford have always been tight and clearly, as the only Conservative-majority council in Greater Manchester, surrounded by a number of Labour councils, we've seen significant ***opposition*** activity into the borough over the last six months or so.

He said that wards that had changed hands also saw a significant increase in turnout. "A number of voters who ordinarily perhaps haven't voted, turned out," he said. "We'll need to reflect on the reasons why they turned out in the way that they did and why they voted in the way that they did."

While it didn't surprise many to see the Conservatives lose their overall control of Trafford council, it had not been predicted that the Greens would land the final blow.

Geraldine Coggins, one of two Green candidates to take seats of the Tories in Altrincham, said:

The media hasn't necessarily noticed, because we're not very surprised. I spoke to a number of people in their 80s who said they had always voted Conservative but were going to vote Green for the first time in their lives, and a number of Labour members who said they were going to vote Green this time. There was a lot of momentum.

Dan Jerrome, who came second in the last set of council elections in the area, said that it shouldn't come as a surprise that Green party candidates could take seats from Conservatives. He said the pair - who are now Greater Manchester's only Green councillors - had campaigned on a number of issues, but pointed to the council plans to chop down trees and large developments that residents felt they hadn't been consulted on.

enltrGreater Manchester's new (and only) Green Party councillors. They say their campaign in Altrincham went below the media's radar but that they aren't surprised they won [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/P5Lfs0WfxJ*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Frances Perraudin (@fperraudin) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 3.47am BST

On the BBC's election programme Liam Fox, the international trade secretary, claimed a few minutes ago that Brexit was not a big factor in the local elections. He told the programme:

I didn't get from voters on the doorstep 'Brexit, Brexit'. That just was not what was coming across. It was about local issues.

But Fox had to be corrected by fellow panellists when he argued that, if Brexit was a factor, Labour would have done better in remain areas like Walsall at these elections. Walsall voted leave, he was told.

Rob Ford, an academic and elections specialist, says Fox is just wrong.

enltrCons doing markedly worse and Lab markedly better in areas with large ethnic minority populations

- Rob Ford (@robfordmancs) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrThe really strong connection between Con performance and EU referendum vote seen in last year's general election is also very clear in this year's local elections. Brexit alignment remains in place. Pace Liam Fox, it was Brexit not bin collections

- Rob Ford (@robfordmancs) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time updated-timeUpdated at 4.15am BST

block-time published-time 3.30am BST

Labour gain Plymouth from Conservatives

Labour have gained Plymouth from the Conservatives.

That is the first council of the night that has switched from one party's majority control to another's.

Here are the figures.

Plymouth Lab gain from C Lab 11, C 8 Lab gain 4, C lose 4 New council: Lab 31, C 26

block-time updated-timeUpdated at 3.31am BST

block-time published-time 3.24am BST

This is from the New Statesman's Stephen Bush.

enltrBasically, this is just the 2017 election - with one crucial difference: the Liberal Democrats are doing a lot better: [*https://t.co/FAJ7ZTHBOP*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Stephen Bush (@stephenkb) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 3.22am BST

Ukip have actually won a seat. This is from Chris Doidge from BBC Radio Derby.

enltrBreaking: Labour leader of [*@DerbyCC*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) Ranjit Banwait loses his seat to UKIP.

- Chris Doidge (@BBCChrisD) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrBoulton ward, [*@DerbyCC*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)UKIP 1602 (Paul Bettany) Labour 1128 (Ranjit Banwait) Conservatives 1086 Lib Dems 165   [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/x0qboJEEen*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Chris Doidge (@BBCChrisD) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 3.21am BST

If the results in London are quite different from the results outside London (see [*3.14am),*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) then in many respects that's just a repeat of what happened at the last general election. Overall there was a modest swing from the Conservatives to Labour in 2017. But the swing in London was much, much larger than anywhere else. Here is another chart from Britain Votes 2017.

Conservative/Labour swing at the general election by region Photograph: Britain Votes 2017

block-time published-time 3.14am BST

Early analysis suggests 1.5% swing from Tories to Labour in London, 1% swing to Tories outside, says BBC

According to John Curtice at the BBC, as reported [*on the BBC blog,*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) their analysis from key wards in London shows "a 1.5% swing from Conservative to Labour, far short of what Labour needs to pick up anything other than perhaps Barnet, but in contrast to the position outside of London where there is so far a 1% swing from Labour to the Conservatives."

block-time published-time 3.11am BST

Here is some comment on the Trafford result. (See [*3.03pm)*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

Tim Montgomerie, who founded the ConservativeHome website, wonders if there was an Andy Burnham effect.

enltrSir Graham Brady confirms Tories have lost Trafford. Anyone have strong views on why? Is there an [*@AndyBurnhamGM*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) effect? (I realise only small swing was needed).

- Tim Montgomerie (@montie) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

From Andrew Fisher, Jeremy Corbyn's policy adviser

enltrLabour now the largest party in Trafford - removing the last Tory council in Greater Manchester [*#Vote2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Andrew Fisher (@FisherAndrew79) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

From the Manchester Evening News's Jennifer Williams

enltrThe Trafford result also means that every single politician round the top table in Greater Manchester is now set to be Labour.

- Jennifer Williams (@JenWilliamsMEN) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 3.03am BST

Conservatives lose Trafford to no overall control

The Conservatives have lost Trafford to no overall control. Here are the figures.

Trafford C lose to NOC Lab 13, C 7, Green 2 Lab gain 4, Green gain 2, C lose 4, LD lose 1, Ind lose 1 New council: Lab 30, C 29, LD 2, Green 2

block-time published-time 2.59am BST

More from Wandsworth.

This is from Matt Singh from Number Cruncher Politics.

enltrWandsworth ward swings: Queenstown 8.8% to LAB Thamesfield 0.8% to CON St Mary's Park is apparently a recount, which suggests 6-7% to LAB

- Number Cruncher Politics (@NCPoliticsUK) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

And this is from Marsha de Cordova, the Labour MP for Battersea.

enltrQueenstown has three Labour councillors for the first time since 1990 - and what fantastic councillor's they are! Massive congratulations Aydin, Maurice & Paula! [*pic.twitter.com/vMqnbqijTo*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Marsha de Cordova MP (@MarshadeCordova) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 2.56am BST

My colleague Ben Quinn has tweeted this from Wandsworth, which he says helps to explain why the Conservatives have fended off the Labour attack.

enltrBut here's part of why the Tories seem to have fended off Labour in Wandsworth They got their vote out in middle class strongholds like Thamesfield, where turnout was up by 6%, holding all 3 seats [*#LE2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/9dvySwrFUV*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Ben Quinn (@BenQuinn75) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 2.52am BST

Labour may have reached 'peak Corbyn', Justine Greening says

On the BBC election programme Justine Greening, the Conservative former education secretary and MP for Putney, said that, after three bad years for her party in London, there were some signs of hope. She said:

Labour were really trying to keep up, literally, the momentum. It doesn't look to me - we've got lots of results to come through - like they've managed to do that. Maybe we are beginning to see something akin to peak Corbyn happening.

block-time published-time 2.43am BST

The results are now in from 53 councils. And only three councils have changed hands.

The Conservatives have gained Basildon and Peterborough - both from no overall control.

And Labour has lost Nuneaton, which is now under no overall control.

Here is another slug of results. I posted a large chunk of them earlier at [*1.29am.*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

Councils where control has changed

Peterborough C gain from NOC C 7, Lab 6, LD 3, Green 1, Ind 1 C gain 1, LD gain 1, Green gain 1, Lab lose 1, UKIP lose 1, Lib lose 1 New council: C 31, Lab 14, LD 6, Ind 5, Lib 2, UKIP 1, Green 1

Councils where control has not changed.

Havant C No change C 13, Lab 1, LD 1 C gain 2, UKIP lose 2 New council: C 31, Lab 2, UKIP 2, Ind 2, LD 1

Sefton Lab No change Lab 17, C 4, LD 2 C gain 3, Lab gain 3, LD lose 4, Ind lose 2 New council: Lab 43, LD 12, C 8, Ind 3

Fareham C No change C 12, LD 3, Ind 1 New council: C 24, LD 5, UKIP 1, Ind 1

Gosport C No change LD 9, C 8, Lab 1 LD gain 4, C lose 3, Lab lose 1 New council: C 18, LD 14, Lab 2

Dudley NOC No change C 14, Lab 10 C gain 6, UKIP lose 6 New council: Lab 35, C 35, UKIP 1, Ind 1

Wolverhampton Lab No change Lab 19, C 3 Lab gain 2, C lose 1, UKIP lose 1 New council: Lab 51, C 9

Portsmouth NOC No change C 6, Lab 4, LD 4 Lab gain 4, LD gain 1, C lose 2, UKIP lose 2, Ind lose 1 New council: C 19, LD 16, Lab 6, Ind 1

Wokingham C No change C 11, LD 4, Lab 2, Ind 1 Lab gain 2, LD gain 1, C lose 3 New council: C 42, LD 8, Lab 3, Ind 1

Rochdale Lab No change Lab 16, C 3, LD 1 LD gain 1, Lab lose 1 New council: Lab 46, C 10, LD 3, Ind 1

Ipswich Lab No change Lab 12, C 3, LD 1 Lab gain 1, C lose 1 New council: Lab 34, C 12, LD 2

Liverpool Lab No change Lab 25, LD 3, Green 2, Lib 1 LD gain 3, Lab lose 3 New council: Lab 76, LD 7, Green 4, Lib 2, Ind 1

Colchester NOC No change C 10, Lab 4, LD 2, Ind 1 C gain 2, LD lose 2 New council: C 25, LD 12, Lab 11, Ind 3

Newcastle-upon-Tyne Lab No change Boundary change Lab up 2, LD down 1, Ind down 1 New council: Lab 56, LD 19, Ind 3

Lincoln Lab No change Lab 7, C 4 C gain 3, Lab lose 2, Ind lose 1 New council: Lab 24, C 9

Hart NOC No change C 4, Ind 4, LD 3 Ind gain 3, C gain 1, R lose 4 New council: C 15, LD 8, R 6, Ind 4

Preston Lab No change Lab 13, C 5, LD 2 Lab gain 2, C lose 2 New council: Lab 35, C 17, LD 5

Chorley Lab No change Lab 14, C 2, Ind 1 Lab gain 2, C lose 1, Ind lose 1 New council: Lab 32, C 13, Ind 2

Sandwell Lab No change Lab 26 Lab gain 3, Ind lose 3 New council: Lab 70, Ind 2

Rugby C No change C 8, Lab 3, LD 3 C gain 1, LD gain 1, Ind lose 2 New council: C 24, Lab 9, LD 9

Tameside Lab No change Lab 17, C 2 New council: Lab 51, C 6

Stevenage Lab No change Lab 8, C 3, LD 2 LD gain 1, Lab lose 1 New council: Lab 26, C 9, LD 4

block-time published-time 2.30am BST

Volunteers counting ballot papers at Wandsworth Town Hall Photograph: Henry Nicholls/Reuters

block-time published-time 2.27am BST

I'm at the count in Wandsworth where it looks increasingly like the Conservatives have held off the much talked about threat of a Labour takeover of a council that has been in Tory hands since 1978.

Sadiq Khan, who is at the count in South London, has been playing down Labour's chances not just of ousting the Tories in a local authority where the mayor's party would need to take 12 Tory seats, but also making more widespread gains.

"I'm looking forward to seeing the us making gains across London," he said, when it was put to him by reporters that he and other Labour figures had "talked up" the possibility of winning Wandsworth. "Of course we may not ***win*** councils but I think winning councillors who are labour is a fantastic achievement."

A rank and file Labour activist put his feelings about the party's chances in Wandsworth more bluntly: "Glum, I'm glum. It was just too big a mountain to climb."

Justin Greening, the Tory MP for Putney, said it appeared that the Conservatives have managed to "fend off" Labour.

Turnout is meanwhile up in many wards here, and by as much as 10 percent in many cases.

block-time published-time 2.25am BST

Matt Singh, who runs the Number Cruncher Politics website, reckons that people are making false assumptions about where the Ukip vote is going. John McDonnell, the shadow chancellor, and others have been arguing that they are going in disproportionate numbers to the Conservatives.

enltrA lot of misreporting of how (eg) the UKIP vote is splitting. You don't know how it's splitting just from look at the net changes in a ward, that requires a proper analysis (and ideally individual level data). I wish people would stop it...

- Matt Singh (@MattSingh\_)

[*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

Liam Fox, the international trade secretary, has just told the BBC that his view is that Ukip voters are just returning to the parties they supported before they flocked to Ukip a few years ago.

On the subject of what happens to the Ukip vote, it is worth flagging up this chart in [*Britain Votes 2017,*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) a useful collection of essays on the general election published by the Hansard Society. In the main essay David Denver says that, overall, the decline in the Ukip vote benefited the Conservatives.

But he also says that although people assumed that the Conservatives would benefit most in those constituencies where Ukip decided not to stand a candidate, actually the ***opposite*** happened and Labour saw their share of the vote rise the most. Here are the figures he cites to back this up.

How absence of Ukip and Green candidates helped Labour and Tory candidates at 2017 election Photograph: Britain Votes 2017

block-time published-time 2.08am BST

The results are now in from 43 of the 150 councils where there are elections.

Here are the figures

Conservatives

Councils: 14 (+2 - Basildon and Peterborough)

Seats: 241 (+45)

Labour

Councils: 23 (-1 - Nuneaton)

Seats: 428 (-13)

Lib Dems

Seats: 65 (+8)

Greens

Seats: 7 (+1)

Ukip

Seats: 0 (18)

block-time published-time 2.03am BST

Conservatives gain control of Peterborough, from no overall control

Results are starting to come in thick and fast now. Here is a round-up from the Press Association.

The Liberal Democrat leader of Colchester Council, Paul Smith, has lost his seat in St Anne's and St John's ward to the Conservatives, who are hoping to take control of the council.

The Conservatives have gained control of Peterborough, winning seven of the 18 seats contested. It was under no overall control.

The Labour target of Carlisle remains in no overall control.

North East Lincolnshire will remain under no overall control after the results were declared in 12 of the 16 wards being contested. The council was a target for both Labour and the Conservatives.

Conservative sources say they expect to remain the largest single party on Worcester City Council. The Green party look set to gain a seat from the Tories.

Labour looks set to take Plymouth from the Conservatives, Labour Party sources say.

The result at Winchester is too close to call, Conservative and Liberal

Democrat sources say. The Conservatives currently have a narrow majority on the council, which is a Liberal Democrat target.

block-time published-time 1.56am BST

On the BBC election programme John McDonnell, the shadow chancellor, said that Labour was making "steady progress" but that "obviously we want to be doing better".

He said the Ukip vote had largely gone to the Tories.

Sir Nick Harvey, the former Lib Dem MP, also told the programme that he thought the Ukip vote had gone to the Conservatives.

block-time published-time 1.52am BST

Here is some reaction to the result in Swindon, where Labour gained one seat from the Conservatives, but the Conservative retained overall control of the council

The Labour group leader Jim Grant said:

I'm bitterly disappointed. We need to sit down and analyse the figures. Turn-out was up all round. We got as many votes as we thought we would need to ***win***. Clearly the Conservatives were able to increase their vote. How I don't know. It may be the collapse of the Ukip vote and that has gone back to the Tories. But we are still in the game here. The majority is reduced to one. Next year one last haul and hopefully we will break the Tory monopoly on control of Swindon borough council. Jeremy [Corbyn] has inspired our active base and that is why we have got so many votes.

The Conservative group leader David Renard said:

We got our positive message across. Labour ran a very negative campaign here. They have thrown a lot of resource, brought in a lot of people and spent a lot of money trying to take up to six of our seats. They failed to take every one. We have shown the Labour party is a long way from forming a government and on the doorstep there is a lot of anti Jeremy Corbyn feeling. There are very few places in southern England where Labour has a foothold.

And this is from Robert Buckland, the South Swindon MP and solicitor general.

Labour were expecting to take control or for their to be no overall control. They failed. It's a very bad night for them and a really strong night for the Tories.

block-time published-time 1.48am BST

Tory vote seems to be rising more than Labour's, says John Curtice

Who's doing well and who's doing badly? This is what John Curtice, the leading psephologist, told the BBC a few minutes ago.

The truth is, [all three main parties] are doing better than they were four years ago in terms of votes won. That's a reflection of the fact that the Ukip vote is down.

However John McDonnell's problem is that the Conservative vote, at least in the votes that we have had so far, which are all from outside London, is going up more than the Labour vote. That therefore means that, relative to the Conservatives at least, Labour are in a somewhat weaker position than they were in indeed in 2014 when most of the seats were [last fought]...

That said, this... is pointing to something like Conservative and Labour being equal, or probably the Conservatives being slightly ahead. This probaby does mean that the Labour party are in a stronger position than they were in the 2017 general election.

But the truth is, in so far as the Labour party would like to be able to demonstrate further progress, to be able to say that actually we're beginning to come up with the kinds of leads in the local elections that we normally associate with ***oppositions*** that are heading for victory, I think John must be somewhat disappointed. The Labour party, relative to the Conservatives at least, are going back as compared with recent local election performances.

block-time published-time 1.36am BST

enltrFollow rolling coverage of results from [*#LocalElection2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)Here's the current state of play   [*https://t.co/LBKYeyD1TV*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/i6qxJGIqS1*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- BBC Politics (@BBCPolitics) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 1.35am BST

At a Momentum election night event, Labour canvassers are taking a rest after a long day of door-stepping.

Laura Parker, the Momentum national co-ordinator, said the fact that the Tories seemed to be doing well in leave areas showed how divided the country was. She said:

There's a more profound fracture in British politics on leave/remain lines. It's clear the Labour party have to continue building in areas over a long period of time that it's lost. It's almost certainly the case the Tories have the same problem in reverse - they will struggle in remain areas and big cities.

This isn't a healthy state of affairs. The distinguishing feature is Labour has a manifesto for the whole country, and of course expectations are high because we did so well in the general elections. But we're comparing our results to 2014; there's only so much we can gain. The Tories have had some of the worst few weeks on record; if I was the Tories I'd be talking up Wandsworth and Kensington too.

Swindon is obviously disappointing. It's a place we were hoping to do better in. It's all relative, that's the thing about local elections.

One of the challenges for Labour is having a much bolder offering about local government but you can only do that when you're in government. For the moment we're mitigating the worst effects of austerity, which is a thankless task.

enltrMomentum are hesitant to predict the results of today's election this soon, but there are free beers and [*@jonlansman*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) is...   [*pic.twitter.com/o3yaS3NwtM*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Nadia Khomami (@nadiakhomami)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 1.29am BST

Here are the results by council that are in so far, according to the Press Association.

Councils where control has changed

Basildon C gain from NOC C 11, Lab 2, Ind 2 C gain 5, Lab gain 2, UKIP lose 5, Ind lose 2 New council: C 24, Lab 11, UKIP 5, Ind 2

Nuneaton & Bedworth Lab lose to NOC C 11, Lab 6 C gain 8, Lab lose 7, Green lose 1 New council: Lab 17, C 16, Green 1

Councils where control has not changed

Tamworth C No change C 8, Lab 1, Vacant 1 C gain 2, Lab lose 1, Ind lose 1 New council: C 22, Lab 5, Ind 1, UKIP 1, Vacant 1

Thurrock NOC No change Lab 9, C 6, Ind 1 Lab gain 3, C gain 1, Ind lose 4 New council: C 20, Lab 17, Ind 12

Tandridge C No change C 4, LD 4, Ind 3, R 3 LD gain 3, Ind gain 3, R gain 2, C lose 8 New council: C 22, LD 9, Ind 7, R 4

Brentwood C No change C 8, LD 4, Lab 1 C gain 1, Ind lose 1 New council: C 25, LD 9, Lab 2, Ind 1

Wigan Lab No change Lab 18, Ind 4, C 3 Ind gain 3, C gain 2, Lab lose 5 New council: Lab 60, Ind 8, C 7

Cannock Chase Lab No change Lab 6, C 5, LD 1, Green 1 C gain 2, Green gain 1, Ind lose 2, UKIP lose 1 New council: Lab 21, C 15, Green 3, Ind 1, LD 1

Hartlepool Lab No change Lab 5, Ind 5, C 1 Ind gain 1, UKIP lose 1 New council: Lab 19, Ind 11, C 3

Swindon C No change C 9, Lab 9, LD 1 Lab gain 1, C lose 1 New council: C 29, Lab 26, LD

St Helens Lab No change Lab 13, C 1, LD 1, Ind 1 Ind gain 1, Lab lose 1 New council: Lab 41, LD 3, C 3, Ind 1

Halton Lab No change Lab 17, LD 1 New council: Lab 52, C 2, LD 2

Castle Point C No change C 9, Ind 5 C gain 4, UKIP lose 2, Ind lose 2 New council: C 27, Ind 14

block-time published-time 1.17am BST

The Tories are also optimistic about seeing off Labour in Westminster, my colleague Pippa Crerar reports.

enltrAnd I've just heard from Tory sources that they're "optimistic" about Westminster.

- Pippa Crerar (@PippaCrerar) [*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 1.16am BST

Labour has conceded defeat in Kensington and Chelsea and said there is little chance of the party taking control of the council, despite the Conservative administration's chaotic handling of the Grenfell Tower disaster.

"We have piled up votes in Labour-held wards," said Labour group leader Robert Atkinson, insisting his party's gains would be limited because the Conservatives have managed to "frighten out" their vote across the west London borough.

Kensington and Chelsea has been controlled by the Conservatives since the council was formed in 1964 and Labour went into this year's election with just 11 out of 50 seats - all representing areas in the poorer, north of the borough near to the burned-out shell of Grenfell Tower.

Last June's catastrophe, combined with the unexpected victory of Labour's Emma Dent Coad in the Kensington parliamentary constituency at the general election, prompted speculation that Jeremy Corbyn's party could be on a cusp of an unlikely breakthrough.

Instead Labour is hoping to gain just a handful of councillors, with hopes pinned on the Chelsea Riverside and St Helen's wards. The Liberal Democrats are targeting a single ward, while the new centrist political movement Advance looks to have sunk without trace.

Despite conceding defeat, Atkinson insisted the election showed how the Conservative council's reputation has been hit by the disaster, even among core Tory supporters in ultra-wealthy parts of the borough.

"Grenfell is a symbol of incompetence of the council," he said. "I've heard that from Chelsea ladies who always thought they had an efficient council. But both during and afterwards the council has just failed."

block-time published-time 1.13am BST

Britain Elects has been calculating what has happened to the share of the vote so far. There has been a swing to the Tories, it says - about 2.5% since 2014.

enltrShare changes of the results we have so far: Con: +9.0 Lab: +4.1 LDem: +3.8 Grn: +2.9 UKIP: -19.3 Swing to Tories.

- Britain Elects (@britainelects)

[*May 4, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 1.11am BST

I've just been speaking to councillor Andrew Western, leader of the Labour group on Trafford council, who is quick to dismiss the idea that his party could ***win*** overall control of the borough. "That was never the plan. We never thought that we could go to overall control this year. Absolutely not," he said. He went on:

To be honest, I think the Tories were suggesting that by way of expectation management. But we never felt that we could take it this time. To ***win*** six seats [the number the party would need to take control] we would have to ***win*** three that we have never won in the history of Trafford.

Even to go to no overall control we would have to ***win*** one seat in Davyhulme East that we've never ever won. So I would say that, for us, no overall control would be a tremendous result. It really would.

Turnout in Trafford is slightly up on the last set of elections in 2016 - 42.9% (73,073 votes) compared to 41% (66,763) - something Western says is good for Labour. "I'd say we're hopeful from the things that we've seen of picking up two or three seats, maybe, but it really is too early to tell." Sean Anstee, the council's Conservative leader, also said, unsurprisingly, that it was too early to make predictions. He said:

We've seen a concerted effort from the Labour party, just as we've seen a concerted effort from our party. We'll know later on tonight who's has been successful.

I think it is important for Greater Manchester [where Trafford is the only Conservative council] to have a diversity of political opinion. We can see in city regions across the UK, where they're dominated by a single party, that that doesn't bring the variety of ideas that you would really want to have.

block-time published-time 1.08am BST

The Tories have sent out a briefing about Labour losing control of Nuneaton & Bedworth. They point out that in 2014 Labour had a 22-seat majority there. And they point out that my Guardian colleague Owen Jones, a very active campaigner for Labour, [*once cited Nuneaton as the sort of seat Labour should* ***win****.*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 1.03am BST

Here are the latest figures from the Press Association, with the results in from 12 of the 150 councils.

Conservatives

Councils: 4 (n/c)

Seats: 62 (+20)

Labour

Councils: 7 (-1)

Seats: 110 (-16)

Lib Dems

Seats: 11 (+3)

Greens

Seats: 1

Ukip

Seats: 0 (-5)

block-time published-time 12.55am BST

My colleague Steven Morris has posted a picture of the Tories celebrating holding on to Swindon.

enltrHappy Tories in Swindon - they have hung on to control. [*pic.twitter.com/LdQMlpRb1A*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- steven morris (@stevenmorris20)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.54am BST

Conservatives gain Basildon

The Conservatives have gained Basildon. This is from the BBC's Nick Sutton.

enltrConservatives gain BASILDON as UKIP loses 10 councillors. [*https://t.co/4ZuF8PS3wX*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*#LocalElections2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/WEyPxBx9OQ*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Nick Sutton (@suttonnick) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.50am BST

The Tories have held Swindon, the BBC reports.

enltrTories have held Swindon - that will be big relief for tory hq and disappointment for Labour, Corbyn visited several times

- Laura Kuenssberg (@bbclaurak) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time updated-timeUpdated at 12.52am BST

block-time published-time 12.48am BST

In a statement released tonight Sadiq Khan, the Labour mayor of London, said that for Labour to ***win*** Wandsworth would be beyond the party's "wildest expectations". He said:

I've been campaigning across London and it's quite remarkable to see us being competitive in boroughs that used to be "no go" areas for Labour in previous years. No more.

It would be truly astonishing if Labour were to take control of Wandsworth council - which has been a flagship Tory council for forty years - and winning here is above even our wildest expectations. We last won here in 1974...

In Wandsworth we stand a real chance of winning councillors in some wards that Labour hasn't represented since I was born - but it would be a real earthquake if we were to ***win*** control of the council - above even our wildest expectations.

Whatever the outcome here tonight, it's clear that London has turned its back on Theresa May's Government - who neither like nor understand Londoners, our values or our way of life.

block-time published-time 12.44am BST

enltrLabour loses control of Nuneaton with the Conservatives taking nine seats Follow [*#LocalElection2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) latest results   [*https://t.co/sJEvO3iz0u*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/DxR0WVVYgE*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- BBC Politics (@BBCPolitics) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.43am BST

Britain Elects has the Nuneaton voting figures.

enltrNuneaton & Bedworth, result: Con: 51.0% (+21.1) Lab: 35.9% (-5.6) Grn: 9.0% (+2.5) Oth: 1.6% (+0.8) Ind: 1.1% (+1.0) UKIP: 0.8% (-17.9) Chgs. w/ 2014

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

The New Statesman's Stephen Bush says these figures show why it is wrong to hold elections by thirds.

enltrThe thirds model is terrible: a clear vote for a Tory council - but it's hung instead. [*https://t.co/jq9tnRkNxs*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Stephen Bush (@stephenkb)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.38am BST

Here are the Nuneaton & Bedworth results from the Press Association. These are the seats that were up for election - not all the seats on the council.

Con: 11 (+8)

Lab: 6 (-7)

Green: 0 (-1)

block-time updated-timeUpdated at 12.42am BST

block-time published-time 12.35am BST

Labour lose control of Nuneaton & Bedworth

According to the Press Association, results are now in from six councils.

Con: 2

Lab: 3 (-1)

NOC: 1 (+)

The council that has changed hands is Nuneaton & Bedworth, which has gone from Labour to no overall control (NOC).

block-time updated-timeUpdated at 12.48am BST

block-time published-time 12.30am BST

More on what the Tories are saying.

enltrTories reporting that Richmond-upon-Thames "isn't looking great" which is surprising - feeling was that it would be tough for Lib Dems to ***win*** despite being in Vince Cable's own back yard. However, Brexit. (The seat voted 75 per cent Remain). Lib Dems saying it's on "knife edge".

- Pippa Crerar (@PippaCrerar) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrPost-Midnight latest: Tories think they'll "just" hold onto Swindon and take Dudley. But will lose Trafford to Labour, and Richmond to Lib Dems. The latter not expected, and would be a major anti-Brexit protest.

- Tom Newton Dunn (@tnewtondunn) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.28am BST

Lib Dem sources say the party expects to make a handful of gains in Liverpool.

block-time published-time 12.28am BST

This is from my colleague Pippa Crerar.

enltrTory sources saying they expect to lose Trafford to Labour, which would be a boost for Jeremy Corbyn who launched his local election campaign there (although Labour sources say they think it will be NOC).

- Pippa Crerar (@PippaCrerar)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.25am BST

Senior Labour and Conservative sources in Dudley, where either party could take control, say it is too close to call, the Press Association is reporting. Labour sources say it could come down to results in just two of the 24 wards being contested, Belle Vale and Wollaston & Stourbridge Town.

block-time published-time 12.22am BST

The Local Government Information Unit has a faster results service.

enltrLAB hold for [*@HaltonBC*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- LGiU (@LGiU)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrWest Oxfordshire: CON HOLD

- LGiU (@LGiU) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrSunderland: LABOUR HOLD

- LGiU (@LGiU) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrWigan: LABOUR HOLD

- LGiU (@LGiU) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrUnsurprisingly [*@SunderlandUK*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) is LAB hold and   [*@BroxbourneBC*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) a CON hold

- LGiU (@LGiU) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time updated-timeUpdated at 12.35am BST

block-time published-time 12.19am BST

The Press Association has posted the first full council result of the night.

Broxbourne

C No change

C 9, Lab 1

C gain 1, Ukip lose 1

New council: C 28, Lab 2

block-time published-time 12.17am BST

The Tories are saying Labour has lost control of Nuneaton. And the party has tweeted this particular result.

enltrSlough (Nuneaton & Bedworth): Con: 66.8% (+25.4) Lab: 33.2% (-25.4) Con GAIN from Labour

- CCHQ Press Office (@CCHQPress) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time updated-timeUpdated at 12.19am BST

block-time published-time 12.10am BST

On the BBC John McDonnell, the shadow chancellor, says it is going to be "a complicated night". It might be "quite boring" too, he says - to protests from the BBC's Laura Kuenssberg. He says suggestions that Labour could make great gains were wrong. Relatively few councils are likely to change hands, he says. And he says it is not clear what will happen to the Ukip vote. He says at the general election two thirds of the Ukip vote went to the Conservatives, and only one third went to Labour. He says Labour's focus is on making "incremental gains".

block-time published-time 12.06am BST

The Conservatives are doing well in Nuneaton, the BBC is reporting. Britain Elects has two of the ward results.

enltrPoplar (Nuneaton & Bedworth) result: Con: 52.0% (+23.0) Lab: 48.0% (-23.0) Con GAIN from Lab. [*#euref*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Britain Elects (@britainelects)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrSlough (Nuneaton & Bedworth) result: Con: 66.8% (+25.4) Lab: 33.2% (-25.4) Con GAIN from Lab.

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 12.02am BST

Conservatives in Welwyn Hatfield could lose overall control, party sources have told the Press Association.

block-time published-time 12.00am BST

These are from the BBC's Laura Kuenssberg.

enltrCouple of early tips - Tories sounding confident of holding Wandsworth, but might be disappointed in Basildon, Lab worried about losing control in Nuneaton, but optimistic about Plymouth

- Laura Kuenssberg (@bbclaurak) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrSenior tories expecting Labour to take Trafford - would be a big ***win*** for them, taking prosperous NW Tory area - currently only Tory council in NW

- Laura Kuenssberg (@bbclaurak) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 11.57pm BST

We've also got a byelection tonight in Northern Ireland. It was triggered by the decision of Sinn Fein's Barry McElduff to resign as West Tyrone MP in January, 10 days after he provoked outrage by posting a video of himself with a Kingsmill-branded loaf on his head on the anniversary of the notorious Kingsmill massacre. McElduff had a majority of more than 10,000 and his Sinn Fein successor Orfhlaith Begley is expected to ***win***.

block-time published-time 11.54pm BST

This is intriguing, from the BBC Essex reporter Charlotte Rose.

enltrMeanwhile in [*#Thurrock*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) UKIP MEP   [*@Tim\_Aker*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) says after tonight's results he may have to think about whether he remains part of UKIP group in Europe   [*#EssexElects*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Charlotte Rose (@CharlotteGRose)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

Ukip are expected to struggle enormously tonight. In 2014 their national share in the local elections was put at 17% on the PNS measure. (See [*11.46pm.)*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) Those elections coincided with the European elections, which Ukip won. But since the party achieved its key aim, and secured a leave vote in the EU referendum, it has been in turmoil. One indication of this is how few candidates it has put up. The figures are in this chart, from John Curtice's PSA briefing.

Number of candidates standing Photograph: PSA/Political Studies Association

block-time published-time 11.46pm BST

Benchmarks for success in the local elections

It is hard to measure success in local elections because the seats and the councils where elections take place are not the same every year and therefore - as John Curtice pointed out in the briefing cited earlier (see [*10.31pm)*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) - the raw results can be misleading.

But parties and their supporters will want to know who is doing well and who is doing badly. Here are three measures you can use, with the relevant benchmarks.

Vote share

After the local elections psephologists look at the vote share the parties achieve and use those figures to calculate what the vote share would have been if people had been voting in the same way across the whole of Britain. They do this by looking at the demographic make-up of the wards where people were voting and extrapolating a national figure, based on what is known about voting behaviour.

Just to make things complicated, there are two versions of this figure. Curtice and his team produce one called the projected national share (PNS) which the BBC uses. And two other psephologists, Colin Rallings and Michael Thrasher produce one they call the national equivalent vote (NEV), which gets used by Sky. They tend to show the same trend, but the actual figures are not always the same.

At some point on Friday we will get PNS and NEV figures for these elections. There are at least three figures you can compare them to.

Vote share at the 2017 general election (for GB)

Con: 43.4%

Lab: 41%

LD: 7.6%

Vote share at 2017 local elections

Con: 38% (PNS); 39% (NEV)

Lab: 27% (PNS); 28% (NEV)

LD: 18% (PNS); 18% (NEV)

Vote share at 2014 local elections (when these seats last fought)

Con: 29% (PNS); 30% (NEV)

Lab: 31% (PNS); 31% (NEV)

LD: 13% (PNS); 11% (NEV)

Seats gained

As Curtice explained (see [*10.31pm),*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) comparing seats gained and lost in one year with the seats gained and lost in another can be grossly misleading, because different numbers of council seats are up for election every year. The only comparison that is remotely half-fair is with what happened in 2014 - when most of these seats were last up for election - although even that is problematic, because the exact number of seats being contested is not the same.

Council seats won/lost in 2014

Con: -236

Lab: +324

LD: -310

Another factor, obviously, if that Labour gained a lot of seats in these councils four years ago, it becomes much harder to gain more.

Councils gained/lost

The same point applies to comparing the number of councils gained/lost with the figures for 2014. But, for what they are worth, here are the figures for that year.

Con: Net loss of 13 councils

Lab: Net gain of 4

LD: Net loss of 2

No overall control: Net increase of 11

block-time published-time 11.44pm BST

More from Swindon.

enltrBlow for Labour in Swindon. The Tories have hung on to Lydiard and Freshbrook - a key target ward for Labour.

- steven morris (@stevenmorris20) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 11.33pm BST

These are from my colleague Steven Morris in Swindon.

enltrSwindon count. Labour activists not sounding confident that they will take control of the council from the Tories.

- steven morris (@stevenmorris20)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrFirst Swindon result - Tory hold in the Chiseldon and Lawn ward. No surprise there. The tight ones are to come.

- steven morris (@stevenmorris20) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 11.32pm BST

The excellent Britain Elects Twitter feed is posting ward by ward results. The first ones are in from Sunderland.

enltrLabour HOLD Silksworth (Sunderland).

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

deltrSilksworth (Sunderland) result: Lab: 52.4% (-0.2) Con: 32.6% (+16.3) LDem: 7.5% (+7.5) Grn: 7.5% (+7.5) No UKIP (-31.1) as prev.

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrLabour HOLD Shiney Row (Sunderland).

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrShiney Row (Sunderland) result: Lab: 54.4% (+2.2) Con: 23.7% (+8.7) Ind: 13.2% (+13.2) Grn: 4.7% (+4.7) LDem: 4.1% (+0.8) No UKIP (-29.4) as prev.

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrLiberal Democrat GAIN Pallion (Sunderland) from Labour.

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrPallion (Sunderland) result: LDem: 60.1% (+57.0) Lab: 29.4% (-18.4) Con: 7.3% (-7.0) Grn: 3.1% (-1.7) LDem GAIN. No UKIP (-30.1) as prev.

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrLabour HOLD Bede (Nuneaton & Bedworth).

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

ltltrBede (Nuneaton & Bedworth) result: Lab: 46.1% (-10.6) Con: 44.2% (+25.2) UKIP: 9.7% (+9.7) No BNP (-12.5) as prev...

- Britain Elects (@britainelects) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 11.10pm BST

The Lib Dems have also been on the phone. Party sources say that in London they're "very confident" of taking Kingston-upon-Thames from the Tories, although the result won't be in until tomorrow at around 5pm. However, they're less confident about neighbouring Richmond, despite it being Sir Vince Cable's own back yard, claiming it remains "on a knife edge". They are fairly upbeat about their chances in St Albans and Eastleigh, but think it's unlikely that they've been successful in winning Hull back from Labour.

Sir Vince Cable at Twickenham polling station earlier today. Photograph: Matthew Chattle/REX/Shutterstock

block-time published-time 11.01pm BST

Labour sources say that they're "hopeful" of making progress in the number of seats they pick up across the country but that the result will be "fairly tight" in several key places. They point out that the collapse of Ukip since 2014 creates an element of uncertainty, although in the general election two thirds of the ex-Ukip vote went to the Tories, and just one third to Labour.

In London, they are keen to stress that the party was starting from a high watermark, having done so well four years ago, which would limit potential gains.

Labour thinks they've got a "fighting chance" in Barnet, North London, citing public disquiet about outsourcing (but no mention of antisemitism) but are claiming they haven't seen the swings they would need to take Tory "crown jewel" councils of Wandsworth or Westminster.

In Kensington & Chelsea, which always looked like a push (though nobody quite knows whether there will be a Grenfell effect) they suggested it was "out of reach".

But they're more optimistic about wiping out the last remaining speck of blue - Trafford - in a sea of red councils around Manchester. However, they predict the town hall would go to no overall control, rather than a Labour ***win***, but that would still be a "massive coup".

The final prediction from Labour sources for now: they're "hopeful" of winning Plymouth from the Tories.

Jeremy Corbyn after voting at a polling station in Pakeman Primary School in Holloway, north London. Photograph: Neil Hall/EPA

block-time published-time 10.53pm BST

According to Sky's Faisal Islam, Survation have a telephone exit poll from Croydon (a Labour-run council, although one the Tories won in 2010) showing a big Labour lead.

enltrCroydon telephone exit poll from Survation of people who have voted: labour 50% Conservatives 37% Libdens 4 Ukip 2 Green 4 in 2014 was 36 Labour, 33 Tory... [*pic.twitter.com/xLnARsjFMT*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Faisal Islam (@faisalislam)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 10.44pm BST

I'm at the count for the Trafford council elections at Lancashire County Cricket Club. The wealthiest of Greater Manchester's ten boroughs is a key target for Labour and Jeremy Corbyn chose the Stretford sports village leisure centre, just across the road, to launch his party's local election campaign in March.

The Tories took overall control of Trafford in 2004, eight years after Labour won the borough in 1996 - a year before Tony Blair's landslide election victory. If Labour manages to gain control tonight it will be seen as a promising sign for their electoral chances on a national level.

Only a third of the council's 63 seats are up for grabs and Labour would need to ***win*** six of the 13 non-Labour seats on offer, as well as retaining those it already has, to take the borough. The Conservatives currently hold Trafford by just two seats, so it would not be a surprise if the local authority slipped into no overall control.

Labour locally has become increasingly confident since the 2017 Greater Manchester mayoral election, when Andy Burnham won 16,000 more votes in the area than his Conservative opponent Sean Anstee, leader of Trafford council. Voters in Trafford also backed remain in the previous year's EU referendum, something the Labour MP for Stretford and Urmston, Kate Green, says comes up on the doorstep.

Labour's campaign has focused on the three key wards of Davyhulme West, Davyhulme East, and Flixton, which - if won - would strip the Tories of their overall control. The party also thinks it has a shot at wealthy Altrincham. Locally Labour has pledged to maintain low council tax rates (which are currently the lowest in Greater Manchester), build social housing, block development on green belt land and stop further council outsourcing.

enltrFirst lot of ballot boxes are in in Trafford. The Tories only need to lose two seats to lose overall control of the council. Labour last held Trafford in 2003. [*#LocalElections*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)   [*pic.twitter.com/ePgI9kNs2c*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

- Frances Perraudin (@fperraudin)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 10.41pm BST

Some assorted election chat.

From Sky's Faisal Islam

enltrSenior Tory in Wandsworth tells me it's looking "tough" after late surge in turnout late in day... and that some of the new GE voters from last year appear to have turned out again.... Though they would say that

- Faisal Islam (@faisalislam) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrSenior Labour source says turnout does seem to be up for them in key battleground London councils, but then also try to manage expectations

- Faisal Islam (@faisalislam) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

From the Sun's Tom Newton Dunn

enltrLocal elections latest, as polls close: senior Tory source tells me it's two v different elections, London and then England 1/3

- Tom Newton Dunn (@tnewtondunn) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrIn London; Labour swamping target areas with bodies. All about stemming losses for Tories, but now quite confident of keeping Hillingdon, plus probably Westminster & Wandsworth too 2/3

- Tom Newton Dunn (@tnewtondunn) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrOutside of capital, Tories think they can make gains - especially in Midland swing seats; eg Dudley, Walsall, Derby. Source: "It's all about who can turn out more of their own". But turnout seems low everywhere 3/3

- Tom Newton Dunn (@tnewtondunn) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrLocal elections latest: Labour source says they're hoping to make progress from 2014, "but we're realistic about our chances, with us being behind in some of the national polls" (it's all about expectation management at this stage of the night folks) 1/3

- Tom Newton Dunn (@tnewtondunn)

[*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrLondon latest: Labour hopeful they can still take Barnet. Less optimistic about overturning Wandsworth or Westminster now, and are already conceding Kensington & Chelsea is out of their reach 2/3

- Tom Newton Dunn (@tnewtondunn) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

enltrOutside London: Labour confident of taking Plymouth (Tories tell me they've lost there too), and hopeful of pushing Tory-held Trafford into NOC. The huge unknown is where the big UKIP vote in 2014 has gone today 3/3

- Tom Newton Dunn (@tnewtondunn) [*May 3, 2018*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

block-time published-time 10.34pm BST

Swindon is hugely significant to Labour. Jeremy Corbyn, Tom Watson, John McDonnell and Momentum activists have all visited the Wiltshire town during this campaign to lend a hand to grassroots members.

At general elections, Swindon is seen at a bellwether - whoever holds the two seats tends to ***win*** power. If Labour does well here tonight, it will also be seen as a sign that the party can make in-roads across the south of England.

Since Gordon Brown's defeat in 2010 both North Swindon and South Swindon have been held by the Tories. Its council has been run by the Tories since 2004. Labour had high hopes of wresting back control in 2014 but its campaign was not helped when Ed Miliband embarrassingly failed to recognise the name of the Labour group leader - Jim Grant.

Grant still heads the group. His party's Swindon manifesto was a solid, no-nonsense affair, promising more council houses, reopening children's Sure Start centres, boosting regeneration of the town centre, promoting the living wage, tackling zero hour contracts.

It also vowed to keep the Lydiard country park and house under council ownership and management. The park hit the headlines in the Swindon Advertiser this week when a cabinet member revealed that visitors who wanted to enjoy a cream tea at the cafe have to order it two days in advance.

Here's the maths for Swindon.

There are 57 councillors on Swindon borough council. Going into the count, 30 were Tory, 25 Labour and two Lib Dem.

Nineteen seats are up for grabs - 10 Tory, eight Labour, one Lib Dem. Labour had high hopes in five seats - four of them Tory and one Lib Dem - including Lydiard and Freshbrook, where park management and cream teas is an issue.

block-time published-time 10.31pm BST

On election night you need Sir John Curtice. The great psephologist will be on the BBC's election programme later but, in case you can't wait, here is some YouTube video of a briefing on the local elections organised by the Political Studies Association on Monday. It is "rather anoraky", as he says himself. (But we like that here.)

Political Studies Association local elections briefing, feature Prof John Curtice and others

The briefing was intended for journalists and Curtice said that he wanted to explain various aspects of the election in the hope of ensuring certain trends do not get misreported on Friday. There was a danger that headlines could be "seriously misleading", he explained.

Curtice said that it was important to remember that London was not representative of England or Britain as a whole.

Literally 42% of the all the seats that are up for grabs on Thursday are located in London. And one thing, therefore, you absolutely have to get into your head is that London does not constitute 42% of England. If, as I'm going to argue, the result in London might prove to be different from that in the rest of England, headline totals of seats won and lost may seriously misrepresent the actual position of the political parties...

There is every reason to anticipate... substantial divergence between remain and leave voting Britain, which therefore means that London is likely to move towards the Labour party but the rest of England could still swing towards the Conservatives. And therefore do not be surprised if, on Friday afternoon, you end up with the BBC coming up with a projected national share that actually has the Tories slightly ahead, even though they may have lost more seats and be losing ground in London. Crucial point, therefore; just remember, the tally of seat gains and losses is potentially seriously misleading because of the dominance of London.

But Curtice also said that, just because it would be hard for Labour to ***win*** councils in London, that would not necessarily mean it was not winning votes.

Equally, and conversely, the Labour party just picking up Barnet will not necessarily tell you the Labour party has not made progress in London. The Labour party's misfortune, in terms of council control, is that there isn't very much for the party to pick up.

block-time published-time 10.09pm BST

The polls have now closed and officials are just starting the process of collecting, verifying and counting the votes that will elect more than 4,000 councillors in 150 councils in England. Most of these seats were last up for election in 2014, when the poll coincided with the European elections, which saw Ukip ***win*** a nationwide election for the first time. In 2015 the local elections took place on the same day as the general election, and in 2017 they were staged in the middle of a general election campaign. And in 2016 the local elections overlapped with elections to the Scottish parliament, the Welsh assembly, the Northern Ireland assembly and for the mayor of London. But this year we've just got local elections basic. It will be the least consequential local elections day for at least five years.

And I'm afraid it is not as if these are make-or-break contests for any of the major political leaders. At Westminster expectations are relatively muted and tonight's results are not expected to lead to repercussions that could challenge the leadership of either Theresa May or Jeremy Corbyn. We may be wrong (we often are), but journalists are not expecting any of the main parties to suffer an all-round disaster.

But don't head for bed yet. This blog operates on the firm basis that there is no such thing as a dull election and tonight will be no exception. Politics matters. And this is the biggest test of political opinion in England since last year's general election. It is also worth remembering that more than 4,000 people will be elected to office. Local government is not a glamorous calling, but it is important and worthwhile and good luck to those who ***win***.

There will be a lot of focus on London tonight because all 32 boroughs in the capital are having "all-out" elections (which means all seats are up for election, not just one third of seats, as is the case with most of the other council elections today.) The 1,833 London seats that are up for grabs comprise 42% of all seats being contested this year. The others are in 34 metropolitan districts, 67 shire districts and 17 unitary councils. There is a guide here.

[*Local elections*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections) Local elections

In addition there are four London mayoral elections - in Hackney, Lewisham, Newham and Tower Hamlets - as well as mayoral elections in Watford and for the new Sheffield city region.

I'm Andrew Sparrow and I will covering the results as they come in through the night, as well as bringing you reaction and analysis. My colleague Jamie Grierson will be taking over after dawn, and then we will be carrying on until all the results are in on Friday evening.

Here is the blog we were running earlier covering events on polling day.

Related: [*Local elections 2018: voters being turned away in ID trial areas - live*](https://www.theguardian.com/commentisfree/2018/may/04/brexit-britain-political-pendulum-local-elections)

19459 2018-05-04T17:45:00Z true 2018-05-03T21:09:59Z false false 2018-05-04T22:22:14Z false UK theguardian.com [*https://gu.com/p/8hlgb*](https://gu.com/p/8hlgb) false true   [*https://media.guim.co.uk/59eaee1a6eef9a5af752dc07cd95f78aab40fbb0/261\_174\_3135\_1881/500.jpg*](https://media.guim.co.uk/59eaee1a6eef9a5af752dc07cd95f78aab40fbb0/261_174_3135_1881/500.jpg) false en Labour has gained control of Tower Hamlets council, over which no party previously had overall control, the Press Association reports. The party has won 23 of the 45 available seats, though some wards are still to declare. With that, we're going to close this live blog. Thanks for reading. According to the Press Association, 149 of the 150 councils have now declared, with only Tower Hamlets' results to come. Here's how the main parties stand: Labour Councils: 73 (-1) Seats: 2,308 (+77) Conservatives Councils: 46 (-2) Seats: 1,230 (-93) Lib Dems Councils: 9 (+4) Seats: 536 (+77) Greens Seats: 39 (+8) Ukip Seats: 3 (-57) The former cabinet minister, Justine Greening, has hit out at her party colleagues in the Eurosceptic European Research Group (ERG), accusing them of behaving a "little bit like Russia... vetoing things that they don't like" during the Brexit deliberations. The rightwing group, led by the Tory MP Jacob Rees-Mogg, must understand that "no one is going to quite get their perfect outcome", the former education secretary told Sky News. The sooner they all realise that and then work through the give and take and find a sustainable long-term solution on Brexit, the sooner we'll be able to get on with the implementation planning around that which is urgent, and the sooner we'll be able to get on with running the country and get on with the domestic agenda - for me the equality of opportunity - and the issues that are really at the heart of what I think people want tackled. Asked if the ERG was being given too much attention, Greening said: Well look, I think what we can't have is a group of MPs who behave a little bit like Russia does on the Security Council - vetoing things that they don't like. We have got to go forward on Brexit as a country together. That will mean give and take and people need to understand that, whatever wing of my party they are on, and whatever elements of the Leave/Remain debate they are on. I'm afraid no one is going to quite get their perfect outcome. She also told the broadcaster she was concerned the Brexit war cabinet would find itself out of step with the Tory party when it discusses what sort of customs arrangement it wants with the European Union post-Brexit. I think it's time for the moderates in the party like myself to work with the prime minister on a sensible approach to the customs policy and a broader package and then make sure this is something we can get through Parliament. Here's an update on the 146 councils out of 150 that have declared so far: Labour Councils: 70 (-1) Seats: 2,133 (+72) Conservatives Councils: 46 (-2) Seats: 1,295 (-85) Lib Dems Councils: 9 (+4) Seats: 528 (+79) Greens Seats: 33 (+3) Ukip Seats: 3 (-57) There is no overall control in 21 councils (-1) Labour retains Hounslow, winning 33 of the available 60 seats. The Conservatives have won six seats so far, with 21 still to declare. Here are some analysis articles about the local elections that are worth reading. Rafael Behr at the Guardian says the political pendulum is stuck. The pendulum is stuck. The traditional laws of political gravity predict a swing away from the party of national government in local elections, but it has been a while since British politics followed the obvious arc of precedent. If last night's council election results conform to any pattern, it is the laudable habit that voters have acquired of giving party leaders cause to scratch their heads and wonder what the hell is going on. There is no big national winner. Since the Tories were braced for a mauling and escaped without one, Theresa May will be feeling relatively relaxed today. Labour needed to demonstrate that last year's general election gains were a staging post on the road to national power; that destiny was calling Jeremy Corbyn. Destiny didn't hang up the phone, but it has put the ***opposition*** on hold. Labour had ambitious targets - Tory bastions in London such as Westminster and Wandsworth - that did not fall. Gary Gibbon at Channel 4 News says the election results will encourage Tory Brexiters. One pro-remain Conservative told me last night's results were "a bit of a disaster for our side." He said they would encourage Tories to see Brexit supporters as their core demographic and prioritise pleasing them. At the same time, he worried, Labour would now feel it has to go hunting lost Brexit support to make up vital electoral ground outside London. The more hardline amongst the Brexit-supporting Tory MPs might be emboldened by the overnight results in some pro-leave areas of England. Those who have been waving around letters to Graham Brady, the chairman of the 1922 committee, calling for a vote of no confidence in Theresa May, could in the tense weeks and months ahead feel that throwing the pieces in the air and seeing where they land, even if it heightens the risk of a general election, is not such a risk as some have suggested and preferable to what they see as a heavily diluted Brexit. Owen Jones at the Guardian says Labour had its best result in London since 1971. When is a victory a defeat? Labour won its best local election results in London - and the Tories their worst results - since 1971. Although the Tories largely benefited nationally from the implosion of Ukip, as things stand, Labour have dozens of net gains. That doesn't mean Labour doesn't need to learn lessons and act on them (it does) or that these results are good enough (they're not). But the surreal triumphalism of Tories and pundits - who are desperate to return to a world before Jeremy Corbyn's Labour won 40% of the vote and ended a generation-old political consensus - is almost pitiful. Faisal Islam at Sky News suggests the results show that both Theresa May and Jeremy Corbyn have passed their moment of peak appeal. Katy Balls at the Guardian says "Corbyn's messiah status has taken a knock". Stephen Fisher, an academic who works with Prof John Curtice on BBC election analysis, says in a Prospect article that Brexit helped to explain voting patterns in the elections - except in areas with Jewish populations. The Conservatives have so far made 163 seat gains and suffered 165 losses. As a result they will likely end the day with a similar overall tally as the one they started with. Most, 89, of the Conservative losses were in London, and most, 132, of their gains were outside London. This differential in the Tory performance is part of a broader pattern whereby the Conservatives won more votes and seats in places which were more supportive of Brexit. As a result, the councils the party has won (Basildon, Peterborough, Redditch) are all places that voted to leave the EU at a rate of 61 per cent or more in 2016. The exception to this rule tells an important story linked to the row over anti-Semitism in the Labour Party. Of the wards across the country where the BBC collected the votes, Labour is up by just 3 points where more than 4 per cent of the population is Jewish, but the party is up by 7 points on average elsewhere. This correlation had a particular impact in both Barnet and Bury where the Jewish population is relatively large. That Labour not only failed to take its (notionally) easiest target in London, but the Conservatives actually managed to gain six seats and take control of Barnet (where 38 per cent voted Remain) is quite remarkable. Stephen Bush at the New Statesman floats the idea that local elections are becoming less useful as a means of predicting general election results because Labour may be increasingly reliant on voters who are inclined not to vote in the locals. I first advanced the theory that Labour's electoral coalition might simply be becoming less likely to turn up in off-years under Ed Miliband as a possible explanation for why Labour were underperforming relative to the opinion polls. Of course, that wasn't true in 2015, but it doesn't mean it won't turn out to be true in the future. Labour's coalition has been getting younger, more likely to live in a city and more diverse pretty steadily since 2001 and it took a big leap forward in that direction in 2017. My feeling is that at some point that is going to mean that the predictive value of local election performances at general elections is going to change and change big. We may have reached that point already, but then again it may not. Bagehot at the Economist says the results show Corbynmania is dead. Mr Corbyn has a proud history of leaving commentators with egg all over their faces. He can summon up charisma when he needs it and has an extraordinary ability to keep battling on regardless of circumstances. He also has some huge advantages on his side. A Tory party that is deeply divided over the most important issue facing the country; an establishment that thinks that Brexit is a Tory-made disaster; a generational divide that has left people under 40 struggling to get their feet on the property ladder; and a widespread sense that the country's infrastructure, from the NHS to the transport system, is on the verge of collapse. Even so, Corbynmania is now officially dead. That's all from me for today. My colleague Kevin Rawlinson is now taking over. The Electoral Reform Society has warned of what it calls a "dark day for politics" after saying that almost 4,000 would-be voters were turned away from polling stations for not having the necessary ID in the five boroughs which tested out voter ID schemes on Thursday. The tally - carried out by the Democracy Volunteers group - estimated that 3,981 people were denied a ballot paper in all, 1.67% of the total number of votes cast. The scheme, which could be extended nationwide in future elections, saw varying ID requirements in Bromley, Woking, Gosport, Watford and Swindon. Critics had warned the trail was targeting a tiny problem of voter impersonation at polling booths, and risked putting off more vulnerable voters who might not hold the necessary documents, for example older people and the homeless. The total was reached by extrapolation of observations in the five areas, which saw 1.67% of voters turned away, and does not take into account those who might have come back later with the correct ID. Darren Hughes, chief executive of the Electoral Reform Society, said: Britain prides itself on being a leading democracy - but it is a dark day for politics when thousands of blameless people turn out to vote only to be refused. Our estimates, based on evidence gathered by electoral observers, reveal the shocking scale of the problem. These trials have been shown up to be the chaotic, undemocratic mess many predicted. Update: To clarify, while Democracy Volunteers provided the 1.67% figure, the extrapolation was done by the Electoral Reform Society; of it is independent. According to the BBC, the Conservative party has reinstated a candidate who won a seat in Sunderland who had been suspended over offensive social media posts, including one about Diane Abbott from several years ago. Abbott has posted a message on Twitter suggesting this shows the Tories are not taking the problem seriously. Here are some results that have come in in the last hour or so. Hackney Lab No change Lab gain 2, C gain 1, LD lose 3 New council: Lab 52, C 5 Lewisham Lab No change Lab gain 1, Green lose 1 New council: Lab 54 Haringey Lab No change LD gain 7, Lab lose 7 New council: Lab 42, LD 15 Newcastle-under-Lyme NOC No change Boundary change Ind down 6, C down 5, Lab down 5 New council: Lab 20, C 18, Ind 3, LD 3 Cherwell C No change C 12, Lab 3, LD 1, Vacant 1 Boundary change Lab up 1, LD up 1, C down 1, Ind down 1 New council: C 36, Lab 9, Ind 1, LD 1, Vacant 1 Manchester Lab No change Boundary change LD up 1, Lab down 1 New council: Lab 94, LD 2 A former mayor whose reinstatement gave the Conservatives control of a council by one seat has "sincerely apologised" over a racial Facebook joke which saw her suspended from the party, the Press Association reports. Rosemary Carroll, who made a post comparing an Asian with a dog last June, rejoined "as the votes were being counted" on Friday, giving the Tories narrow control of Pendle council in Lancashire. Conservative group leader Paul White said: The post was shared in error but Rosemary fully accepted the potential upset caused and sincerely apologised. Having served her suspension period she rejoined the party and completed additional diversity training. Carroll, a former mayor of Pendle who represents the Earby ward, previously said she meant to ***delete*** the post but accidentally published it in error. Leader of the Labour group, Mohammed Iqbal, said the situation was an "appalling state of affairs". He said: Here's a councillor who brought shame on the borough on an international level and was welcomed back into the fold with open arms simply to grab control to the council. She turned up with a Conservative rosette literally as the votes were being counted. Dan Jarvis used his victory after being elected as Sheffield city region's mayor to call for a wider devolution deal for Yorkshire. The post has only just been established, and the job does not yet come with agreed powers, an agreed budget, or even an agreed salary. He said: I understood that the exceptional nature of my candidacy [ie, remaining an MP] would raise some eyebrows and it has. But I believed then, as I know now, that the exceptional circumstances of this mayoralty and the importance of devolution for the future of the UK meant that I couldn't stand on the sidelines and that I had to step forward. I say this because I believe that the issue of devolution goes to the heart of two of the most important ***strategic*** issues that our country faces - how we respond to the causes of Brexit and how we prepare for a post-Brexit Britain. If we are to find the right answer to these questions we must be prepared to reform every aspect of our political system. Labour has retained control of Birmingham council, the Press Association reports. It has got 51 of the 101 seats, with 14 two-councillor wards yet to declare. Birmingham, which is the largest council in Britain, is one of the areas that has had all-out council elections (with all seats being up for grabs, not just the usual one third) following boundary changes. These are from the BBC's Kathryn Stanczyszyn. Lord Heseltine, the Conservative former deputy prime minister, has told Sky News that he thinks the election results amount to a "stalemate". He says he thinks Labour under Jeremy Corbyn has hit a "glass ceiling". The Lib Dems have gained South Cambridgeshire from the Conservatives. Here are the figures. South Cambridgeshire LD gain from C Boundary change LD up 16, Lab up 1, C down 25, Ind down 4 New council: LD 30, C 11, Lab 2, Ind 2 Labour's two most senior mayors have both within the last few minutes said that party must do more to address its antisemitism problem. Andy Burnham, the mayor of Greater Manchester, told Sky News that Labour had to take a "much firmer grip" on the issue because the anger against the party was "painfully real". He said: It is clear that antisemitism was a very real issue in this campaign, not everywhere, but in areas where particularly there is a large Jewish community. That is true here in Greater Manchester. If you look at the Kersal ward in Salford, I was out there myself and it was a pretty sobering experience, to be honest, because the hurt and the anger is painfully real in those places. So what I would say back to Ken Livingstone and others how have made this argument that it's all a smear designed to just undermine Jeremy Corbyn, let's hope that these elections draw a very firm line under these arguments and basically knock it out, because the truth of the matter is there is a very real sense of rawness in the Jewish community. And the Labour party needs now to reach out in a much more convincing way to those communities and take a much firmer grip on this issue of antisemitism, and come to a resolution on some of the outstanding issues on it. And Sadiq Khan, the mayor of London, said Jewish people in the capital did not fee comfortable voting for Labour. He told the BBC. I think there are lots of voters, Jewish people in London, who don't feel comfortable voting Labour. That can't be right. It can't be right that anybody feels that the Labour party is a safe place for anyone who is an antisemitic person. Antisemitism is racism. We should have no truck with that. We need to make sure that we investigate any allegations made against anybody. I'm really please Jeremy Corbyn has now tasked the new general secretary, Jennie Formby, to investigate speedily those members of our party against whom allegations have been made. They should be kicked out if those allegations are upheld. The Labour MP Dan Jarvis has been elected mayor of Sheffield city region on the second count. Here are the second round voting figures. Dan Jarvis (Lab) 144,154 Ian Walker (C) 50,619 Boris Johnson, the foreign secretary, is arguing that the local election results show why the government should remain committed to taking the UK out of the customs union. Jacob Rees-Mogg, the Conservative MP and chair of the European Research Group, which is pushing for a harder Brexit, is saying the same thing. Commenting on this Tweet... Rees-Mogg responded with this: Here are some more results that have come in over the last hour or so. Islington Lab No change New council: Lab 47, Green 1 Woking C No change C 5, LD 3, Lab 1, Ind 1 LD gain 1, C lose 1 New council: C 16, LD 8, Lab 3, Ind 3 Blackburn with Darwen Lab No change Boundary change Lab down 7, C down 4, LD down 2 New council: Lab 37, C 13, LD 1 Camden Lab No change Lab gain 4, LD gain 1, C lose 4, Ind lose 1 New council: Lab 43, C 7, LD 3, Green 1 Elmbridge NOC No change C 10, LD 3, R 3 C gain 3, LD gain 1, R lose 4 New council: C 24, R 15, LD 9 Watford LD No change LD 9, Lab 3 LD gain 1, Lab lose 1 New council: LD 26, Lab 10 Crawley Lab No change Lab 8, C 4 New council: Lab 20, C 17 According to the Press Association, 133 out of 150 councils have now declared. Here are the latest figures. Conservatives Councils: 44 (no change) Seats: 1,142 (-44) Labour Councils: 63 (-1) Seats: 1,741 (+75) Lib Dems Councils: 6 (+2) Seats: 408 (+39) Greens Seats: 33 (+4) Ukip Seats: 3 (-55) And here is the BBC's estimate of what the House of Commons would look like if there were to be a general election with people voting in the same way as they did at the local elections. The BBC projection, like the Sky projection (see 2.18pm), anticipates a hung parliament. But the BBC has Labour on course to gain 21 seats, and the Tories on course to lose 38 seats, while Sky just anticipates more modest Tory losses. There's a different between the two projections because the BBC and Sky use different methods to calculate how the local election results can be converted into a national share. The Liberal Democrats have gained Three Rivers, south-west Hertfordshire, from no overall control, the Press Association reports. They had eight councillors elected last night compared to four for the Conservatives and one for Labour. Here are the figures. Three Rivers LD gain from NOC LD 8, C 4, Lab 1 LD gain 1, Ind lose 1 New council: LD 20, C 16, Lab 3 The Labour MP Chuka Ummuna told the World at One that he wanted the party's national executive committee to conduct a proper inquiry into why it did not do better at the elections. He said: From a Labour point of view there needs to be a proper post-mortem - I think the national executive committee should appoint somebody to do that - on this result. We haven't gone forwards and if we are looking to form an election-winning majority, we cannot be confident of that happening based on the results yesterday. The sole Green councillor in Islington, Caroline Russell, has held her seat in Highbury East. This is from Caroline Lucas, the Green party co-leader. What do these projected national share (PNS) figures (see 2.31pm) actually mean? As usual, it depends. How it's good for Labour Labour is getting the same of the vote as the Conservative party. They did not at the 2017 general election, and so in that respect they are moving forwards. Labour is also doing much better relative to the Tories than it was in the 2017 local elections (which were held a few weeks before the general election). In that contest the Tories had an 11-point lead on PNS. At 35%, Labour's local election share of the PNS is the highest it has been since 2012 (when it was 38%). That was a year when the Lib Dem vote had collapsed, because of Nick Clegg going into the coalition, but the big Ukip rise had not fully materialised. How it's bad for Labour ***Opposition*** parties almost always have to be ahead in mid-term local elections if they are going to go on and ***win*** the subsequent general election. Labour is not ahead. Labour is doing worse relative to the Tories on this measure than it was in 2014, when most of these seats were last fought. Four years ago Labour came out two points ahead on PNS. (The figures are here.) It is also doing worse than it did relative to the Tories in 2016, when on a relatively disappointing local elections night Jeremy Corbyn's Labour was still one point ahead of the Tories on PNS. Excluding general election years, this is the first year since 1988 when Labour has been in ***opposition*** and it has not been ahead of the Conservatives on PNS at the local elections. There is a table with all the PNS figures going back to 1982 here. The BBC has now produced its projected national share figure. This is not the share of the vote figure in the actual elections (a fairly meaningless figure, because the councils where elections took place were not representative of Britain as a whole.) It is a calculation as to what the vote share would have been if all wards in Britain had voted in the same way as people voted yesterday. (More on how this works here.) These are the figures: Conservatives: 35% Labour: 35% Lib Dems: 16% Others: 14% Labour has retained Crawley after winning seven of the 12 seats being contested, the Press Association reports. The Conservatives won four, with one result to come. And the Tories are on course to retain control of Woking council in Surrey. According to Sky News, if there were a general election and people voted as they did in the local elections yesterday, there would be a hung parliament. Here are their figures. The only party that would celebrate a result like this would be the Lib Dems. They won 12 seats at the 2017 election, and so on the basis of this notional result, they would be up 14. Theresa May won 317 seats last year. On the basis of this result, she would be down 12. And Jeremy Corbyn, who won 262 seats at the general election, would be down one seat too. The Labour MP Dan Jarvis is on course to be elected mayor of the new Sheffield city region, but he did not ***win*** on the first round (ie, he did not get more than 50% of first preference votes.) Here are the first round results. Dan Jarvis (Lab) 122,635 (47.99%) Ian Walker (C) 37,738 (14.77%) Hannah Kitching (LD) 27,146 (10.62%) Mick Bower (Yorkshire) 22,318 (8.73%) Rob Murphy (Green) 20,339 (7.96%) David Allen (Eng Dem) 14,547 (5.69%) Naveen Judah (Save NHS) 10,837 (4.24%) The last four candidates have been eliminated, and their second-preference votes are being counted. Turnout was just 25.36%. Turning away from the local elections for a moment, my colleague Rajeev Syal has some good news for the Unite general secretary Len McCluskey. From my colleague Heather Stewart Here's a BBC video clip with Prof John Curtice explaining what he thinks the election results means. His main takeaway is that, apart from the collapse of the Ukip vote, not a huge amount changed since 2014. Conservatives have lost Mole Valley, Surrey, to no overall control after losing one seat to the Liberal Democrats, the Press Association reports. The first results of the day are in from Manchester, with Labour holding on to all three seats in the Woodhouse Park ward, on a turnout of 18.04%, the Press Association reports. Manchester is holding "whole council" elections rather than the usual thirds, due to boundary changes; 32 wards will elect 96 councillors. Turnout ranges from 17% in Fallowfield to 46% in Chorlton. Good afternoon. I'm Andrew Sparrow, taking over from Jamie Grierson. Last week my colleagues Jessica Elgot and Heather Stewart reported that the Labour MP Heidi Alexander - a centrist, in Labour terminology, not a Corbynite - was thinking of standing down as an MP to take up a post working for Sadiq Khan at City Hall. According to Channel 4 News' Michael Crick, we may get the announcement this afternoon. Rokhsana Fiaz was comfortably elected as mayor of Newham, east London with the Labour candidate achieving 73% share of the vote, Dan Sabbagh writes. She said she would use her mayoralty to "put people at the heart of what we do" and suggested that a Labour party rocked by the antisemitism crisis needed to do the same. "In this borough I will make sure we work closely with Muslim, Jewish and other communities to build bridges. I'm desperately sorry Labour lost in Barnet and I'm sure the party will reflect closely on what has happened in Barnet and elsewhere," she said, speaking to the Guardian a few minutes after she was elected. Fiaz takes over the former Olympic borough after 23 years of rule by Sir Robin Wales, who she defeated in a primary contest earlier this year. The new mayor's share of the vote was 12 percentage points higher than Wales achieved in 2014. One of her first steps will be to introduce a consultative youth citizen assembly in the borough; she also plans to review the finances in a borough that had to write off £52m in loans for the repurposing of the Olympic stadium for football in December. Liberal Democrat former cabinet minister, Ed Davey, said it had been a "brilliant night" for his party. Speaking at the Kingston-upon-Thames count, Davey said: "We've won councils like Richmond, we might well ***win*** here in Kingston, and there are one or two other counts coming later elsewhere in the country where we might well ***win*** control of the council. "So we might end up winning more councils net from the previous position than any other party." Davey, who said the party had focused on local issues rather than simply Brexit in its campaigning, added: "Across the country this looks like a real fightback for the Liberal Democrats." Labour sources at the count in Birmingham say it doesn't look like a good performance for them, reports political editor Heather Stewart. All of the seats are up for grabs, and they're being fought on new boundaries - but reports suggest Labour is struggling in white, working-class wards; while advancing in the inner city. Birmingham is hosting the Conservative party conference this year, as the party celebrates the success of Andy Street in winning the metropolitan mayorality. With the balance of power on the city council before yesterday's poll 79 Labour seats to 29 Tories, there is no danger of Labour losing control, say those on the ground - but the party's majority could be significantly reduced. The count is ongoing. In the West Midlands, Conservatives gained control of Redditch, taking two seats from Labour and one from Ukip. They have 16 seats out of 29, with two results to go. Latest tally from the Press Association: State of parties after 101 of 150 councils Conservatives: 31 councils; 892 seats (-26) Labour: 52 councils (-1); 1,444 seats (+59) LibDems: 4 councils (+1); 327 seats (+40) Green: 22 seats (+7) UKIP: 3 seats (-47) Independent: 58 seats (-57) Liberal: 1 seat (-1) Ratepayers and Residents: 41 seats No overall control: 14 councils There is mounting interest in the result in Birmingham, where there are suggestions Labour could lose, in what would be significant blow to the party. The Conservatives have already made gains in West Midlands, in Dudley and Walsall. Labour's failure to take Barnet council from the Conservatives is directly related to the antisemitism scandal that has plagued the national party, say local activists and councillors. The north-west London council was Labour's prime target in the capital. The party hoped to seize control from the Conservative-led administration whose focus on outsourcing earned them the nickname "Easycouncil". Sadiq Khan, the mayor of London, said Barnet was a Conservative "crown jewel" Labour could ***win***, but overnight the Tories took back the council from no overall control. Barry Rawlings, Barnet's Labour leader, laid the blame directly on the party's antisemitism crisis, which has led to Jewish leaders and members of the community protesting against Jeremy Corbyn in Westminster: I want to speak directly to our Jewish brothers and sisters. I am extremely grateful to members of the Jewish community who cast votes for Labour. But too many didn't. It wasn't because they disagreed with our manifesto, but because they felt the Labour party has failed to deal with antisemitism on a national level. They are right. The prime minister has visited Wandsworth in south London to congratulate Conservatives on seeing off a challenge from Labour to hold on to control despite losing six seats. Theresa May said: "Labour thought they could take control, this was one of their top targets and they threw everything at it, but they failed. "The people of Wandsworth re-elected a Conservative council, and that's for a simple reason. You charge the second lowest council tax in the country, you provide excellent local services like the weekly bin collection. "That's the message of these elections across the country - that Conservative councils deliver great local services at lower taxes." To cheers from activists waving Conservative banners, May added: "We've seen other success in London. We've held Hillingdon, Barnet, Westminster. "And outside of London, we've made progress in places like Dudley and Walsall. We've taken control in Basildon and Peterborough. And that's all the result of the really hard work of our councillors, our activists, our supporters and our revitalised campaign machine. "But we won't take anything for granted. We will continue to work hard for local people and we will build on this success for the future." Labour's deputy leader Tom Watson told the BBC: "We have consolidated the base we made after the General Election. If you looked at the national polls, it showed the parties were neck-and-neck and we have done rather better than that in some areas." Mr Watson said Labour now has more councillors in London than at any time since the 1970s. "You can always do better, but we think we have consolidated our base and we are quietly satisfied with the result," he said. The Conservatives became the biggest political party in the Black Country town of Walsall today, and are expected to form a minority administration. The Tories ended up with 30 seats, while Labour lost two to be left with 26, with the remaining four seats split between the Liberal Democrats and independents. They also made gains from UKIP, who lost all three of their councillors in Walsall. Previously Labour was in control with 28 seats to the Tories' 24. Walsall Conservative leader Mike Bird is confident of getting the support he requires to run a minority administration. Labour was expected to hang on to power, with some activists claiming they would take an overall majority. It follows the Conservatives' Eddie Hughes unexpected victory in the general election last year in Walsall North. Labour has called on the Government to scrap voter ID as a matter of urgency after a trial saw people in England turned away from polling booths for not carrying the necessary documents. Cat Smith MP, shadow minister for voter engagement and youth, said: There was absolutely no case for introducing voter ID in the first place but after yesterday's fiasco, it is impossible for the Government to justify rolling it out. After completely ignoring a number of serious warning signs, the Government decided to pilot discriminatory measures which denied people their right to vote. We cannot allow the Conservative Party to undermine our democracy, which is why Labour is calling on the Government to scrap their voter ID plans as a matter of urgency. Ken Livingstone has been on Sky News talking about the local election results and the impact of allegations of antisemitism on the Labour party, from which he is currently suspended. Livingstone, who has been accused of antisemitism himself, denied previously labelling Adolf Hitler as a Zionist. He said: If you go on Jerusalem's Holocaust memorial website, one of the documents you can download is about the deal that the Zionists did with Hitler did with the Zionists in the thirties. Hitler wanted to get all the Jews out of journey, and the Zionists wanted to move them all and create a Jewish state in Palestine. They collaborated, they didn't like each other but they collaborated together to do that." The former Labour MP and London mayor accepted that claims that he was antisemitic had hit the result in Barnet, where the Tories gained control: If anybody believes I said Hitler was a Zionist then yes, that is damaging. What's been so bad is that two years on this smear about me is still there unchallenged." Sky News presenter Adam Boulton suggested that "the best advice might be not to bring Hitler into contemporary politics". "I only do it when I ask a question like you've just done," Livingstone said. "I've never written a speech or article about Hitler. "It always gets you into trouble if you tell the truth," he added. Asked if he should just retire, Livingstone said: "I'm not going to my grave without this issue being resolved." Livingstone said the antisemitism row was a "distraction" from discussing Labour policies and also blamed moderate Labour MPs for attacking the party leader, Jeremy Corbyn. He said: "If we hadn't had two years of Labour MPs undermining Jeremy, if they'd been out there campaigning, we only needed to take another seven seats and Jeremy would be leading a minority government ... his policies connects with people." He added: "Part of the problem is for the last month everything in the media about the Labour party has been about antisemitism. Any serious debate about our policies just hasn't happened." Livingstone said he was optimistic that he will not be expelled from the party. The leader of the Barnet Labour Group, Barry Rawlings, has issued a statement, in which he addresses the group's "Jewish brothers and sisters". He said Labour has failed to deal with "anti-semitism". He said: I want to thank all Labour members in Barnet for their support and hard work, not just over the past few weeks, but over the past four years, and our wonderful candidates who could not have done anything more. We campaigned hard, we gave the Conservatives a tough time over their failure to run a fair, effective Council for the people of Barnet, and we have built, and will continue to build, good relationships with all of Barnet's communities. That wasn't enough this time. I am confident we can bounce back from this but to do so we will need to work harder still. I want to speak directly to our Jewish brothers and sisters. I am extremely grateful to all members of the Jewish community who cast votes for Labour yesterday. But too many didn't. It wasn't because they disagreed with our manifesto, but because they felt the Labour Party has failed to deal with anti-Semitism at a national level. They are right. I pledge that Barnet Labour will be a beacon to the rest of the Labour Party in tackling and defeating this anti-Semitism virus that has infected our party. For me dealing with anti-Semitism, Islamophobia, and all forms of hate is not an electoral issue, ***win*** or lose, it's a moral responsibility that defines who we are as a Party. I am so proud of the work we have done both within and across communities, faiths, backgrounds. We either fix this or our values of equality, social justice and human rights die. I pledge that Barnet Labour will be at the forefront of this collective effort by the Party we all love and wish to see succeed. Jeremy Corbyn, leader of the Labour Party, has issued a statement on the local election results. Labour achieved a solid set of results in the local elections. We have consolidated and built on the advances we made at last year's General Election, when we won the largest increase in Labour's share of the vote since 1945. In these elections we have won seats across England in places we have never held before. We won Plymouth from the Tories, who lost control of Trafford, their flagship northern council. And Labour has won even more council seats than at our high watermark of 2014. Last year Labour showed the difference we can make in a full national campaign. This year our members and supporters campaigned in impressive numbers. And their energy, talent and enthusiasm will continue to take Labour's message of real change to communities across the whole country. In a sign of how worried they are about Labour's advance, the Tories talked up our chances to unrealistic levels, especially in London. The results show they're right to be worried - we came within a whisker of winning Wandsworth for the first time in over 40 years. The Labour Party is now well placed to fight and ***win*** the next General Election - and form a government that will work for the many, not the few. Labour MP Lisa Nandy says last night's performance for Labour, losing ground in Wigan, Bolton and Dudley, underlines the fact that Labour's message is failing to appeal to voters in Britain's towns. While Labour comfortably held her own local council of Wigan last night, the Conservatives got more votes there than at any time since 1979. "For a lot of people who choose to forgo the fast pace and diversity and access to culture of cities, the reason they do that is because they value the sense of community you feel very strongly in places like mine," she says. She says politicians, including Labour, have failed to address the decline in local jobs and opportunities that has eroded this sense of community. "Towns like mine have really found themselves at the sharp end over the last 30 years. Demographic changes mean we have an ageing population - young people who used to go away to study and come back, have found there's nothing to come back to. Wages are low, which accounts for the decline of high streets and pubs." "People have looked to politics for some time to solve this and seen us obsessed with a city-centric model which is reliant on the benefits trickling down." She warns: "Unless Labour gets to grips with that, the next election is far from secure, with Labour piling up the votes in cities, and the Tories having a near-monopoly on the countryside". "It's about jobs, jobs, jobs jobs," she says. "Politicians need to catch up. Whoever gets this towns argument will ***win*** the next general election and the one after that." Theresa May has tweeted congratulations to a couple of councils, which saw holds and gains for her Conservative party in the local elections. State of parties after 98 of 150 councils: Conservatives: 30 councils; 878 seats (-31) Labour: 50 councils (-1); 1,424 seats (+57) LibDems: 4 councils (+1); 324 seats (+41) Green: 21 seats (+6) UKIP: 2 seats (-44) Independent: 61 seats (-49) Liberal: 1 seat (-1) Ratepayers and Residents: 37 seats (-4) No overall control: 14 councils Ukip general secretary Paul Oakley has insisted it was not "all over" for the party and has defended his party by comparing it favourably to the Black Death. He said the plague had caused a lot of disruption in the Middle Ages before going "dormant". "It's not all over at all," Oakley told BBC Radio 4's Today programme. "Think of the Black Death in the Middle Ages. It comes along and it causes disruption and then it goes dormant, and that's exactly what we are going to do. Our time isn't finished because Brexit is being betrayed." Challenged over whether he wanted to compare his party to a plague that killed millions of people, Oakley said: "Absolutely. What's wrong with that?" He pointed to positive outcomes from the Black Death: "It also led to economic growth and the Renaissance. It got rid of the whole issue of servitude, basically, and allowed people to go into the towns and escape their landlords and create their own businesses." Anti-racism group, Hope Not Hate, has hailed the demise of "far right and radical right" political parties in the local elections. Hope Not Hate said it had been a "disastrous" night for Ukip, which it accused of plying anti-Muslim rhetoric under its leader Gerard Batten. Far-right parties - such as the British National Party and Anne Marie Waters' For Britain Movement - also failed across the board, the group said. Nick Lowles, chief executive of HOPE not hate, said: "We should take a moment to enjoy the decline of extremist parties. It's down to the hard work of thousands of anti-racist campaigners up and down the country, as well as incompetence and defections on the part of Ukip and the far right." The Guardian's associate editor, Dan Sabbagh, has written an analysis of the local election results. Labour made limited progress, but failed to produce the kind of surge that would allow the party to claim it is a government-in-waiting, he writes, while Theresa May can be modestly relieved, although the results do not necessarily point to her party winning an overall Westminster majority either. Read the full piece here: More from Jeremy Corbyn on the local election results. Asked whether the night's results showed that Labour had passed the point of "peak Corbyn", Corbyn said: "No, no, there is much more to come and it's going to get even better." The Labour leader told Sky News: "We were defending seats that were last won in 2014, which was a particularly good year for Labour in local government. "Obviously, I am disappointed at any places where we lost a bit of ground, but if you look at the overall picture, Labour gained a lot of seats across the whole country, we gained a lot of votes in places we never had those votes before." He added: "We are ready for a general election whenever it comes. A year ago, a general election was surprisingly called and we had the biggest swing to Labour for decades. "We are absolutely ready for it. We have got members, we have got organisation, we have got enthusiasm." The Jewish Labour Movement, the affiliated society for Jewish Labour supporters, say they will be holding an urgent meeting with Labour's new general secretary Jennie Formby to discuss the impact anti-semitism had on the party's local election results. JLM's spokesman Ivor Caplin said: "For the second time within a year, England has seen the electoral impact of the Labour Party's problem with antisemitism. "For the Party of anti-racism to lose seats because of antisemitism is a sad chapter in our proud history. JLM will be meeting with Jennie Formby next week and will be urgently raising this." Labour's Jess Phillips take on the local election results: In other election news, Sinn Fein are celebrating in Northern Ireland with a by-election victory in West Tyrone. Orfhlaith Begley, 26, declared herself a history maker as she became the first woman elected as MP for the West Tyrone constituency. The solicitor from the Co Tyrone village of Carrickmore secured an almost 8,000 majority in the parliamentary by-election, ahead of second placed Democratic Unionist Thomas Buchanan, though Sinn Fein's percentage of the vote did drop from more than 50% in last year's general election to 47%. The political newcomer comfortably held on to a seat relinquished by party colleague Barry McElduff when he quit amid a furore over a controversial social media post. McElduff resigned as MP for the area in January, 10 days after a controversy flared when he posted a video of himself with a Kingsmill-branded loaf on his head on the anniversary of the notorious Kingsmill massacre. Jeremy Corbyn made an early-morning visit to Plymouth to celebrate his party seizing control of the city's council. Surrounded by cheering activists at Plymouth Hoe, the Labour leader said he was "delighted" by the result, adding: "The South West has the unenviable title of being the low-pay capital of Britain. That's got to change and a Labour government will offer that change. "Today, winning Plymouth is a sign Labour is back in this part of Britain. Labour is back to gain parliamentary seats. "The mission of Labour is always to stand for a decent society and stand up against poverty in Britain, and that means local government must be properly funded by central government, and local councils that want to deal with the housing crisis and the social care crisis, and want a cleaner, better environment, are the ones that they should be supporting." Brandon Lewis, the Conservative party chairman, said his party had a "reasonable night, a good night". "We've seen interesting results across the country," he told BBC Radio 4 Today programme. "When we look at what Labour were predicting... that simply hasn't happened." "When they were claiming the whole of London was going to turn red, they've not gained a single council." Asked if the Tories have problem in urban areas, he said: "We're working hard all over the country. We have to work and learn from that over the next few years as we go towards the next general election as we're delivering on those domestic agendas on issues that matter to people in their lives every day. Adam Langleben, a Labour councillor who lost his seat in Barnet, told the Guardian: We knew this was a possibility since last night, that this was worse than the general election in 2017. Things have definitely shifted since June. Every Jewish Labour household we visited, people said, "not this time." Activists were being told, "this is a racist party, an anti-Semitic party", doors were slammed in their faces. We as Jewish Labour activists were told we were endorsing anti-semitism. The reason we have lost here is the inability to deal with this issue and to tackle anti-semitism. Jeremy Corbyn was supposed to come here tomorrow for a victory speech. We want him to come to Barnet anyway, to apologise to Jewish Labour activists, to Barnet Labour and to the Jewish community here so we can start the healing process. We won this election on ideas, the Tories just ran a relentlessly negative campaign. But just look at the wards with high Jewish populations where we lost, East Barnet, Brunswick Park, West Hendon. The seats with even higher Jewish populations, where Labour didn't target as hard, the Tories have huge landslides. The Labour leadership and people around them have seen the signs for a long time and they have not acted. I'm not quitting, this is about the health of our democracy. We have two parties of government in this country and one has a sickness that it needs to deal with. People need to join the party; they need to educate people and those who are anti-Semitic need to be immediately expelled. But first of all, the party can start by listening to Jewish activists and the community. Andrew Gwynne, Labour's national campaign coordinator and a shadow communities minister, admitted the anti-semitism row had led to the Conservative victory in Barnet. "It disappoints me," he said on BBC Radio 4's Today Programme. We have got a job to do to rebuild trust and confidence with the Jewish community across the country. I'm sure that is the case. I see it as my job to help rebuild that trust with the Jewish community. There are so many Jewish people who do share Labour's values. Looking at the overall picture, Gwynne said "there was always going to be a limited number of gains we could make". "It was an election of consolidation," he said. He cited Labour victory in Trafford as a significant achievement but admitted there had been some "disappointing results in other parts of the country". Asked about Labour's performance in London, Gwynne said: "We did pick up seats in those areas." "What we've seen is that politics is very polarised," he said. "All published opinion polls show Labour and Tories pretty much neck and neck." Here's some reaction from the Twitter commentariat to the result in Barnet, which saw the Conservative ***win*** control, taking it back from "no overall control". The Conservatives have won control of Barnet Council, taking it back from no overall control. The seat was a Labour target and political commentators on Twitter are already putting the result down to the anti-semitism row engulfing the Labour party. Barnet has a significant Jewish population, according to census data, with the second largest religious group being Jewish. Earlier, a defeated Labour councillor in West Hendon tweeted an apparent reference to the party's anti-Semitism row, saying "we must NEVER have another election like this" after the Conservatives took all three seats from the party in the ward. Outgoing councillor Adam Langleben, who also sits on the national executive committee of Jewish Labour, tweeted: "No community group should have their vote dictated by their safety. That should shame us UKLabour." The results are now in from 94 of the 150 councils holding elections. Here are the latest figures. Conservatives Councils: 28 (-1) Seats: 776 (-11) Labour Councils: 48 (-1) Seats: 1,291 (+44) Lib Dems Councils: 4 (+1) Seats: 324 (+45) Greens Seats: 21 (+6) Ukip Seats: 2 (-41) That's all from me. My colleague Jamie Grierson is taking over now. Here are the latest results from London. Conservatives Councils: 4 (-1 - Richmond) Seats: 271 (-46) Labour Councils: 8 (no change) Seats: 434 (+29) Lib Dems Councils: 2 (+1 - Richmond) Seats: 94 (+18) On the Today programme Caroline Lucas, the Green party's co-leader, said the Greens had had "a really good night". She said that they were now the official ***opposition*** in Richmond, that they had seats on four new councils and that some of the best results they were expecting were yet to come in, in places like Islington and Lambeth. Martha Kearney, the presenter, said the BBC's analysis was that the Greens were only getting 6.5% in the wards they were fighting, a drop of 1.5% compared with 2014. In their morning email, the New Statesman's Stephen Bush and Dulcie Lee reckon that the biggest winner of election night was the Lib Dems. Here's an excerpt. Much to everyone's surprise, the winner of the local elections is.... Vince Cable. The Liberal Democrats harvested local discontent effectively in Sunderland, gave Labour a fright in Hull, won back Richmond at a clip, held onto Sutton, Eastleigh and Cheltenham and are at time of writing the biggest gainers as far as seat gains go It will silence - at least for a while - the noises off about Cable and his leadership. I'm finally leaving Kensington town hall following a disappointing night for Labour. The party had hoped to make gains in the west London borough, which is still dealing with the aftermath of the Grenfell Tower disaster, amid speculation that it had an outside chance of taking control of the council. Instead Labour gained just one councillor as the Conservatives won another overwhelming majority, maintaining their control of a borough they have run since 1964. Labour even failed to take wards such as Chelsea Riverside, which it had been confident of winning from the Tories, as some local party activists suggested Grenfell had not been the deciding issue for most voters in the election, especially in the wealthier south of the borough. The final results left the Tories with 36 seats, and Labour on 13. "We all recognise we still need to rebuild trust," said Conservative leader Elizabeth Campbell. "We must be and we will be open to all voices of our communities." "We all live in the shadow of Grenfell. Grenfell was, Grenfell is, and Grenfell will be our first priority." There were few signs of a revival for the Lib Dems, who clung on to their single councillor while showing few signs of progress elsewhere, even in a borough that voted 69% in favour of remain at the EU Referendum. It was even worse for the new Advance Together political party, which had been compared to French President Emmanuel Macron's En Marche movement. It ran candidates in most wards, declaring that the "narrow demands of party politics has ill-served the people of Kensington & Chelsea". The people of Kensington & Chelsea felt otherwise and the party came consistently last. Kensington and Chelsea is London's smallest borough by population and just 37,000 ballots were returned in Thursday's election. Despite this the final results were only declared at 6.30am, hours after many other larger councils had finished counting and gone home. Bleary-eyed Labour activists were left wondering what went wrong. Richard Angell, director of Progress, the Blairite pressure group in the Labour party (which is much disliked by the Corbynites), says Labour would not ***win*** a general election on the basis of these results. Nickie Aiken, the Conservative leader of Westminster city council, claimed her party's victory in the borough was partly a vote against Momentum. She said: Labour thought they could take Westminster city council, and the people of Westminster sent a very clear message that Westminster would remain Conservative. The Labour party threw everything they had at us today. We had hordes of Momentum supporters throughout Westminster, particularly in the south, and the people of Westminster sent them the message 'We do not like your politics'. More from Prof John Curtice, the BBC's elections analyst, on Labour. He said: There is very little in the way of Labour gains. Yes, they have denied the Tories control of Trafford but that's a very strong remain area. Beyond that, there isn't very much for the Labour party to celebrate. In London, with only a few wards yet to declare results, the Conservatives have retained control of Kensington and Chelsea. And Labour have retained control of Brent after winning 33 seats, with the Conservatives on three and 24 results still to come. The Tories have taken all three West Hendon seats from Labour in Barnet, the Press Association reports. This is from the Independent's Benjamin Kentish. Theresa May has emerged unscathed from her first major electoral test since the general election. In a night that saw all the major parties make some initial gains as the Ukip vote collapsed, preliminary analysis suggested that outside London there was a swing from Labour to the Conservatives. In London the trend was different, but Labour failed to secure some of the high-profile council gains that some in the party had been hoping might prove possible. Overall it was a mixed night, and very few councils have so far changed hands (see 4.02am), but that was a relief to the Conservatives who know that in local elections governing parties often do much worse. With results in from 87 of the 150 councils in England holding elections, all three main parties had achieved net gains in numbers of seats. Labour was on 1,072 seats (+30), the Conservatives 642 (+16) and the Lib Dems 278 (+24). Labour had won 44 councils (-1), the Conservatives 27 (no change) and the Lib Dems 3 (no change). Ukip were the biggest losers of the night. With results in from 87 councils, they had lost 35 seats, and won just 2. The BBC said its analysis of voting suggested that the Conservatives and Labour were either level-pegging, or else one party was marginally ahead of the other. Prof John Curtice, who analyses the figures for the BBC, said an early analysis of the figures suggested there had been a 1% swing to the Conservatives outside London, compared with 2014, but a swing to Labour in the capital. But his team is still analysing the results and firm figures will be released later. The Conservatives comfortably held off Labour challenges to some of their flagship councils in London. They have retained control of Wandsworth and Westminster, and Labour has conceded that the Tories will also hold Kensington and Chelsea. Governing parties expect to lose ground in mid-term local elections, but in some areas they were making progress. They gained control of Basildon and Peterborough, both from no overall control. Labour claimed the results showed the party had consolidated its position. It did not achieve a dramatic breakthrough, and party figures admitted the results were "mixed", but it gained Plymouth from the Conservatives and won enough seats in Tory-led Trafford to tip it into no overall control. Curtice said, if Labour and the Conservatives ended the day roughly equal in terms of the national share of the vote, that would allow Labour to claim it had made progress since the general election, when the Tories were ahead. (See 5.37am.) The Lib Dems have won back Richmond from the Conservatives and are confident of gaining back Kingston-upon-Thames too, when counting there concludes later today. This is from Sky's Lewis Goodall. On the BBC Jonathan Ashworth has just said that Labour has been too slow to deal with some of the allegations of antisemitism against party members. He said that one problem was that, when cases got taken to the national executive committee for disciplinary action, some NEC members were too willing to give the offenders the benefit of the doubt. Prof John Curtice and his team analyse the election results to produce an estimate for the national share of the vote. (See 11.46pm.) He said that there was a small swing to the Conservatives, compared with four years ago, outside London, but that London was different. He said, in terms of the share of the vote, they were not quite sure whether Labour and the Conservatives were "exactly even-stevens" or whether one party was slightly ahead. He went on: Although these results are not particularly good for Labour, they are better, relatively speaking, than they were in the general election last year. So you certainly can't argue that the Labour party has not made any progress as compared with last year's general election [where the Tories were ahead]. But, on the other hand, you can't necessarily argue the Labour party is in a stronger position than they were in the 2016 local elections as well as the 2014 local elections [in both of which Labour ended up ahead]. Jonathan Ashworth, the shadow health secretary, told BBC News that the results were "mixed" for Labour. But he said the party was making progress. And he claimed that Labour thought, on the basis of the way people voted tonight, it would ***win*** the Putney parliamentary seat, which is currently held by the Conservative Justine Greening with a a majority of 1,554. On the same programme John Curtice disputed this. He said that he thought the Tories would hold Putney on the basis of these results. But he said his own analysis of the Wandworth result suggested the Conservatives would now be on course to ***win*** Battersea (a seat Labour gained from the Tories at the general election, with a majority of 2,416). This is from Jonathan Carr-West, chief executive of the Local Government Information Unit, on the results so far. We've only seen a few councils change hands at this stage in the results but at present it looks like a better night for the Conservatives than many would have anticipated, while Labour results have not quite lived up to expectations. In London, Labour were targeting flagship Conservative councils like Wandsworth and Westminster but have fallen short despite increasing their number of seats. Labour needed to talk up the possibility of gains to get their vote out, but now risk disappointment even though Wandsworth and Westminster (both Conservative for more than 40 years) were always going to be a long shot. Outside London the picture is one of Conservative consolidation. In places like Swindon, Nuneaton, Basildon and Southend, Labour need to ***win*** if they are to ***win*** a general election but the Conservatives are tightening their grip. Meanwhile, the Lib Dems made big strides in terms of numbers of councillors and swept away the Conservatives in Richmond presumably benefiting from being the only major party opposed to Brexit in the borough that recorded one of the highest remain votes in the country. Overall though, we seem to be seeing an entrenchment of the status quo; a divided Britain in which big cities vote Labour and everywhere else votes Conservative. A much-touted Labour attempt to wrestle control of Wandsworth - controlled by the Tories since 1978 - was foiled after the Conservatives successfully concentrated resources in key strongholds amid a significantly increased turnout. However, Labour came close on a night when it gained seven seats on a flagship Tory council that has been known for its ultra low council tax and outsourcing of local services since 1978. The final results left the Tories on 33 seats, Labour on 26 and one in the hands of Malcolm Grimston, a former Conservative-turned independent who had the largest personal vote of the night (4002). Even before the results started to come in, London's Mayor Sadiq Khan had earlier sought to manage expectations when he arrived at the count in South London where his party had needed to take 12 Tory seats to ***win*** outright control. "Of course we may not ***win*** councils but I think winning councillors who are Labour is a fantastic achievement," he said, when it was put to him by reporters that he and other Labour figures had "talked up" the possibility of winning Wandsworth. While Labour did make gains at the expense of the Tories, the latter fended of the challenge by bringing home increased votes to retain control of all seats in wards such as Fairfield, Thamesfield and Southfields. Ravi Govindia, the Tory leader of the council, said: The strategy was to take the message to every household to every door to every resident and convince them that this was a council that had not run out of steam. Bright spots for Labour included Queenstown, where it made a gain from the Tories, and where councillors included 25-year-old Aydin Emre Dikerdem, who won a by-election in 2016. Another story of the night was the sheer irrelevance of explicitly anti Brexit parties in a part of London that recorded a 75% for Remain during the referendum on membership of the EU. Both the Liberal Democrats and Renew, a new party seeking to carve out ground on the centre, failed to make any real threats to the Tories or Labour in what was entirely a two-horse race. Renew's founder, former Foreign Office anti-terrorist officer Chris Coghlan, said that he was "pretty happy" with Renew's performance in target wards such as Balham, where he finished ahead of the three Liberal Democrats. Here are the figures from Richmond. This is from OnLondon's Dave Hill, who says the electoral pact that the Lib Dems and the Greens were operating in the borough seems to have worked. And the Conservatives have held Westminster too. Westminster C No change Lab gain 4, C lose 4 New council: C 41, Lab 19 According to the Press Association's Ian Jones, only 19 more councils will declare tonight. The Conservatives have held Wandsworth. It is a flagship Tory low tax borough, quoted approvingly by Theresa May at PMQs on Wednesday, and Labour would loved to have won it, although that was always a very high ask. Labour hasn't won it since 1974. Here are the figures. Wandsworth C No change Lab gain 7, C lose 6, Ind lose 1 New council: C 33, Lab 26, Ind 1 Jonathan Ashworth, the shadow health secretary, has just told BBC News that he thinks the Ukip vote is going to different parties. In some areas it was going to the Lib Dems, he said. That sounded counter-intuitive, he accepted, but it was in some respects a protest vote. Here are the latest figures for London. Conservatives Councils: 1 Seats: 76 (+10) Labour Councils: 2 Seats: 118 (+3) Lib Dems Councils: 1 Seats: 33 (-11) Here is another slug of results. Welwyn Hatfield C No change C 8, LD 6, Lab 5 LD gain 3, C lose 2, Lab lose 1 New council: C 25, Lab 15, LD 8 Bradford Lab No change Lab 20, C 8, LD 2 Lab gain 3, C gain 1, Ind lose 2, LD lose 1, Green lose 1 New council: Lab 52, C 22, Ind 7, LD 7, Green 2 Winchester C No change LD 9, C 6 LD gain 2, C lose 1, Ind lose 1 New council: C 23, LD 22 Hillingdon C No change C gain 2, Lab lose 2 New council: C 44, Lab 21 Daventry C No change C 11, Lab 2 Lab gain 2, UKIP lose 2 New council: C 30, Lab 5, LD 1 North East Lincolnshire NOC No change C 10, Lab 5, LD 1 C gain 3, Lab gain 2, UKIP lose 3, LD lose 1, Ind lose 1 New council: Lab 19, C 18, LD 4, Ind 1 Sutton LD No change C gain 10, Ind gain 1, LD lose 11 New council: LD 33, C 18, Ind 3 Waltham Forest Lab No change Lab gain 3, C lose 2, Ind lose 1 New council: Lab 46, C 14 Eastleigh LD No change Boundary change C down 2, Ind down 2, LD down 1 New council: LD 32, C 4, Ind 3 Cheltenham LD No change LD 17, C 3, Ind 1 LD gain 3, Ind lose 2, C lose 1 New council: LD 32, C 6, Ind 2 The Lib Dems have gained Richmond and they are confident of gaining Kingston too, party sources says. They also held Sutton, Eastleigh and Cheltenham. They claim holding Sutton was significant because the Conservatives fought it hard. On the BBC Jonathan Ashworth, the shadow health secretary, says the results are pretty good for Labour. "We are making gains in the sorts of constituencies that will decide the next election," he says, citing Chingford, Putney and Plymouth as examples. The Conservative MP Johnny Mercer, a former soldier and MP for Plymouth Moor view, told the BBC that the government's approach to defence had contributed to the Conservatives losing the city's council. He said: We've lost control of the council. I think across the country, clearly, it's not been a good night for Labour, but certainly challenging down here. It's pretty clear to me the biggest factor in this city is defence. It always has been. I've made very public my concerns around the handling of defence at the moment and what the vision is. On Sky News Sky's election expert Michael Thrasher was asked whether it was fair to say this was a bad night for Labour. He did not want to go that far. But it was "certainly not a good night", he said. Liam Fox, the international trade secretary, told the programme the results were at the higher end of his party's expectations. He claimed that the results would lead to Labour party members wondering whether, under Jeremy Corbyn, the party was too London-centric. More news snaps from the Press Association. Labour looks set to retain control of its mayoral seat in Tower Hamlets with a party source saying they are "very confident" John Biggs will be returned The Liberal Democrats have gained control of the London Borough of Richmond upon Thames after winning at least 38 of the 54 seats. The Conservatives have retained control of Hillingdon, after winning 35 of the 65 seats. The Conservatives have retained control of Winchester City Council despite losing one seat to the Liberal Democrats. Here are the figures for Derby. Derby Lab lose to NOC C 8, Lab 5, LD 2, UKIP 2 C gain 2, UKIP gain 1, Lab lose 3 New council: Lab 23, C 20, LD 5, UKIP 3 Carrie Symonds, the Conservative party's director of communications, has taken to Twitter to gloat. Wandsworth might have voted remain by 75% in the referendum on membership of the EU, but another story of tonight was the sheer irrelevance of explicitly anti Brexit parties. Both the Liberal Democrats and Renew, a new party seeking to carve out ground on the centre, failed to make any real threats to the Tories or Labour in what was entirely a two-horse race. If there is a tiny 'civil war' among the remain parties however, it was members Renew who were patting themselves on the back. Its founder, former Foreign Office anti-terrorist officer Chris Coghlan, said that he was "pretty happy" with Renew's performance in target wards such as Balham, where he finished ahead of the three Liberal Democrats. The figures are small however: Coghlan polled 568 in a ward where three Tories romped home with more than 7,000 votes between them. So what happened to the 75% remain vote? The answer may or may not be down to the fact that this was about bins rather than Brexit. "The results will have been blurred by the fact that this was a local election," said Coghlan. "We are also a startup and it's about building ourselves as a party that is fundamentally about more than just being anti-Brexit." According to the Press Association, results are now in from 71 of the 150 councils where elections have been taking place. Here are the figures. Conservatives Councils: 20 (nc) Seats: 412 (+27) Labour Councils: 37 (-1) Seats: 743 (+9) Lib Dems Councils: 2 (nc) Seats: 180 (+21) Greens Seats: 15 (+4) Ukip Seats: 2 (-29) And here are the councils that have changed hands. Conservative gains Basildon (from no overall control) Peterborough (from no overall control) Conservative losses Trafford (to no overall control) Plymouth (to Labour) Labour gains Plymouth (from Conservative) Labour losses Nuneaton & Bedworth (to no overall control) Derby (to no overall control) Labour has become the biggest party in Trafford, winning four seats from the Tories to take their total to 30. After a surprise double ***win*** by the Green party in Altrincham, the Conservative party was left with 29 seats, down from 33. "I'm absolutely ecstatic," said Andrew Western, leader of the Labour group on Trafford council. "This is far beyond our expectations. We hoped to tip the council into no overall control tonight, but to have become the largest party at the same time is a fantastic bonus. We could not be happier." Conservative council leader Sean Anstee said his party would have to reflect on the results. He said: Elections in Trafford have always been tight and clearly, as the only Conservative-majority council in Greater Manchester, surrounded by a number of Labour councils, we've seen significant ***opposition*** activity into the borough over the last six months or so. He said that wards that had changed hands also saw a significant increase in turnout. "A number of voters who ordinarily perhaps haven't voted, turned out," he said. "We'll need to reflect on the reasons why they turned out in the way that they did and why they voted in the way that they did." While it didn't surprise many to see the Conservatives lose their overall control of Trafford council, it had not been predicted that the Greens would land the final blow. Geraldine Coggins, one of two Green candidates to take seats of the Tories in Altrincham, said: The media hasn't necessarily noticed, because we're not very surprised. I spoke to a number of people in their 80s who said they had always voted Conservative but were going to vote Green for the first time in their lives, and a number of Labour members who said they were going to vote Green this time. There was a lot of momentum. Dan Jerrome, who came second in the last set of council elections in the area, said that it shouldn't come as a surprise that Green party candidates could take seats from Conservatives. He said the pair - who are now Greater Manchester's only Green councillors - had campaigned on a number of issues, but pointed to the council plans to chop down trees and large developments that residents felt they hadn't been consulted on. On the BBC's election programme Liam Fox, the international trade secretary, claimed a few minutes ago that Brexit was not a big factor in the local elections. He told the programme: I didn't get from voters on the doorstep 'Brexit, Brexit'. That just was not what was coming across. It was about local issues. But Fox had to be corrected by fellow panellists when he argued that, if Brexit was a factor, Labour would have done better in remain areas like Walsall at these elections. Walsall voted leave, he was told. Rob Ford, an academic and elections specialist, says Fox is just wrong. Labour have gained Plymouth from the Conservatives. That is the first council of the night that has switched from one party's majority control to another's. Here are the figures. Plymouth Lab gain from C Lab 11, C 8 Lab gain 4, C lose 4 New council: Lab 31, C 26 This is from the New Statesman's Stephen Bush. Ukip have actually won a seat. This is from Chris Doidge from BBC Radio Derby. If the results in London are quite different from the results outside London (see 3.14am), then in many respects that's just a repeat of what happened at the last general election. Overall there was a modest swing from the Conservatives to Labour in 2017. But the swing in London was much, much larger than anywhere else. Here is another chart from Britain Votes 2017. According to John Curtice at the BBC, as reported on the BBC blog, their analysis from key wards in London shows "a 1.5% swing from Conservative to Labour, far short of what Labour needs to pick up anything other than perhaps Barnet, but in contrast to the position outside of London where there is so far a 1% swing from Labour to the Conservatives." Here is some comment on the Trafford result. (See 3.03pm) Tim Montgomerie, who founded the ConservativeHome website, wonders if there was an Andy Burnham effect. From Andrew Fisher, Jeremy Corbyn's policy adviser From the Manchester Evening News's Jennifer Williams The Conservatives have lost Trafford to no overall control. Here are the figures. Trafford C lose to NOC Lab 13, C 7, Green 2 Lab gain 4, Green gain 2, C lose 4, LD lose 1, Ind lose 1 New council: Lab 30, C 29, LD 2, Green 2 More from Wandsworth. This is from Matt Singh from Number Cruncher Politics. And this is from Marsha de Cordova, the Labour MP for Battersea. My colleague Ben Quinn has tweeted this from Wandsworth, which he says helps to explain why the Conservatives have fended off the Labour attack. On the BBC election programme Justine Greening, the Conservative former education secretary and MP for Putney, said that, after three bad years for her party in London, there were some signs of hope. She said: Labour were really trying to keep up, literally, the momentum. It doesn't look to me - we've got lots of results to come through - like they've managed to do that. Maybe we are beginning to see something akin to peak Corbyn happening. The results are now in from 53 councils. And only three councils have changed hands. The Conservatives have gained Basildon and Peterborough - both from no overall control. And Labour has lost Nuneaton, which is now under no overall control. Here is another slug of results. I posted a large chunk of them earlier at 1.29am. Councils where control has changed Peterborough C gain from NOC C 7, Lab 6, LD 3, Green 1, Ind 1 C gain 1, LD gain 1, Green gain 1, Lab lose 1, UKIP lose 1, Lib lose 1 New council: C 31, Lab 14, LD 6, Ind 5, Lib 2, UKIP 1, Green 1 Councils where control has not changed. Havant C No change C 13, Lab 1, LD 1 C gain 2, UKIP lose 2 New council: C 31, Lab 2, UKIP 2, Ind 2, LD 1 Sefton Lab No change Lab 17, C 4, LD 2 C gain 3, Lab gain 3, LD lose 4, Ind lose 2 New council: Lab 43, LD 12, C 8, Ind 3 Fareham C No change C 12, LD 3, Ind 1 New council: C 24, LD 5, UKIP 1, Ind 1 Gosport C No change LD 9, C 8, Lab 1 LD gain 4, C lose 3, Lab lose 1 New council: C 18, LD 14, Lab 2 Dudley NOC No change C 14, Lab 10 C gain 6, UKIP lose 6 New council: Lab 35, C 35, UKIP 1, Ind 1 Wolverhampton Lab No change Lab 19, C 3 Lab gain 2, C lose 1, UKIP lose 1 New council: Lab 51, C 9 Portsmouth NOC No change C 6, Lab 4, LD 4 Lab gain 4, LD gain 1, C lose 2, UKIP lose 2, Ind lose 1 New council: C 19, LD 16, Lab 6, Ind 1 Wokingham C No change C 11, LD 4, Lab 2, Ind 1 Lab gain 2, LD gain 1, C lose 3 New council: C 42, LD 8, Lab 3, Ind 1 Rochdale Lab No change Lab 16, C 3, LD 1 LD gain 1, Lab lose 1 New council: Lab 46, C 10, LD 3, Ind 1 Ipswich Lab No change Lab 12, C 3, LD 1 Lab gain 1, C lose 1 New council: Lab 34, C 12, LD 2 Liverpool Lab No change Lab 25, LD 3, Green 2, Lib 1 LD gain 3, Lab lose 3 New council: Lab 76, LD 7, Green 4, Lib 2, Ind 1 Colchester NOC No change C 10, Lab 4, LD 2, Ind 1 C gain 2, LD lose 2 New council: C 25, LD 12, Lab 11, Ind 3 Newcastle-upon-Tyne Lab No change Boundary change Lab up 2, LD down 1, Ind down 1 New council: Lab 56, LD 19, Ind 3 Lincoln Lab No change Lab 7, C 4 C gain 3, Lab lose 2, Ind lose 1 New council: Lab 24, C 9 Hart NOC No change C 4, Ind 4, LD 3 Ind gain 3, C gain 1, R lose 4 New council: C 15, LD 8, R 6, Ind 4 Preston Lab No change Lab 13, C 5, LD 2 Lab gain 2, C lose 2 New council: Lab 35, C 17, LD 5 Chorley Lab No change Lab 14, C 2, Ind 1 Lab gain 2, C lose 1, Ind lose 1 New council: Lab 32, C 13, Ind 2 Sandwell Lab No change Lab 26 Lab gain 3, Ind lose 3 New council: Lab 70, Ind 2 Rugby C No change C 8, Lab 3, LD 3 C gain 1, LD gain 1, Ind lose 2 New council: C 24, Lab 9, LD 9 Tameside Lab No change Lab 17, C 2 New council: Lab 51, C 6 Stevenage Lab No change Lab 8, C 3, LD 2 LD gain 1, Lab lose 1 New council: Lab 26, C 9, LD 4 I'm at the count in Wandsworth where it looks increasingly like the Conservatives have held off the much talked about threat of a Labour takeover of a council that has been in Tory hands since 1978. Sadiq Khan, who is at the count in South London, has been playing down Labour's chances not just of ousting the Tories in a local authority where the mayor's party would need to take 12 Tory seats, but also making more widespread gains. "I'm looking forward to seeing the us making gains across London," he said, when it was put to him by reporters that he and other Labour figures had "talked up" the possibility of winning Wandsworth. "Of course we may not ***win*** councils but I think winning councillors who are labour is a fantastic achievement." A rank and file Labour activist put his feelings about the party's chances in Wandsworth more bluntly: "Glum, I'm glum. It was just too big a mountain to climb." Justin Greening, the Tory MP for Putney, said it appeared that the Conservatives have managed to "fend off" Labour. Turnout is meanwhile up in many wards here, and by as much as 10 percent in many cases. Matt Singh, who runs the Number Cruncher Politics website, reckons that people are making false assumptions about where the Ukip vote is going. John McDonnell, the shadow chancellor, and others have been arguing that they are going in disproportionate numbers to the Conservatives. Liam Fox, the international trade secretary, has just told the BBC that his view is that Ukip voters are just returning to the parties they supported before they flocked to Ukip a few years ago. On the subject of what happens to the Ukip vote, it is worth flagging up this chart in Britain Votes 2017, a useful collection of essays on the general election published by the Hansard Society. In the main essay David Denver says that, overall, the decline in the Ukip vote benefited the Conservatives. But he also says that although people assumed that the Conservatives would benefit most in those constituencies where Ukip decided not to stand a candidate, actually the ***opposite*** happened and Labour saw their share of the vote rise the most. Here are the figures he cites to back this up. The results are now in from 43 of the 150 councils where there are elections. Here are the figures Conservatives Councils: 14 (+2 - Basildon and Peterborough) Seats: 241 (+45) Labour Councils: 23 (-1 - Nuneaton) Seats: 428 (-13) Lib Dems Seats: 65 (+8) Greens Seats: 7 (+1) Ukip Seats: 0 (18) Results are starting to come in thick and fast now. Here is a round-up from the Press Association. The Liberal Democrat leader of Colchester Council, Paul Smith, has lost his seat in St Anne's and St John's ward to the Conservatives, who are hoping to take control of the council. The Conservatives have gained control of Peterborough, winning seven of the 18 seats contested. It was under no overall control. The Labour target of Carlisle remains in no overall control. North East Lincolnshire will remain under no overall control after the results were declared in 12 of the 16 wards being contested. The council was a target for both Labour and the Conservatives. Conservative sources say they expect to remain the largest single party on Worcester City Council. The Green party look set to gain a seat from the Tories. Labour looks set to take Plymouth from the Conservatives, Labour Party sources say. The result at Winchester is too close to call, Conservative and Liberal Democrat sources say. The Conservatives currently have a narrow majority on the council, which is a Liberal Democrat target. On the BBC election programme John McDonnell, the shadow chancellor, said that Labour was making "steady progress" but that "obviously we want to be doing better". He said the Ukip vote had largely gone to the Tories. Sir Nick Harvey, the former Lib Dem MP, also told the programme that he thought the Ukip vote had gone to the Conservatives. Here is some reaction to the result in Swindon, where Labour gained one seat from the Conservatives, but the Conservative retained overall control of the council The Labour group leader Jim Grant said: I'm bitterly disappointed. We need to sit down and analyse the figures. Turn-out was up all round. We got as many votes as we thought we would need to ***win***. Clearly the Conservatives were able to increase their vote. How I don't know. It may be the collapse of the Ukip vote and that has gone back to the Tories. But we are still in the game here. The majority is reduced to one. Next year one last haul and hopefully we will break the Tory monopoly on control of Swindon borough council. Jeremy [Corbyn] has inspired our active base and that is why we have got so many votes. The Conservative group leader David Renard said: We got our positive message across. Labour ran a very negative campaign here. They have thrown a lot of resource, brought in a lot of people and spent a lot of money trying to take up to six of our seats. They failed to take every one. We have shown the Labour party is a long way from forming a government and on the doorstep there is a lot of anti Jeremy Corbyn feeling. There are very few places in southern England where Labour has a foothold. And this is from Robert Buckland, the South Swindon MP and solicitor general. Labour were expecting to take control or for their to be no overall control. They failed. It's a very bad night for them and a really strong night for the Tories. Who's doing well and who's doing badly? This is what John Curtice, the leading psephologist, told the BBC a few minutes ago. The truth is, [all three main parties] are doing better than they were four years ago in terms of votes won. That's a reflection of the fact that the Ukip vote is down. However John McDonnell's problem is that the Conservative vote, at least in the votes that we have had so far, which are all from outside London, is going up more than the Labour vote. That therefore means that, relative to the Conservatives at least, Labour are in a somewhat weaker position than they were in indeed in 2014 when most of the seats were [last fought]... That said, this... is pointing to something like Conservative and Labour being equal, or probably the Conservatives being slightly ahead. This probaby does mean that the Labour party are in a stronger position than they were in the 2017 general election. But the truth is, in so far as the Labour party would like to be able to demonstrate further progress, to be able to say that actually we're beginning to come up with the kinds of leads in the local elections that we normally associate with ***oppositions*** that are heading for victory, I think John must be somewhat disappointed. The Labour party, relative to the Conservatives at least, are going back as compared with recent local election performances. At a Momentum election night event, Labour canvassers are taking a rest after a long day of door-stepping. Laura Parker, the Momentum national co-ordinator, said the fact that the Tories seemed to be doing well in leave areas showed how divided the country was. She said: There's a more profound fracture in British politics on leave/remain lines. It's clear the Labour party have to continue building in areas over a long period of time that it's lost. It's almost certainly the case the Tories have the same problem in reverse - they will struggle in remain areas and big cities. This isn't a healthy state of affairs. The distinguishing feature is Labour has a manifesto for the whole country, and of course expectations are high because we did so well in the general elections. But we're comparing our results to 2014; there's only so much we can gain. The Tories have had some of the worst few weeks on record; if I was the Tories I'd be talking up Wandsworth and Kensington too. Swindon is obviously disappointing. It's a place we were hoping to do better in. It's all relative, that's the thing about local elections. One of the challenges for Labour is having a much bolder offering about local government but you can only do that when you're in government. For the moment we're mitigating the worst effects of austerity, which is a thankless task. Here are the results by council that are in so far, according to the Press Association. Councils where control has changed Basildon C gain from NOC C 11, Lab 2, Ind 2 C gain 5, Lab gain 2, UKIP lose 5, Ind lose 2 New council: C 24, Lab 11, UKIP 5, Ind 2 Nuneaton & Bedworth Lab lose to NOC C 11, Lab 6 C gain 8, Lab lose 7, Green lose 1 New council: Lab 17, C 16, Green 1 Councils where control has not changed Tamworth C No change C 8, Lab 1, Vacant 1 C gain 2, Lab lose 1, Ind lose 1 New council: C 22, Lab 5, Ind 1, UKIP 1, Vacant 1 Thurrock NOC No change Lab 9, C 6, Ind 1 Lab gain 3, C gain 1, Ind lose 4 New council: C 20, Lab 17, Ind 12 Tandridge C No change C 4, LD 4, Ind 3, R 3 LD gain 3, Ind gain 3, R gain 2, C lose 8 New council: C 22, LD 9, Ind 7, R 4 Brentwood C No change C 8, LD 4, Lab 1 C gain 1, Ind lose 1 New council: C 25, LD 9, Lab 2, Ind 1 Wigan Lab No change Lab 18, Ind 4, C 3 Ind gain 3, C gain 2, Lab lose 5 New council: Lab 60, Ind 8, C 7 Cannock Chase Lab No change Lab 6, C 5, LD 1, Green 1 C gain 2, Green gain 1, Ind lose 2, UKIP lose 1 New council: Lab 21, C 15, Green 3, Ind 1, LD 1 Hartlepool Lab No change Lab 5, Ind 5, C 1 Ind gain 1, UKIP lose 1 New council: Lab 19, Ind 11, C 3 Swindon C No change C 9, Lab 9, LD 1 Lab gain 1, C lose 1 New council: C 29, Lab 26, LD St Helens Lab No change Lab 13, C 1, LD 1, Ind 1 Ind gain 1, Lab lose 1 New council: Lab 41, LD 3, C 3, Ind 1 Halton Lab No change Lab 17, LD 1 New council: Lab 52, C 2, LD 2 Castle Point C No change C 9, Ind 5 C gain 4, UKIP lose 2, Ind lose 2 New council: C 27, Ind 14 The Tories are also optimistic about seeing off Labour in Westminster, my colleague Pippa Crerar reports. Labour has conceded defeat in Kensington and Chelsea and said there is little chance of the party taking control of the council, despite the Conservative administration's chaotic handling of the Grenfell Tower disaster. "We have piled up votes in Labour-held wards," said Labour group leader Robert Atkinson, insisting his party's gains would be limited because the Conservatives have managed to "frighten out" their vote across the west London borough. Kensington and Chelsea has been controlled by the Conservatives since the council was formed in 1964 and Labour went into this year's election with just 11 out of 50 seats - all representing areas in the poorer, north of the borough near to the burned-out shell of Grenfell Tower. Last June's catastrophe, combined with the unexpected victory of Labour's Emma Dent Coad in the Kensington parliamentary constituency at the general election, prompted speculation that Jeremy Corbyn's party could be on a cusp of an unlikely breakthrough. Instead Labour is hoping to gain just a handful of councillors, with hopes pinned on the Chelsea Riverside and St Helen's wards. The Liberal Democrats are targeting a single ward, while the new centrist political movement Advance looks to have sunk without trace. Despite conceding defeat, Atkinson insisted the election showed how the Conservative council's reputation has been hit by the disaster, even among core Tory supporters in ultra-wealthy parts of the borough. "Grenfell is a symbol of incompetence of the council," he said. "I've heard that from Chelsea ladies who always thought they had an efficient council. But both during and afterwards the council has just failed." Britain Elects has been calculating what has happened to the share of the vote so far. There has been a swing to the Tories, it says - about 2.5% since 2014. I've just been speaking to councillor Andrew Western, leader of the Labour group on Trafford council, who is quick to dismiss the idea that his party could ***win*** overall control of the borough. "That was never the plan. We never thought that we could go to overall control this year. Absolutely not," he said. He went on: To be honest, I think the Tories were suggesting that by way of expectation management. But we never felt that we could take it this time. To ***win*** six seats [the number the party would need to take control] we would have to ***win*** three that we have never won in the history of Trafford. Even to go to no overall control we would have to ***win*** one seat in Davyhulme East that we've never ever won. So I would say that, for us, no overall control would be a tremendous result. It really would. Turnout in Trafford is slightly up on the last set of elections in 2016 - 42.9% (73,073 votes) compared to 41% (66,763) - something Western says is good for Labour. "I'd say we're hopeful from the things that we've seen of picking up two or three seats, maybe, but it really is too early to tell." Sean Anstee, the council's Conservative leader, also said, unsurprisingly, that it was too early to make predictions. He said: We've seen a concerted effort from the Labour party, just as we've seen a concerted effort from our party. We'll know later on tonight who's has been successful. I think it is important for Greater Manchester [where Trafford is the only Conservative council] to have a diversity of political opinion. We can see in city regions across the UK, where they're dominated by a single party, that that doesn't bring the variety of ideas that you would really want to have. The Tories have sent out a briefing about Labour losing control of Nuneaton & Bedworth. They point out that in 2014 Labour had a 22-seat majority there. And they point out that my Guardian colleague Owen Jones, a very active campaigner for Labour, once cited Nuneaton as the sort of seat Labour should ***win***. Here are the latest figures from the Press Association, with the results in from 12 of the 150 councils. Conservatives Councils: 4 (n/c) Seats: 62 (+20) Labour Councils: 7 (-1) Seats: 110 (-16) Lib Dems Seats: 11 (+3) Greens Seats: 1 Ukip Seats: 0 (-5) My colleague Steven Morris has posted a picture of the Tories celebrating holding on to Swindon. The Conservatives have gained Basildon. This is from the BBC's Nick Sutton. The Tories have held Swindon, the BBC reports. In a statement released tonight Sadiq Khan, the Labour mayor of London, said that for Labour to ***win*** Wandsworth would be beyond the party's "wildest expectations". He said: I've been campaigning across London and it's quite remarkable to see us being competitive in boroughs that used to be "no go" areas for Labour in previous years. No more. It would be truly astonishing if Labour were to take control of Wandsworth council - which has been a flagship Tory council for forty years - and winning here is above even our wildest expectations. We last won here in 1974... In Wandsworth we stand a real chance of winning councillors in some wards that Labour hasn't represented since I was born - but it would be a real earthquake if we were to ***win*** control of the council - above even our wildest expectations. Whatever the outcome here tonight, it's clear that London has turned its back on Theresa May's Government - who neither like nor understand Londoners, our values or our way of life. Britain Elects has the Nuneaton voting figures. The New Statesman's Stephen Bush says these figures show why it is wrong to hold elections by thirds. Here are the Nuneaton & Bedworth results from the Press Association. These are the seats that were up for election - not all the seats on the council. Con: 11 (+8) Lab: 6 (-7) Green: 0 (-1) According to the Press Association, results are now in from six councils. Con: 2 Lab: 3 (-1) NOC: 1 (+) The council that has changed hands is Nuneaton & Bedworth, which has gone from Labour to no overall control (NOC). More on what the Tories are saying. Lib Dem sources say the party expects to make a handful of gains in Liverpool. This is from my colleague Pippa Crerar. Senior Labour and Conservative sources in Dudley, where either party could take control, say it is too close to call, the Press Association is reporting. Labour sources say it could come down to results in just two of the 24 wards being contested, Belle Vale and Wollaston & Stourbridge Town. The Local Government Information Unit has a faster results service. The Press Association has posted the first full council result of the night. Broxbourne C No change C 9, Lab 1 C gain 1, Ukip lose 1 New council: C 28, Lab 2 The Tories are saying Labour has lost control of Nuneaton. And the party has tweeted this particular result. On the BBC John McDonnell, the shadow chancellor, says it is going to be "a complicated night". It might be "quite boring" too, he says - to protests from the BBC's Laura Kuenssberg. He says suggestions that Labour could make great gains were wrong. Relatively few councils are likely to change hands, he says. And he says it is not clear what will happen to the Ukip vote. He says at the general election two thirds of the Ukip vote went to the Conservatives, and only one third went to Labour. He says Labour's focus is on making "incremental gains". The Conservatives are doing well in Nuneaton, the BBC is reporting. Britain Elects has two of the ward results. Conservatives in Welwyn Hatfield could lose overall control, party sources have told the Press Association. These are from the BBC's Laura Kuenssberg. We've also got a byelection tonight in Northern Ireland. It was triggered by the decision of Sinn Fein's Barry McElduff to resign as West Tyrone MP in January, 10 days after he provoked outrage by posting a video of himself with a Kingsmill-branded loaf on his head on the anniversary of the notorious Kingsmill massacre. McElduff had a majority of more than 10,000 and his Sinn Fein successor Orfhlaith Begley is expected to ***win***. This is intriguing, from the BBC Essex reporter Charlotte Rose. Ukip are expected to struggle enormously tonight. In 2014 their national share in the local elections was put at 17% on the PNS measure. (See 11.46pm.) Those elections coincided with the European elections, which Ukip won. But since the party achieved its key aim, and secured a leave vote in the EU referendum, it has been in turmoil. One indication of this is how few candidates it has put up. The figures are in this chart, from John Curtice's PSA briefing. It is hard to measure success in local elections because the seats and the councils where elections take place are not the same every year and therefore - as John Curtice pointed out in the briefing cited earlier (see 10.31pm) - the raw results can be misleading. But parties and their supporters will want to know who is doing well and who is doing badly. Here are three measures you can use, with the relevant benchmarks. Vote share After the local elections psephologists look at the vote share the parties achieve and use those figures to calculate what the vote share would have been if people had been voting in the same way across the whole of Britain. They do this by looking at the demographic make-up of the wards where people were voting and extrapolating a national figure, based on what is known about voting behaviour. Just to make things complicated, there are two versions of this figure. Curtice and his team produce one called the projected national share (PNS) which the BBC uses. And two other psephologists, Colin Rallings and Michael Thrasher produce one they call the national equivalent vote (NEV), which gets used by Sky. They tend to show the same trend, but the actual figures are not always the same. At some point on Friday we will get PNS and NEV figures for these elections. There are at least three figures you can compare them to. Vote share at the 2017 general election (for GB) Con: 43.4% Lab: 41% LD: 7.6% Vote share at 2017 local elections Con: 38% (PNS); 39% (NEV) Lab: 27% (PNS); 28% (NEV) LD: 18% (PNS); 18% (NEV) Vote share at 2014 local elections (when these seats last fought) Con: 29% (PNS); 30% (NEV) Lab: 31% (PNS); 31% (NEV) LD: 13% (PNS); 11% (NEV) Seats gained As Curtice explained (see 10.31pm), comparing seats gained and lost in one year with the seats gained and lost in another can be grossly misleading, because different numbers of council seats are up for election every year. The only comparison that is remotely half-fair is with what happened in 2014 - when most of these seats were last up for election - although even that is problematic, because the exact number of seats being contested is not the same. Council seats won/lost in 2014 Con: -236 Lab: +324 LD: -310 Another factor, obviously, if that Labour gained a lot of seats in these councils four years ago, it becomes much harder to gain more. Councils gained/lost The same point applies to comparing the number of councils gained/lost with the figures for 2014. But, for what they are worth, here are the figures for that year. Con: Net loss of 13 councils Lab: Net gain of 4 LD: Net loss of 2 No overall control: Net increase of 11 More from Swindon. These are from my colleague Steven Morris in Swindon. The excellent Britain Elects Twitter feed is posting ward by ward results. The first ones are in from Sunderland. The Lib Dems have also been on the phone. Party sources say that in London they're "very confident" of taking Kingston-upon-Thames from the Tories, although the result won't be in until tomorrow at around 5pm. However, they're less confident about neighbouring Richmond, despite it being Sir Vince Cable's own back yard, claiming it remains "on a knife edge". They are fairly upbeat about their chances in St Albans and Eastleigh, but think it's unlikely that they've been successful in winning Hull back from Labour. Labour sources say that they're "hopeful" of making progress in the number of seats they pick up across the country but that the result will be "fairly tight" in several key places. They point out that the collapse of Ukip since 2014 creates an element of uncertainty, although in the general election two thirds of the ex-Ukip vote went to the Tories, and just one third to Labour. In London, they are keen to stress that the party was starting from a high watermark, having done so well four years ago, which would limit potential gains. Labour thinks they've got a "fighting chance" in Barnet, North London, citing public disquiet about outsourcing (but no mention of antisemitism) but are claiming they haven't seen the swings they would need to take Tory "crown jewel" councils of Wandsworth or Westminster. In Kensington & Chelsea, which always looked like a push (though nobody quite knows whether there will be a Grenfell effect) they suggested it was "out of reach". But they're more optimistic about wiping out the last remaining speck of blue - Trafford - in a sea of red councils around Manchester. However, they predict the town hall would go to no overall control, rather than a Labour ***win***, but that would still be a "massive coup". The final prediction from Labour sources for now: they're "hopeful" of winning Plymouth from the Tories. According to Sky's Faisal Islam, Survation have a telephone exit poll from Croydon (a Labour-run council, although one the Tories won in 2010) showing a big Labour lead. I'm at the count for the Trafford council elections at Lancashire County Cricket Club. The wealthiest of Greater Manchester's ten boroughs is a key target for Labour and Jeremy Corbyn chose the Stretford sports village leisure centre, just across the road, to launch his party's local election campaign in March. The Tories took overall control of Trafford in 2004, eight years after Labour won the borough in 1996 - a year before Tony Blair's landslide election victory. If Labour manages to gain control tonight it will be seen as a promising sign for their electoral chances on a national level. Only a third of the council's 63 seats are up for grabs and Labour would need to ***win*** six of the 13 non-Labour seats on offer, as well as retaining those it already has, to take the borough. The Conservatives currently hold Trafford by just two seats, so it would not be a surprise if the local authority slipped into no overall control. Labour locally has become increasingly confident since the 2017 Greater Manchester mayoral election, when Andy Burnham won 16,000 more votes in the area than his Conservative opponent Sean Anstee, leader of Trafford council. Voters in Trafford also backed remain in the previous year's EU referendum, something the Labour MP for Stretford and Urmston, Kate Green, says comes up on the doorstep. Labour's campaign has focused on the three key wards of Davyhulme West, Davyhulme East, and Flixton, which - if won - would strip the Tories of their overall control. The party also thinks it has a shot at wealthy Altrincham. Locally Labour has pledged to maintain low council tax rates (which are currently the lowest in Greater Manchester), build social housing, block development on green belt land and stop further council outsourcing. Some assorted election chat. From Sky's Faisal Islam From the Sun's Tom Newton Dunn Swindon is hugely significant to Labour. Jeremy Corbyn, Tom Watson, John McDonnell and Momentum activists have all visited the Wiltshire town during this campaign to lend a hand to grassroots members. At general elections, Swindon is seen at a bellwether - whoever holds the two seats tends to ***win*** power. If Labour does well here tonight, it will also be seen as a sign that the party can make in-roads across the south of England. Since Gordon Brown's defeat in 2010 both North Swindon and South Swindon have been held by the Tories. Its council has been run by the Tories since 2004. Labour had high hopes of wresting back control in 2014 but its campaign was not helped when Ed Miliband embarrassingly failed to recognise the name of the Labour group leader - Jim Grant. Grant still heads the group. His party's Swindon manifesto was a solid, no-nonsense affair, promising more council houses, reopening children's Sure Start centres, boosting regeneration of the town centre, promoting the living wage, tackling zero hour contracts. It also vowed to keep the Lydiard country park and house under council ownership and management. The park hit the headlines in the Swindon Advertiser this week when a cabinet member revealed that visitors who wanted to enjoy a cream tea at the cafe have to order it two days in advance. Here's the maths for Swindon. There are 57 councillors on Swindon borough council. Going into the count, 30 were Tory, 25 Labour and two Lib Dem. Nineteen seats are up for grabs - 10 Tory, eight Labour, one Lib Dem. Labour had high hopes in five seats - four of them Tory and one Lib Dem - including Lydiard and Freshbrook, where park management and cream teas is an issue. On election night you need Sir John Curtice. The great psephologist will be on the BBC's election programme later but, in case you can't wait, here is some YouTube video of a briefing on the local elections organised by the Political Studies Association on Monday. It is "rather anoraky", as he says himself. (But we like that here.) The briefing was intended for journalists and Curtice said that he wanted to explain various aspects of the election in the hope of ensuring certain trends do not get misreported on Friday. There was a danger that headlines could be "seriously misleading", he explained. Curtice said that it was important to remember that London was not representative of England or Britain as a whole. Literally 42% of the all the seats that are up for grabs on Thursday are located in London. And one thing, therefore, you absolutely have to get into your head is that London does not constitute 42% of England. If, as I'm going to argue, the result in London might prove to be different from that in the rest of England, headline totals of seats won and lost may seriously misrepresent the actual position of the political parties... There is every reason to anticipate... substantial divergence between remain and leave voting Britain, which therefore means that London is likely to move towards the Labour party but the rest of England could still swing towards the Conservatives. And therefore do not be surprised if, on Friday afternoon, you end up with the BBC coming up with a projected national share that actually has the Tories slightly ahead, even though they may have lost more seats and be losing ground in London. Crucial point, therefore; just remember, the tally of seat gains and losses is potentially seriously misleading because of the dominance of London. But Curtice also said that, just because it would be hard for Labour to ***win*** councils in London, that would not necessarily mean it was not winning votes. Equally, and conversely, the Labour party just picking up Barnet will not necessarily tell you the Labour party has not made progress in London. The Labour party's misfortune, in terms of council control, is that there isn't very much for the party to pick up. The polls have now closed and officials are just starting the process of collecting, verifying and counting the votes that will elect more than 4,000 councillors in 150 councils in England. Most of these seats were last up for election in 2014, when the poll coincided with the European elections, which saw Ukip ***win*** a nationwide election for the first time. In 2015 the local elections took place on the same day as the general election, and in 2017 they were staged in the middle of a general election campaign. And in 2016 the local elections overlapped with elections to the Scottish parliament, the Welsh assembly, the Northern Ireland assembly and for the mayor of London. But this year we've just got local elections basic. It will be the least consequential local elections day for at least five years. And I'm afraid it is not as if these are make-or-break contests for any of the major political leaders. At Westminster expectations are relatively muted and tonight's results are not expected to lead to repercussions that could challenge the leadership of either Theresa May or Jeremy Corbyn. We may be wrong (we often are), but journalists are not expecting any of the main parties to suffer an all-round disaster. But don't head for bed yet. This blog operates on the firm basis that there is no such thing as a dull election and tonight will be no exception. Politics matters. And this is the biggest test of political opinion in England since last year's general election. It is also worth remembering that more than 4,000 people will be elected to office. Local government is not a glamorous calling, but it is important and worthwhile and good luck to those who ***win***. There will be a lot of focus on London tonight because all 32 boroughs in the capital are having "all-out" elections (which means all seats are up for election, not just one third of seats, as is the case with most of the other council elections today.) The 1,833 London seats that are up for grabs comprise 42% of all seats being contested this year. The others are in 34 metropolitan districts, 67 shire districts and 17 unitary councils. There is a guide here. In addition there are four London mayoral elections - in Hackney, Lewisham, Newham and Tower Hamlets - as well as mayoral elections in Watford and for the new Sheffield city region. I'm Andrew Sparrow and I will covering the results as they come in through the night, as well as bringing you reaction and analysis. My colleague Jamie Grierson will be taking over after dawn, and then we will be carrying on until all the results are in on Friday evening. Here is the blog we were running earlier covering events on polling day. 108754 false Boris Johnson leaves a polling station on Thursday. Dan Jarvis making a speech after being elected as the Sheffield city region's mayor Andy Burnham Projection for how local elections would translate into general election result Paul Oakley Jeremy Corbyn at a polling station yesterday Brandon Lewis Andrew Gwynne campaigning in 2017 Conservative/Labour swing at the general election by region Volunteers counting ballot papers at Wandsworth Town Hall How absence of Ukip and Green candidates helped Labour and Tory candidates at 2017 election Number of candidates standing Sir Vince Cable at Twickenham polling station earlier today. Jeremy Corbyn after voting at a polling station in Pakeman Primary School in Holloway, north London.

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**Body**

Zagreb, 12 December 2017 (Hina) - Plenkovic expects Slovenia, Hungary to scrap blockade of Croatia's OECD entryZAGREB, Dec11(Hina) - Croatia expects both Slovenia and Hungary to honour the decision that European Union member states should support each other in joining theOrganisation for Economic Co-operation and Development (OECD), Prime Minister Andrej Plenkovic saidon Monday."The principled position is that we should all support each other. There is a platform, a very clear political decision, and I expect both Slovenia and Hungary to honour this EUdecision and support Croatia on the journey to the OECD asthat, in the end, is also in their interest because of our economic relations, trade,and the strengthening of Croatia among financial and other international organisations that deal with the economy," Plenkovic said after talks with OECD secretary-general Angel Gurria at OECD's HQ in Paris.They already met in Davos at the beginning of the year, when Plenkovic said Croatia was interested in joining the OECD. In late January, the government sent a letter of intent about membership.However, Slovenia and Hungary haveannounced they will block Croatia's candidacy, Slovenia because of Croatia's refusal to recognisea border arbitration ruling, and Hungary because of the relations between Croatia's oil company INA and Hungary's MOL. The OECD has 35 member states, the most developed world economies.Plenkovic said today Croatia wanted the OECD's help in economic and structural reforms as it possessed very important expert knowledge of the economy, finance, combating corruption, public procurement, the tax policy and everything else that could help Croatia meet its national reform programme."We expect that, in the weeks ahead,the ambitions of the six countries-aspirants which wish to join the organisation will be discussed at the level of the OECD Council.

We expect that in the process that will last the next year, year and a half, our talks will intensify and that Croatia will gain access to various international legal documents which the OECD has, thus gradually heading formembership.The secretary general's position is very affirmative of Croatia and we will continue this dialogue during 2018."Later on Monday, Plenkovic met with representatives of the French-Croatian parliamentary friendship group and Croatian emigrants in that country."It is nice to be here again, in the Croatian Embassy in Paris where I spent five years in the second half of the last decade," Plenkovic said.The PM said that over half a million French tourists visited Croatia last year and expressed confidence Croatia and France would step up economic cooperation within the framework of the ***strategic*** partnership, which the two countries signed in 2010.On Tuesday, Plenkovic is due to attend the One Planet Summit on climate change together with about 50 heads of state or government.FM: Croatia committedto bilateral solution to border row with SloveniaZAGREB, Dec11(Hina) - Zagreb sticks to its position that the border dispute between Croatia and Slovenia should be addressed bilaterally, Croatia's Foreign and European Affairs Minister Marija Pejcinovic Buric said in Brussels on Monday after a recent statement byEuropean Commission's Vice President Frans Timmermans that this was a dispute between two countries and the announcementby Slovenia's Foreign Minister Karl Erjavec about Ljubljana's intention to sue Croatia over this row.Timmermans, whom European Commission President Jean-Claude Juncker recently tasked with mediating in the Croatia-Slovenia border row, said this past Thursday that he was in contact with the governments of Croatia and Slovenia in an effort to help the two neighboursresolve their border dispute, however, he was not yet certain he would visit Zagreb and Ljubljana.Let me be clear. It is a border dispute between two (EU) member-states and the European Commission hopes that the issue can be solved without a delay in a constructive dialogue between them,the First Vice President said then.Erjavec said on Friday that the Slovenian ministry was making intensive preparations for a legal action against Croatia over itsrefusal to accept an arbitration award on their border issue. This summer theHague-based Permanent Court of Arbitration handed down aruling which Croatia dismissed as it had already withdrawn from the proceedings, which it deemed compromised due to Slovenia's interference in the process in an inappropriate manner.Pejcinovic Buric said in Brussels today that Croatia's position "remains unchanged. Being two NATO and EU member-states, we should settle this issue bilaterally."She went on to say that "it is advisable to work on a bilateral solution, and the mediation of the European Commission canonly be a next step" when all other optionsavailable to Zagreb and Ljubljana are exhausted.She said that she was glad to hear Timmermans make acomment in similarvein.The Croatian minister said that it was good to see that Slovenian Prime Minister Miro Cerar distanced himself from Erjavec's statement."We deeply believe that the two friendly countries should reach an agreement and that our relations should go beyond theborder demarcation line," she added.Issue of JerusalemThe Croatian minister today attended a European Union ministerial conference on the latest developments in the Middle East and on the EU's support forefforts to preserve peace in that region in the context of U.S. President Donald Trump's decision to recognise Jerusalem as the capital city of Israel.The status of Israel is a matter that should be agreed by the Palestinian and Israeli sides, and any premature relocation of U.S. embassy to that city is not a good move, the Croatian minister said after the ministerial conference.Israeli Prime Minister Benjamin Netanyahu attended the Brussels meeting.The EU ministers discussed Washington's plan torelocateits embassy in Israel, and they agreed to stick to international standards and conclusions made by the UN Security Council regarding this topic, the Croatian minister said.The EU ministers and Netanyahu also discussed economic cooperation, and Pejcinovic Buric said that Zagreb perceived Israel as a friendly country and a technologically advanced economy which could offer Croatiagood solutions in agriculture and some other sectors.Croatia on Monday formally joined a European Union defencepactknown as PESCO. The 25 participating EU states are set to begin working on a series of joint defenceprojects next year.Of the 28 EU member states, only Malta, Denmark and the UK have not joined PESCO.FinMin: Croatia at this point doesn't want to commit itself to euro adoption dateZAGREB, Dec 11 (Hina) - Croatia at this point does not want to commit itself to a specific date for joining the euro area but wants to implement a good and well-reasoned public consultation on euro adoption, Finance Minister Zdravko Maric told reporters on the margins of a conference on the costs and benefits of euro adoption, organised by the Croatian National Bank (HNB)."At this point we do not want to commit ourselves to a date. We should do what we have set out to do and that is a good and well-reasoned public consultation and today's conference is a contribution to that," Maric said when asked when Croatia would be ready to adopt the euro."We are aware of all the homework that weneed to do before knocking at the door of the currency mechanism and someone on the other side opening that door. Things will certainly be much quicker after that," he said, adding that Croatia already now met basically all the Maastricht criteria.Maric said that the benefits of euro adoption for the economy and society in general were many, but there were also costs, and Croatia should ensure that the costs were as low as possible and the benefits as great as possible.He also cited certain political criteria. "Adopting the euro does not depend only on us, but we also have to ask the European Central Bank, the European Commission and the member states."Asked to comment on the European Commission's latest proposal concerning the reform of the euro area, Maric said that the focus in the coming months would be on four pillars to deepen the monetary union, but added that details of these steps were not known right now."It's good that I have been attending Euro Group meetings for two consecutive months, we have been participating in discussions and we know what is going on and the direction in which the deepening of the monetary union is going," the minister said.Asked about government measures to reduce public debt, Maric said that the government would continue implementing its plan in that regard. He recalled that the public debt to GDP ratio had been reduced in 2016 for the first time and was projected to decrease to 80 percent, or even below 80 percent, of GDP this year. He said that this was to be achieved based on economic growth, fiscal consolidation and the activation of state assets.Central bank conference discusses euro introductionZAGREB, Dec11(Hina) - Croatian National Bank (HNB) governor Boris Vujcic said on Monday the benefits of introducing the euro in Croatia could be relatively bigger than in some countries that had already introduced it, while Slovak Finance Minister Peter Kazimir said entering the euro area had contributed to a 10% GDP growth in his country.They were speaking at a conference on the benefits and costs of introducing the euro at which Slovakia's and Slovenia's experiences were presented.Kazimir said Slovakia introduced the euro in 2009 and that its GDP had risen 10% since. The eurois part of my country's success story and after its introduction public support of the euro has increased, he added.He underlined the importance of a political consensus on the introduction of the euro, saying the biggest problem was explaining and assuring citizens that they were now part of a club resting on solidarity, including with countries like Greece and Spain.Kazimir said the advantages of introducing the euro were significant, citing export growth, faster convergence processes, big savings on transaction costs and a stronger role in decision making.Vujcic said the strategy for introducing the euro as Croatia's official currency, created by the HNB and the government, showed that the benefits could be significant,lasting and relatively bigger than in some other countries, while costs would be mainly small in intensity and one-off in character.Such findings stem from the fact that Croatia is a small, open and highly euroised country with a high degree of financial and trade links with euro area countries, Vujcic said, adding that the euro would eliminate the foreign exchange risk.Zagreb Institute of Economics head Maruska Vizek said there were warnings fromthe European Commission and the International Monetary Fund that thestructural deficit was deteriorating. She said that in her opinion Croatia would not be capable of adopting the euro because for the past five years in a row it had not been capable of sufficiently slashing the public debt.She said the government's technical spending would increase in 2018 and that Croatia was currently riding a wave of favourable economic circumstances, while the next five years would bring many uncertainties.Vizek said Croatia could certainly enter the European Exchange Rate Mechanism (ERM) but that she did not think Croatiacould keep up the pace of reducing the difference between the current and public debtand the maximum allowed for entering the euro area.Zeljko Lovrincevic of the Zagreb Institute of Economics said the European Union encouraged every country willingto enter the process of introducing the euro. He said today's conference should have been about the strength of Croatia's institutions, competitiveness, contracts and labour market, the first pillars that are expected to withstand the first impactof a downwardcycle in the euro areawhich he said might coincide with the introduction of the currency in Croatia.Asked about Poland's and the Czech Republic's delay in introducing the euro, analyst Velimir Sonje said they were structurally different than Croatia. Croatia is a small and open economy, whereas Poland is more closed and markedly bigger and stronger, he added.Zagreb Faculty of Economics and Business professor Marijana Ivanov said it was necessary to prevent an appreciation of the kuna until Croatia's entry to ERM II as well as during membership. Upon entering ERM II, it would be far better for Croatia to enterwith a central parity rate of 7.8 instead of the existing 7.5 against the euro, which is not a big difference but which would mean a lot to many entrepreneurs and exporters, she added.fDi Magazine commends Croatia's efforts to attract investors in tourismZAGREB, Dec11(Hina) -FDi's inaugural Tourism Editor's Choice Awards for tourism single out the countries that have devised specific and successful strategies to attract investment.According to thefDi Tourism Locations of the Future 2017/18 – Editor’s Choice Awards, Belize, Croatia and Jamaica are just three of the countries punching above their weight.Croatia is becoming increasingly important as a filming location for both TV shows and films, including HBO’s "Game of Thrones" series and more recently "Robin Hood". Some 250,000 tourists are believed to have visited as a direct result of the "Game of Thrones" franchise, helping the country ***win*** the Film Industry specialism award.The country was also commended for its efforts to attract investors in the tourism sector, winning an Incentives award. Croatia’s Act on Investment Promotion offers investors a range of incentives for establishing hospitality and tourism accommodation facilities rated at four- and five-star level. In addition, investors can enjoy incentives for education and training, grants for capital costs of projects and 0% corporate income tax for up to 10 years."As a tourism destination, each yearCroatia is generating better and better results, but what particularly makes us happy is that it is also constantly working on innovations and promotion of further investments. In 2018, investments in Croatia's tourism are expected to go up 15% compared to 2017 and 40% compared to 2016," Croatian Tourism Minister Gari Capelli said Monday, adding that this was the best indicator that Croatia is an attractive investment destination.The Tourism Ministry said in a press release that approximately EUR 940 million would be invested in Croatia's tourism next year.The ministry added that investments in 2017 amounted to EUR 817 million and in 2016 slightly over EUR 670 million.According to Croatia’s National Agency for Investments and Competitiveness, it was forecast that the country would welcome 90 million overnight stays by the end of 2017, and the need for hotel beds is increasing. Croatia also won the award for Accommodation Upgrades. It saw the opening of 40 new or refurbished hotels in 2016, a figure set to rise to 50 in 2017.Zagreb again voted best Christmas holiday destination in EuropeZAGREB, Dec 11 (Hina) - Zagreb has been voted best Christmas holiday destination in Europe for the third year in a row in an online poll on the European Best Destinations website, Zagreb's Tourist Board said on Monday.Zagreb won in a competition with 20 cities and is the only one holding the best Christmas holiday destination title for three consecutive years.A total of 200,596 people from 131 countries voted in the poll and Zagreb received 38,830 votes. Colmar, France came second with 24,625 votes.Zagreb has not earned the title with the Advent season's dazzle and diverse programme alone, but also with jumps in arrivals and bed/nights, the Tourist Board said. In the first nine days of this year's Advent, December 1-10, there were 37,685 arrivals, up 28% on the year, and 68,480 nights, an annual increase of 23%.Domestic guests generated 20,158 nights (+22%), while foreigners accounted for 48,322 (+24%). The most numerous foreigners came from Italy, Austria, Bosnia and Herzegovina, the UK and the US.Advent in Zagreb lasts until January 7.New keel set for polar cruise shipZAGREB, Dec 11 (Hina) - A keel was laid at the Brodosplit shipyard on Monday for a cruise ship to sail in polar regions which will be leased by Polar Expeditions Inc. and have permission to sail in the Arctic and the Antarctic, where the ice is up to 1.5 metres thick."This is the first Class LR PC6 polar ship to be produced in the world. Polar cruises are a growing trend and specific ships with added value are built for such navigation, and this ship will be ready to cruise already in the spring of 2019," the president of Brodosplit's management board, Tomislav Debeljak, said.He explained that the ship's renter - Polar Expeditions Inc. - will be obliged to buy the ship at any time the company decides to do so during the period of a ten-year lease from Brodosplit.Asked about the value of the ship, Debeljak said that that was confidential.The ship will be 108 metres long and almost 18 metres wide, and it will be able to accommodate 196 passengers in 85 cabins.The construction project leader, Frane Matulic, told reporters that building this ship will be exceptionally demanding because it will be sailing in Arctic and Antarctic waters where the ice is up to 1.5 metres thick."This ship will be able to push huge icebergs and this is a great step forward for Brodosplit," Matulic said.The ship will be equipped with twenty dinghies for passengers to be able to access interesting spots in the Arctic and the Antarctic, he added.A representative from Polar Expeditions Inc., Wynand von Gessel, underscored that he was certain that passengers would be satisfied with the new ship.Association of Agrokor's suppliers to be established WednesdayZAGREB, Dec11 (Hina) - The coordinating body of Agrokor's producers and suppliers announced in a statement on Monday it would establish an association of Agrokor's suppliers to protect their common interests.The producers and suppliers within the coordinating body have decided to formalise their relations by establishing an association of Agrokor's suppliers to improve communication with the public and all stakeholders in processes relating to a future settlement at Agrokor, the statement said.A founding meeting of the association was scheduled for Wednesday, December 13, in Zagreb.The statement said that the future association would be inclusive and open to all suppliers regardless of their size and type of claim in order to protect their common interests and would act as a partner to domestic banks and the government-appointed emergency administration at Agrokor in the time ahead.Vocational training has to be strategically developed, says ministerZAGREB, Dec 11 (Hina) - Minister of Science and Education, Blazenka Divjak underscored at a conference on modernising vocational education and training in Zagreb on Monday that she was exceptionally against a new system being developed parallel to vocational training with the intention of replacing it.On the contrary, Divjak said that a system of vocational training should bebe jointly thought out and strategically developed.She explained that vocational schools were notthe only ones that hada development component but that vocational schools as centres of competencies hadto attract employers, founders, agencies, all those who couldcontribute to developing a quality system that wouldmake vocations attractive.Minister Divjak was one of the key speakers at the conference on how to modernisevocational education and training, a project worth 2.35 million Swiss francs (HRK 15 million) and financed pursuant to a framework agreement between Switzerland and Croatia as part of an implementation cooperation programme to reduce economic and social inequality within the European Union's broader neighbourhood.The project's coordinator, Andreja Uroic Landelic said that negotiations with theSwiss Federal Institute for Vocational Education and Training began in October 2014. The framework agreement was signed in June 2015 and an agreement was signed on 21 March this year.The project will be co-financed with 85% of the funds coming from the Swiss Confederation and the remaining 15% will be provided by Croatia.The project started on 1 June and will continue until 30 April 2020, she said.There are two targets of the 35-month-long project: a vocational curriculum tailored for the labour market and vocational schools capable of promoting labour-based learning.Addressing the conference,the Swiss Ambassador to Croatia, Stefan Estermann, expressed support for the project.Round table held on strengthening judiciary's independenceZAGREB, Dec 11 (Hina) - Although the impression citizens have of the justice system is mainly negative, the situation is improving, a round table on the strengthening of the independence of the justice system and the rule of law heard on Monday.The round table was organised by the Documenta Centre for Dealing with the Past on the occasion of International Anti-Corruption Day, December 9."Citizens can be dissatisfied with Croatia's justice system, but it's a reflection of the society we live in and, as the whole society makes progress, so willthe justice system," said Drazen Jelenic, first deputy chief state prosecutor. He added that the recommendations of the Council of Europe Group of States against Corruption (GRECO) spoke to that.In its October 2016 report, GRECO said that, concerning the prevention of corruption among lawmakers, judges and countyattorneys, Croatia had fully met threeand partly four of 11 recommendations."A lot is being done regarding the justice system, there is a vision, but unfortunately, one of GRECO'simportant recommendations hasn't been met - to raise the quality of the justice system's communication with the public about what is good, and there's a lot of good," Jelenic said.A code of ethics for MPs would be very important, notably when it comes to commenting on the work of the justice system and specific cases, he added.Survey shows 68% of citizens have negative opinion of how judiciary worksThe round table heard the findings of a survey from 2016 which showthat 68% of citizens have a generally negative opinion of how the justice system works, 59% have no confidence in courts and 40% believe corruption in widespread in judicial institutions.Supreme Court judge and GRECO president Marin Mrcela said such surveys should be taken with reservations, citing a Transparency International survey in which 74% of respondents said the justice system was corrupt, but only 3% knew someone who had given a bribe.He said the negative public perception of the judiciary was due to the duration of proceedings, which sometimes took decades, some verdicts which shocked the public although subject to appeal, and politicians who often criticised the judicial authority.Mrcela said another reason were the media because they often reported on cases inexpertlyor published unverified data, such as that 20 corrupt judges were mentioned in a Security and Intelligence Agency report. "I'm not saying the situation is great. It must be much better and there's still a lot to do. However, many good decisions are not written about."Minister says new technologies should improve judiciary, public perceptionJustice Minister Drazen Bosnjakovic said the implementation of new technologies must result in a faster and better justice system as well as in a change of the public perception of its performance.One of such measures is the publication of judges' declarations of assets. The round table heard that judges were against it, but Bosnjakovic said he did not hearthat in talks with court presidents and judges."We want the declarations of assets to be published. We think it would contribute to restoring confidence in the justice system because in these times, when everyone suspects that the level of perception of corruption in the justice system is extremely high, this would be a small step to show that we have nothing to hide."Commenting on the survey showing that 68% of citizens have a generally negative opinion of how the justice system works and are unhappy with the influence of politics, Bosnjakovic said it was an impression, rather than the reality."I don't doubt those figures, but there are very complex cases in the justice system... It's important to say thatthere are big cases which are under public scrutiny and they very often overshadow a whole score of cases that are resolved well. We are a country which has about 1.6 million new cases annually and we resolve even more. Hundreds of thousands of cases are resolved in an orderly manner but that's not talked about."The minister said that"several years ago" there were 1.6 million pending cases, whereas now there were 500,000. "So, some work has been done," he added.15th anniversary of adoption of const. law on ethnic minorities' rights markedZAGREB, Dec 11, 2017 (Hina) - The constitutional law on national minorities' rightshas contributed to developing minority rights in Croatia, however, the high standards achieved cannot be final, according to some of the opinions presentedon Monday at a conference organised on the occasion of the 15th anniversary of the adoption of the law.The conference, held in the national parliament in Zagreb, brought together the authors of the law, politicians, religious dignitaries, academiciansand foreign diplomats.The constitutional law, on the one hand, certainly had a huge role in the process of integrating national minorities into Croatia society and on the other, it was also important in preservation of minorities' cultural and ethnic identity and in protecting them from ghettoisation and assimilation, the chairman of the Croatian Council for National Minorities,Aleksandar Tolnauer said.Minority rights means to achieve equal rightsThe law rounded off the model for exercisingrights, including, increasing the number of delegates in parliament from five to eight, participation of members of minorities in local affairs via councils and with minority representatives. It also enabled the establishment of the state-level Council as an umbrella organisation, the use of minority languages - orally and in writing as well as education in the language and script of national minorities, achieving cultural autonomy and so on, Tolnauer said.He recalled that the Croatian citizens "are living in conditions of recession and crisis which was always fertile ground for the emergence of intolerance,and xenophobia and prejudice against minorities" and underscored that minority rights are no extra rights but a means by which minorities can achieve the same rights as other citizens.It was not easy to adopt that law and it took a long time, however, what is important is that it was adopted by consensus, Deputy Parliament Speaker Furio Radin said.The period when the law was adopted wasturbulent,the end of one period and the start of another, the end of the 1990s marked by war and the beginning of a new area named a period of democracy, he said and added that the constitutional law contributed to developing minority rights.One of the authors of the law, Constitutional Court Judge Mato Arlovic underscored that the court consideredminority rights to be a human rights and freedoms.Law has withstood the test of timeThe constitutional law has withstood the test of time. It impacted Croatia's credibility in the world, President Kolinda Grabar-Kitarovic's envoy, Mate Granic, said, recalling that the first minority law was adopted in 1991 andwas one of the conditions for Croatia's international recognition.SDP chief: All elected local branch headshave my support, but...ZAGREB, Dec11(Hina) - Social Democratic Party (SDP) leader, Davor Bernardic on Monday commented on the election of Zeljko Sabo to head the Vukovar party branch and said that all heads of local branches elected by the will of the party's grassrootshad his support however,he added that it wasnecessary to seriously discuss who waseligible to be a candidate in the party, which he said, would be regulated by the new party Statute."It is a fact that the manwas charged withattempted political corruption while on the other hand we've had the opportunity to see political corruption at the highest level. (HNS leader Ivan) Vrdoljak, (former SDP member Tomislav) Saucha who are in an allegiance for thesake of interest with the Croatian Democratic Union (HDZ) and are saving and maintaining Plenkovic's government," Bernardic told the national broadcaster Hrvatski Radio, in reference to Sabo, a former mayor of Vukovar who was convicted of attempted bribery involving atown councillor and who served a sentence of seven months in prison.SDP has to consider the possibility of introducing criteria. "Something I wanted to introduce a few months' ago, which unfortunately did not gain support and things in SDP will probably change," he said.Asked whether as the leader of the largest ***opposition*** party he was automatically at the helm of the ***Opposition*** or if he hadto fight for that title, Bernardic saidthat theleader of the largest party in oppositionwas by default the leader of the ***Opposition***.Asked about his invitation to other ***opposition*** leaders for cooperation and whether he was prepared for a snap election or in three years' time, he said that the "media arewriting about coalitions at a time which isn't an election period.""We will start talking about coalitions when the elections become current. SDP has a ***strategic*** alliance with the Croatian Peasants' Party (HSS) and as far as future coalitions with the SDP are concerned, we can go into coalition with those parties that will support increasing the minimum wage, regulating employment contracts and so on...anyone who wishes to join that platform is welcome," he said.In reference to the Bridge party rejecting his suggestion for cooperation, Bernardic said that "we will never close the door on anyone," and addedthat all he was interested in was a coalition with citizens.Bernardic: HDZ undertakes to cooperate with ICTYCommenting on today's commemoration for General Slobodan Praljak and the reactions to the conviction ofsix Bosnian Croat wartime political and military leaders and the way Croatian authorities reacted, he underscored, "HDZ undertook to cooperate with the International Criminal Tribunal for the former Yugoslavia (ICTY) in The Hague and extradited all those Croatiangenerals.""It is a fact that Croats from Bosanska Posavina (northern Bosnia and Herzegovina) were completely expelled, thanks to HDZ's policies. It is a fact that after the war, 200,000 left their homes in Bosnia and Herzegovina. It is a fact that Croats are a dying race in Bosnia and Herzegovina thanks to HDZ's policies. It is also a fact that that anyone who slaughtered men, shot children and raped women has to answer for war crimes and that a war crime is a war crime, no matter how hard someone tries to cover that up and someone has to answer for that," said Bernardic.There was no joint criminal enterprise, he underscored. There was individual responsibility.Asked whether convicted generals should be stripped of their decorations, Bernardic said, "it would be best if you ask (Prime Minister Andrej) Plenkovic that at the next summit in Brussels."Friends and fellow soldiers organise commemoration for late General PraljakZAGREB, Dec11(Hina) - Many friends and fellow fighters as well as distinguished public figurespacked Zagreb's Vatroslav Lisinski Hall on Monday for a commemoration in tribute to Slobodan Praljak, who poisoned himself on 30 November in a courtroom of the UN warcrimes tribunal (ICTY) when itupheld his 20-year sentence for war crimes committed during the Croat-Bosniak conflict in Bosnia and Herzegovina in 1993."Slobodan Praljak was a man full of life, and his main irresistible feature was his sincere patriotism... He was a general who defended his homeland and he did credit to his army," said Pavao Miljavac, who is the president of the association of retiredCroatian generals Hrvatski Casnicki Zbor.Miljavac recalled that Praljak had never been satisfied with mediocrity and always strove for excellence, as evidenced bythe fact that he graduated from three faculties. Heparticularly praised Praljak's professional skills in warfare."Unfortunately, the trial before the (International Criminal Tribunal for the former Yugoslavia) at The Hague was an unfairbattle," Miljavac said, adding that Praljak' suicide was actually his attempt to dismissall the accusations against himself and to protect the dignity of people whom he had commanded."He took his life in front offlabbergasted observers who incold bloodinflicted injustice, being sure that there was no way to defeat them. But they were wrong," Miljavac said.Croatian Democratic Union (HDZ) lawmaker Miroslav Tudjman, who is a member of the association of retired Croatian generals, addressed the commemoration in his private capacity and as a friend of Praljak."SlobodanPraljak did not want to live as a war criminal for even aminuteas he was not a war criminal," Tudjman said and recalled that just before taking poison Praljak shouted that he rejected the tribunal's verdict with contempt.Tudjmansaid that the judgement handed down on 30 November was unfair as it did not provide victims with satisfaction because the tribunal failed to punish those who actually committed those war crimes.Tudjman insists that Praljak also rejected the verdict as it did not reflecthistorical truths and facts about the conflict between the Muslims (Bosniaks) and the Croats in central Bosnia.Other speakers at the commemoration also praised Praljak for his sincerity and generosity towards his fellow fighters.The commemoration began with Ivan Gundulic's "Ode to Freedom" which actor Dragan Despot read out.In attendancewere Defence Minister Damir Krsticevic,War Veterans' Affairs Minister Tomo Medved, HDZ Vice-President Milijan Brkic, former HDZ officialsVladimir Seks, Luka Bebic, Andrija Hebrang, Ivan Penic, ICTY convict Dario Kordic and war veteran activists.Youth Initiative for Human Rights calls on citizens to pay tribute to victims of Croat-Bosniak conflictThe Youth Initiative for Human Rights, a nongovernmental organisation, on Monday called on Croatians to join in lighting candles for victims of the Croat-Bosniak conflict during the war in Bosnia and Herzegovina. The campaign was tobe held in downtown Zagreb between 5and 6 pm today.The NGO said in a press release that it wanted to express itssympathy withvictims of war crimes committed by Croat troops.We want to show to the families of those victims and to those who survived war crimes that Croatia is not unanimous in glorifying war criminals and war crimes, the associationsaid.We want to showthat there are people who are tireless in demanding that crimes committed on behalf of or in the name of Croatia should be admitted and punished, the NGO said, among other things.On 30 November, the ICTY Appeals Chamber upheld the sentences against six wartime Bosnian Croat civilian and military leaders in the Prlic et al. case. Former Herceg-Bosna PM Jadranko Prlic was sentenced to 25 years' imprisonment, former defence minister Bruno Stojic and former HVO chiefs-of-staff Praljak and Milivoj Petkovic to 20 years each, former HVO military police commander Valentin Coric to 16 years, and the chief of the POW exchange office, Berislav Pusic, to ten.As soon as his verdict was upheld, Praljakdrank poison in the court room, dying inhospital shortly later.Group of activists light candles for victims of war crimes in BosniaZAGREB, Dec 11 (Hina) - Organised by the Youth for Human Rights Initiative, dozens of citizens lit candles and laid roses in Zagreb's French Republic Square on Monday for the victims of crimes committed by the Bosnian Croat Defence Council (HVO) and the Croatian Army (HV) during the 1990s war in Bosnia and Herzegovina (BiH).The NGO organised the candle lighting out of solidarity with all the victims of the Croat forces in BiH, one of its coordinators, Nikola Puharic, told reporters. "We gathered here because we wanted to show that there is a Croatia which does not show solidarity with war criminals but with the victims."He said they were disappointed with the government and the Zagreb city authorities because they expressed big solidarity with war criminals and did not sufficiently condemn the crimes for which some HVO and HV members were responsible.Puharic said the NGO wanted to send the message that young generations needed something better and "a condemnation of Croatia's aggressive activity in BiH."He said there was a silent majority in Croatia which condemned every war crime and every war criminal, adding that it was necessary to responsibly deal with the past, condemn every crime and not show solidarity with war criminals."We must show solidarity with the victims, implement transitional justice mechanisms, send reparations and an apology to the victims, and work so that every crime is prosecuted," Puharic said.Journalists Association slams death threats against Natasa Bozic SaricZAGREB, Dec 11 (Hina) - The Croatian Journalists Association (HND) on Monday condemned in the strongest terms the insults and death threats which journalist Natasa Bozic Saric received on social media after her Sunday's weekly TV show.She reported the threats to the police and the HND urges the authorities to urgently find and punish the author of the threats, the HND said in a press release.After her "TNT" show on N1 television which discussed the events of the week, Bozic Saric received the threat that her head should be cut off, presumably because of a talk on general Slobodan Praljak and her question if he should be stripped of his decorations, the HND said, adding that this was a continuation of pressures on journalists, "including death threats, physical assaults and attempted murders."Praljak recently committed suicide after the Hague war crimes tribunal upheld his 20-year sentence for crimes committed in Bosnia and Herzegovina.In the last few years the HND has recorded 40 cases of threats and attacks, only in several was the perpetrator punished or is on trial, and they mainly involve perpetrators who did not hide their identity, the HND said. In all other cases neither the HND nor the journalists attacked are receiving any information about the investigations or if they have even been launched, it added.The HND said "there is no political will to solve the cases of assaults on journalists."Bosnian association: War victims should receive reparations from regional fundZAGREB, Dec11(Hina) - Bosnian associations of Bosniak war victims believe it isjust and necessary that war victims should receive compensation, best from a fund to be formed by Croatia, Bosnia and Herzegovina (BiH), and Serbia, the president of theBiH association of former concentration camp inmates, Jasmin Meskovic, said in Sarajevo on Monday."We wouldn't want to damageanyone. Neitherthe Croatian government nor policy, neitherCroatian citizens nor victims. We just have a position that we won't give up. Reparation for victims must be carried out," he told Hina.Meskovic said the "least painful" solution would bethe establishment of a reparationfund based on an agreement between Croatia and BiHgiven that the Hague war crimes tribunal's judgement in the Prlic et al. case established Croatia's responsibility for events in BiH in 1993. He added that Serbia should not evade its share ofthe responsibility and pay reparations too.He said the reparation fund was "a hand of reconciliation. If they say they don't want it or won't do it, lawyers will take matters into their hands and we will withdraw."TheBiHassociation of former concentration camp inmates will initiatea regional conference at which BiH, Serbia and Croatia would agree the establishment of a joint reparation fund. Meskovic said something similar was already happening as Croatia is paying Bosnian Croat war victims from its budget, in line with constitutional and legal commitments.He said the victims would receive reparations from the new regional fund regardless of ethnicity and that this was "the first and best option." If the initiative receivesnosupport, individual or class action suits willbe filed and a decision on which course to take will be made by the end of this week, he added.Meskovic said theBiHassociation of former concentration camp inmates was consulting lawyers in BiH and Croatia about their options following the Hague tribunal's conviction of six former Bosnian Croat political and military leaders, but that no decisions could bemade before they sawa translation of the entire judgement.Speaking of Croatia, he said filing individual reparation suits was probably the last option and that the establishment of a regional reparations fund would be the most just solution.He saidtheBiHassociation of former concentration camp inmates received daily expressions of support from Croatia, adding thatthis was encouraging as such individuals and organisations clearly distanced themselves from all the crimes committed during the 1990s war and wanted reconciliation.Meskovicsaid he would like BiH to do more on that front. "Then, as now, the victims are on their own."Ex-Bosnian Army members arrested on suspicion of HVO General Santic's murderZAGREB, Dec 11 (Hina) - Five men, including a former high-ranking officer in the Army of Bosnia and Herzegovina, Hamdija Abdic, also known as Tigar, were arrested on Monday in the areas of Bihac and Cazin, northwestern Bosnia and Herzegovina on suspicion of involvement in the murder of the wartime Bosnian Croat general Vlado Santic, local authorities in Bihac said.The official press release only gives the initals of the five arrestees, however, local media outlets reported that Abdic and his four fellow soldiers were nabbed on suspicion of kiling General Santic in the night between 8 and 9 March 1995.Santic, who had the HVO general's rank, went missing on 9 March 1995. He was last seen in the hotel Sedra, outside Bihac, in the company of Bosnian Army General Atif Dudakovic. Santic's son insists that Dudakovic orchestrated the killing of his father. Since Santic's disappearance, other Croat officials from time to time have pointed the finger at General Dudakovic who in 1995 was the commander of the Bosnian Army's Fifth Corps, with headquarters in Bihac. Several eyewitnesses already confirmed that Bosnian Army soldiers, including Abdic, had forcibly taken Santic out of the hotel on 8 March 1995.Some eyewitnesses have also testified that General Santic had been taken from the hotel to the old railway station building in Bihac, which was the headquarters of the Bosnian Army military police, and that later that night he had been brought out from the building on stretchers, which was interpreted as indicating that he was still alive but severely beaten.Family insists case be treated as war crimeFollowing the apprehension of the five suspects, the family of the late General Santic said they were sure that the arrested men were responsible for Santic's killing.However, members of the Santic family say they are dissatisfied with the fact that the case is not being treated as a war crime but only as a murder case, according to a statement gave by the family's lawyer.Bosnian military attache in Netherlands arrested for war crimesZAGREB, Dec11(Hina) - Bosnian Armed Forces Colonel Enes Jahic, Bosnia and Herzegovina'smilitary attache in the Netherlands, was arrested in BiH on Monday on suspicion of involvement in war crimes against Serbs in 1992.BiHState Court spokeswoman Boris Grubesic told local media Jahic was brought in for questioning after being arrested at a border crossing as he was entering the country.He is under investigation for a crime the Bosniak troops of theArmy of BiH and Konjic police committed in the village of Bradina in May 1992. Dozens of civilians were killed and the entire Serb population was expelled andtheir houses and the Orthodox Church were set on fire. Two boys, aged five and six, were shot dead.Thirteen former Army of BiH soldiers and police were arrested for this crime last week. Jakic was reportedly one of those who commanded the attack on the village as the headof a special police unit from Konjic.The BiH Defence Ministry website says Jahic was decorated by the US in 2014 for his work in ***strategic*** planning and military analysis at the United States Central Command HQ in Tampa, Florida, where he took part in an exchange programme.New highway section within Corridor Vc in north Bosnia open to trafficZAGREB, Dec11(Hina) - A newEUR 17.5-million10-kilometre-longhighwaysection within Corridor Vc corridorpassing though Bosnia and Herzegovina was inaugurated on Monday.For the time being, only locals in the area of Odzak in the Bosanska Posavina region will benefit from the new section of the motorway as the section is yet to be connected to the new bridge over the Sava River, at Svilaj, towards Croatia, but also to the Bosnian section of the road, leading to the south of the country.The Svilaj-Odzak section of the highway was entirely financed by grants given through theWestern Balkans Investment Framework (WBIF).WBIFis a regional blending facility supporting EU enlargement and socio-economic development in Albania, Bosnia and Herzegovina, Kosovo, Macedonia, Montenegro, and Serbia.The Bosnia-Herzegovina partof the pan-EuropeanCorridor Vc is planned to run for 330 km from the north to the south of the country. Approximately 130 kilometres have been built so far.Slovenia prefers delay of NLB privatisation in fear of possible litigation from CroatiaZAGREB, Dec 11 (Hina) - Following the Croatian clients's decision to transferold foreign savings accounts from the now defunct Ljubljana Banka to Croatian banks so that their frozen deposits could be paid out, the market value of the New Ljubljanska Banka (NLB) is between EUR 350 million and EUR400 million lower than its real value, Slovenia's Prime Minister Miro Cerar said on Monday.Explaining in parliament why the government has decided at the end of its term to negotiate with the European Commission on Ljubljana's plan to postpone the sale of NLB for three years, Cerar said that the aim was for Slovenia's tax payers to be affected as little as possible.Cerar denied accusations that it was irresponsible to ask for the delay, while critics find possible postponementwas jeopardising the country's credibility with the European Commission and further reducing the value of the bank.According to Cerar, the government had intended to fulfilits obligation of selling three-quarters of NLB but pulled out of the sale after financial consultants warned that the bank's potential liabilities in the lawsuits with Zagrebacka Banka and Privredna Banka Zagreb, concerning transferred savings of Croatian clients, could amount to between EUR 350 millionto EUR 400 million, which is too high a risk for the sale this year.Cerar added that the government has been in talks with the European Commission for the past six months over the privatisation that his predecessor agreed to during the time of the financial and banking crisis."For Slovenia it is important that NLB remains a strong bank in the region of southeast Europe and that is our main objective," Cerar said.He confirmed that in the event of the consensual postponement of the sale, Slovenia would also propose that an independent administrator would manage the bank until its final privatisation.In other news:President temporarily relocates her office to Bjelovar-Bilogora CountyZAGREB, Dec11, 2017 (Hina) - Croatian President Kolinda Grabar-Kitarovic temporarily relocated her office to Bjelovar-Bilogora County on Monday.At a receptionheld on that occasion, the president said the northern city of Bjelovar was an example of how to run an ambitious, proactive policy, without waiting for state measures."However, state measures must not, and hopefully will not, fail to take place as it is high time for us to turn to measures which will help create new jobs," Grabar-Kitarovic said."It is necessary to change the development paradigm as soon as possible and stop focusing only on the four biggest cities. Development must be polycentric and county headquarters such as Bjelovar finally become development centres," she said and praised the measure aimed at turning Bjelovar into Croatia's first "tax free" city, namely to exempt investors from paying municipaltaxes.Grabar-Kitarovic, however, pointed out the fact that Bjelovar-Bilogora Countyhas been constantly losing population since 1968. Between 2001 and 2011, the county's population dropped by 10,000, she said.The president was welcomed by Bjelovar Mayor Dario Hrebak and Bjelovar-Bilogora County Prefect Damir Bajs.Milan Blaževic new commander of Croatian Coast GuardZAGREB, December 12, 2017 (Hina) - Navy Captain Milan Blazevic has taken over the Duty of Croatia's Coast Guard Commander, the Croatian Defence Ministry said in a press release Monday.Blazevic took over the duty from Commodore Ivo Raffanelli, the ministry said.Indian Cinema Days at Zagreb's Metropolis Cinema on Dec 11-16ZAGREB, Dec 11 (Hina) - Indian Cinema Days will be held at the Metropolis Cinema at the Museum of Contemporary Art in Zagreb on December 11-16, featuring five recent films.The event kicks off with Bang Bang, an action comedy directed by Siddharth Anand. A remake of the American film Knight and Day starring Tom Cruise and Cameron Diaz, it tells the story of a young bank receptionist who gets mixed up with a man of a mysterious background.It will be followed by Anand L. Rai's Tanu Weds Manu, a romantic comedy about a young Indian man who returns home from London to find himself a perfect wife, and Vikas Bahl's Queen, a comedy drama about a Delhi girl from a traditional family who sets out on a solo honeymoon after her marriage gets cancelled.Mary Kom, a biographical drama by Omung Kumar, chronicles the life of Indian boxer Mary Kom, who went through several hardships before audaciously accomplishing her ultimate dream.The festival will round off with Amole Gupte's Hawaa Hawaai, a family sports film about a boy dreaming of becoming a skating champion.The festival takes place under the auspices of the Indian Embassy in Zagreb and in collaboration with the Metropolis Cinema.All the films have Croatian and English subtitles, and admission is free.Petrokemija shareholders decide on recapitalisationZAGREB, Dec 11 (Hina) - Shareholders in the Petrokemija artificial fertiliser manufacturer decided at an extraordinary assembly on Monday to launch the process of injecting fresh capital in the amount of HRK 450 million into the plant.The company's equity will be increased through the issuance of 45 million regular shares at a nominal value of HRK 10 per sharewith the use of the right of being excused of the obligation to release a prospectus related to a public offer and with the complete exclusion of priority rights of existing shareholders in registering new shares.The minimum amount that an individual investor can pay to register new sharesis HRK 780,000 and the investor cannot register less than 78,000 new shares.Petrokemija's equity would hence be increased from HRK 42.9 million by a maximum of HRK 450 million to HRK 492.9 million.Earlier, Petrokemija reported that it had received several binding bids that were forwarded to the Restructuring and Sale Centre (CERP) and that Ministry for State Assets for further procedure.According to media reports, 11 companies are interested in investing in the Kutina fertiliser factory, including Austria's Borealis, Poland's Azoty, the Croatian PPD company and the INA oil company as well as the Fatima Group from Pakistan, the European Bank for Reconstruction and Development (EBRD) and several funds.In mid-November, State Assets Minister Goran Maric said that the recapitalisation would certainly succeed and bring the company at least HRK 400 million in fresh capital.In the first nine month's of the year, Petrokemija generated a total revenue of HRK 1.45 billion, which is 0.9% less on the year while the company's losses amounted to HRK 119.5 million.In the same period last year that loss was HRK 29.7 million.HZZ: 188,056 unemployed at the end of NovemberZAGREB, Dec11(Hina) -A total of 188,056jobseekers were registered with the Croatian Employment Service (HZZ) at the end of November 2017, which was 4.2% or 7,652 persons more than at the end of October 2017 and 19% or 44,211persons fewer than at the end of November 2016, the HZZ said on Monday.Daily data from the HZZ shows that the number of unemployed persons will continue to increase throughout December, given that the number is currently standing at 188,780, with 13,840 open vacancies.In November 2017, there were 4,790 newly-registered job seekers and another 1,279 who just finished school.A total of 20,150 people were ***deleted*** from the unemployment data base in November, which is 15.8% less than in November 2016.Construction work in Sept up 0.9% y-o-yZAGREB, Dec 12 (Hina) - The volume of construction work in Croatia increased by 0.9% in September 2017 compared with September 2016, but decreased by 0.1% compared with August 2017, figures released by the National Bureau of Statistics (DZS) show.In September 2017, compared with September 2016, the volume of construction work on buildings rose by 8.4%, while the volume of construction work on other structures fell by 6.1%.In the first nine months of 2017, compared with the same period of 2016, construction activity increased by 1.4%. Work on buildings increased by 5.9%, while work on other structures dropped by 2.9%.ZSE indices riseZAGREB, Dec 11 (Hina) - The main Zagreb Stock Exchange indices rose on Monday with the Crobex increasing by 0.29% to 1,854.45 points compared to Friday while the specialised Crobex10 grew by 0.56% to 1,086.29 points.Regular turnover amounted to HRK 8.46 million, which is about HRK 5.2 million higher than on Friday.The most liquid stock was of the Koncar electrical industry with a turnover of HRK 3.7 million. The price of its shares jumped by 0.71% to HRK 700.The Valamar Riviera tourism company generated a turnover of HRK 2.5 million with the price of its share slipping by 0.2% to HRK 44.(EUR 1 = HRK7.540134THIS BULLETIN INCLUDES NEWS ITEMS RELEASED BY 0830 HRS TUESDAY. (Hina) ms Masthead Brief News Bulletin is published by the Croatian News Agency HINA Marulićev trg 1610 000 ZagrebCroatia web:[*www.hina.hr*](http://www.hina.hr) mail: [*hina@hina.hr*](mailto:hina@hina.hr) phone: (+385 1) 48 08 660; fax (+385 1) 48 08 822 Publisher: Branka Gabriela Valentić, DirectorEditor in Chief: Serđo Obratov Bulletin Editor: Marija Šestan

ZAGREB, Dec11(Hina) - Zagreb sticks to its position that the border dispute between Croatia and Slovenia should be addressed bilaterally, Croatia's Foreign and European Affairs Minister Marija Pejcinovic Buric said in Brussels on Monday after a recent statement byEuropean Commission's Vice President Frans Timmermans that this was a dispute between two countries and the announcementby Slovenia's Foreign Minister Karl Erjavec about Ljubljana's intention to sue Croatia over this row.

ZAGREB, Dec 11 (Hina) - Croatia at this point does not want to commit itself to a specific date for joining the euro area but wants to implement a good and well-reasoned public consultation on euro adoption, Finance Minister Zdravko Maric told reporters on the margins of a conference on the costs and benefits of euro adoption, organised by the Croatian National Bank (HNB).

ZAGREB, Dec11(Hina) - Croatian National Bank (HNB) governor Boris Vujcic said on Monday the benefits of introducing the euro in Croatia could be relatively bigger than in some countries that had already introduced it, while Slovak Finance Minister Peter Kazimir said entering the euro area had contributed to a 10% GDP growth in his country.

ZAGREB, Dec11(Hina) -FDi's inaugural Tourism Editor's Choice Awards for tourism single out the countries that have devised specific and successful strategies to attract investment.

ZAGREB, Dec 11 (Hina) - Zagreb has been voted best Christmas holiday destination in Europe for the third year in a row in an online poll on the European Best Destinations website, Zagreb's Tourist Board said on Monday.

Zagreb won in a competition with 20 cities and is the only one holding the best Christmas holiday destination title for three consecutive years.

A total of 200,596 people from 131 countries voted in the poll and Zagreb received 38,830 votes. Colmar, France came second with 24,625 votes.

Zagreb has not earned the title with the Advent season's dazzle and diverse programme alone, but also with jumps in arrivals and bed/nights, the Tourist Board said. In the first nine days of this year's Advent, December 1-10, there were 37,685 arrivals, up 28% on the year, and 68,480 nights, an annual increase of 23%.

Domestic guests generated 20,158 nights (+22%), while foreigners accounted for 48,322 (+24%). The most numerous foreigners came from Italy, Austria, Bosnia and Herzegovina, the UK and the US.

Advent in Zagreb lasts until January 7.

ZAGREB, Dec 11 (Hina) - A keel was laid at the Brodosplit shipyard on Monday for a cruise ship to sail in polar regions which will be leased by Polar Expeditions Inc. and have permission to sail in the Arctic and the Antarctic, where the ice is up to 1.5 metres thick.

"This is the first Class LR PC6 polar ship to be produced in the world. Polar cruises are a growing trend and specific ships with added value are built for such navigation, and this ship will be ready to cruise already in the spring of 2019," the president of Brodosplit's management board, Tomislav Debeljak, said.

He explained that the ship's renter - Polar Expeditions Inc. - will be obliged to buy the ship at any time the company decides to do so during the period of a ten-year lease from Brodosplit.

Asked about the value of the ship, Debeljak said that that was confidential.

The ship will be 108 metres long and almost 18 metres wide, and it will be able to accommodate 196 passengers in 85 cabins.

The construction project leader, Frane Matulic, told reporters that building this ship will be exceptionally demanding because it will be sailing in Arctic and Antarctic waters where the ice is up to 1.5 metres thick.

"This ship will be able to push huge icebergs and this is a great step forward for Brodosplit," Matulic said.

The ship will be equipped with twenty dinghies for passengers to be able to access interesting spots in the Arctic and the Antarctic, he added.

A representative from Polar Expeditions Inc., Wynand von Gessel, underscored that he was certain that passengers would be satisfied with the new ship.

ZAGREB, Dec11 (Hina) - The coordinating body of Agrokor's producers and suppliers announced in a statement on Monday it would establish an association of Agrokor's suppliers to protect their common interests.

The producers and suppliers within the coordinating body have decided to formalise their relations by establishing an association of Agrokor's suppliers to improve communication with the public and all stakeholders in processes relating to a future settlement at Agrokor, the statement said.

A founding meeting of the association was scheduled for Wednesday, December 13, in Zagreb.

The statement said that the future association would be inclusive and open to all suppliers regardless of their size and type of claim in order to protect their common interests and would act as a partner to domestic banks and the government-appointed emergency administration at Agrokor in the time ahead.

ZAGREB, Dec 11 (Hina) - Minister of Science and Education, Blazenka Divjak underscored at a conference on modernising vocational education and training in Zagreb on Monday that she was exceptionally against a new system being developed parallel to vocational training with the intention of replacing it.

ZAGREB, Dec 11 (Hina) - Although the impression citizens have of the justice system is mainly negative, the situation is improving, a round table on the strengthening of the independence of the justice system and the rule of law heard on Monday.

ZAGREB, Dec 11, 2017 (Hina) - The constitutional law on national minorities' rightshas contributed to developing minority rights in Croatia, however, the high standards achieved cannot be final, according to some of the opinions presentedon Monday at a conference organised on the occasion of the 15th anniversary of the adoption of the law.

ZAGREB, Dec11(Hina) - Social Democratic Party (SDP) leader, Davor Bernardic on Monday commented on the election of Zeljko Sabo to head the Vukovar party branch and said that all heads of local branches elected by the will of the party's grassrootshad his support however,he added that it wasnecessary to seriously discuss who waseligible to be a candidate in the party, which he said, would be regulated by the new party Statute.

ZAGREB, Dec11(Hina) - Many friends and fellow fighters as well as distinguished public figurespacked Zagreb's Vatroslav Lisinski Hall on Monday for a commemoration in tribute to Slobodan Praljak, who poisoned himself on 30 November in a courtroom of the UN warcrimes tribunal (ICTY) when itupheld his 20-year sentence for war crimes committed during the Croat-Bosniak conflict in Bosnia and Herzegovina in 1993.

ZAGREB, Dec 11 (Hina) - Organised by the Youth for Human Rights Initiative, dozens of citizens lit candles and laid roses in Zagreb's French Republic Square on Monday for the victims of crimes committed by the Bosnian Croat Defence Council (HVO) and the Croatian Army (HV) during the 1990s war in Bosnia and Herzegovina (BiH).

The NGO organised the candle lighting out of solidarity with all the victims of the Croat forces in BiH, one of its coordinators, Nikola Puharic, told reporters. "We gathered here because we wanted to show that there is a Croatia which does not show solidarity with war criminals but with the victims."

He said they were disappointed with the government and the Zagreb city authorities because they expressed big solidarity with war criminals and did not sufficiently condemn the crimes for which some HVO and HV members were responsible.

Puharic said the NGO wanted to send the message that young generations needed something better and "a condemnation of Croatia's aggressive activity in BiH."

He said there was a silent majority in Croatia which condemned every war crime and every war criminal, adding that it was necessary to responsibly deal with the past, condemn every crime and not show solidarity with war criminals.

"We must show solidarity with the victims, implement transitional justice mechanisms, send reparations and an apology to the victims, and work so that every crime is prosecuted," Puharic said.

ZAGREB, Dec 11 (Hina) - The Croatian Journalists Association (HND) on Monday condemned in the strongest terms the insults and death threats which journalist Natasa Bozic Saric received on social media after her Sunday's weekly TV show.

She reported the threats to the police and the HND urges the authorities to urgently find and punish the author of the threats, the HND said in a press release.

After her "TNT" show on N1 television which discussed the events of the week, Bozic Saric received the threat that her head should be cut off, presumably because of a talk on general Slobodan Praljak and her question if he should be stripped of his decorations, the HND said, adding that this was a continuation of pressures on journalists, "including death threats, physical assaults and attempted murders."

Praljak recently committed suicide after the Hague war crimes tribunal upheld his 20-year sentence for crimes committed in Bosnia and Herzegovina.

In the last few years the HND has recorded 40 cases of threats and attacks, only in several was the perpetrator punished or is on trial, and they mainly involve perpetrators who did not hide their identity, the HND said. In all other cases neither the HND nor the journalists attacked are receiving any information about the investigations or if they have even been launched, it added.

The HND said "there is no political will to solve the cases of assaults on journalists."

ZAGREB, Dec11(Hina) - Bosnian associations of Bosniak war victims believe it isjust and necessary that war victims should receive compensation, best from a fund to be formed by Croatia, Bosnia and Herzegovina (BiH), and Serbia, the president of theBiH association of former concentration camp inmates, Jasmin Meskovic, said in Sarajevo on Monday.

ZAGREB, Dec 11 (Hina) - Five men, including a former high-ranking officer in the Army of Bosnia and Herzegovina, Hamdija Abdic, also known as Tigar, were arrested on Monday in the areas of Bihac and Cazin, northwestern Bosnia and Herzegovina on suspicion of involvement in the murder of the wartime Bosnian Croat general Vlado Santic, local authorities in Bihac said.

The official press release only gives the initals of the five arrestees, however, local media outlets reported that Abdic and his four fellow soldiers were nabbed on suspicion of kiling General Santic in the night between 8 and 9 March 1995.

Santic, who had the HVO general's rank, went missing on 9 March 1995. He was last seen in the hotel Sedra, outside Bihac, in the company of Bosnian Army General Atif Dudakovic. Santic's son insists that Dudakovic orchestrated the killing of his father. Since Santic's disappearance, other Croat officials from time to time have pointed the finger at General Dudakovic who in 1995 was the commander of the Bosnian Army's Fifth Corps, with headquarters in Bihac. Several eyewitnesses already confirmed that Bosnian Army soldiers, including Abdic, had forcibly taken Santic out of the hotel on 8 March 1995.

Some eyewitnesses have also testified that General Santic had been taken from the hotel to the old railway station building in Bihac, which was the headquarters of the Bosnian Army military police, and that later that night he had been brought out from the building on stretchers, which was interpreted as indicating that he was still alive but severely beaten.

Family insists case be treated as war crime

Following the apprehension of the five suspects, the family of the late General Santic said they were sure that the arrested men were responsible for Santic's killing.

However, members of the Santic family say they are dissatisfied with the fact that the case is not being treated as a war crime but only as a murder case, according to a statement gave by the family's lawyer.

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**Body**

Washington: The Library of Congress, The Government Washington: of USA has issued the following house proceeding:

 The PRESIDING OFFICER. The clerk will report the nomination. The senior assistant legislative clerk read the nomination of Thomas Lee Robinson Parker, of Tennessee, to be United States District Judge for the Western District of Tennessee. The PRESIDING OFFICER. The Senator from Utah. Tribute to Chris Campbell Mr. HATCH. Mr. President, I rise to pay tribute to a trio of excellent staffers, all of whom served with distinction on the Senate Finance Committee for a number of years and who recently left the committee to pursue other ventures.

First, Mr. President, I would like to say a few words about Chris Campbell, a longtime friend and trusted adviser, who until recently served as the Republican staff director on the committee. Last summer, he was nominated and confirmed to serve as Assistant Secretary of the Treasury for Financial Institutions. I have known Chris for more than 17 years, and I cannot overstate his importance and contributions to my years of work here in the Senate. Chris joined my campaign for President back in 2000, where I immediately recognized his talent and leadership abilities and appointed him to be my national field director, although he was relatively young and inexperienced at the time. Needless to say, I don't blame Chris for how that particular campaign turned out. In fact, that same year, I asked him to serve as director for my Senate reelection campaign, which thankfully met with much better results. After that, he came to Washington to serve on my staff on the Senate Judiciary Committee. [[Page S90]] I have long urged my staffers to get as much education as possible to enhance their understanding and gain new perspectives. I nagged Chris about this during my Presidential campaign. Eventually, after working on my staff for a few years, he wanted to upgrade his bachelor's degree in political science from the University of California at Santa Barbara with an MBA from the Thunderbird School of Global Management. A short time after receiving his MBA and a brief stint in the private sector, Chris desired to return to public service, and when he returned to Washington, I hired him back without hesitation and asked him to serve as my legislative director, a post he held until 2011 when I took over as the lead Republican on the Finance Committee and appointed him to be the staff director. During his time on the committee staff, Chris quarterbacked every major effort we undertook. This includes successes like the approval of free-trade agreements, the bipartisan renewal of trade promotion authority and the modernization of U.S trade laws, the repeal and replacement of the Medicare sustainable growth rate, and the long-term funding of the Federal highway trust fund, just to name a few. Of course, his work on the long-term tax reform effort was invaluable. We began our work on tax reform right out of the gate in 2011 and worked with Chairman Baucus and others to drive it forward. Chris was a key part of all of the work we did over the years to advance tax reform. While his move to Treasury came just before the final stages of that effort, I was fortunately able to benefit from his continued advice and counsel as we moved closer to and eventually crossed the finish line. Chris is a shrewd but effective negotiator and a brilliant legislative strategist. Congressional Quarterly named him one of the seven most influential non-elected people working in Congress, and Roll Call put him on its list of the 50 most influential staffers on Capitol Hill for 7 straight years. Clearly, I am not the only one who recognizes his abilities. I know the other members of the Finance Committee--on both sides of the aisle--have also acknowledged and benefited from his years of work. Still, even with all of his accomplishments, what stands out most to me about Chris Campbell is his life story. He is a great example of how hard work and education can help a person become much more than what some statistician might predict. Chris grew up in Hemet, CA, as one of six children who struggled--and that is putting it lightly--to make ends meet. He didn't grow up with family connections or powerful benefactors, but thanks to his diligence and determination and no shortage of natural ability, he became one of the most effective and influential staffers on Capitol Hill, and he now serves in a key leadership role in the administration. While it pained me to see him head off to Treasury, I have been comforted to know that the President knows how to pick the best people and that the Department of the Treasury is being well served. I personally want to thank Chris for his years in working with me, for his candid and thoughtful advice, and for his commitment to public service. I wish him all the best in his future endeavors, which I am quite sure will be just as successful as his time here. Tribute to Becky Shipp Mr. President, I would like to say a few words about another former staffer, Becky Shipp, who also left the Finance Committee staff a few months ago to pursue another venture. While I have known Becky for more years than either she or I would like to count, I can tell you that she served tirelessly on the Senate Finance Committee for more than 10 years. She saw chairmen come and go and was an institution here in her own right. In my time on the Hill, I have come to know many different staffers, all of whom got involved in the government for all types of well- meaning and patriotic reasons. They each have some expertise, some interest, and some motivation that helps them get through the hard times that staff encounter with the stressful conditions and the below- market pay. I have long said that Senators and staff take on sacred obligations when we come to work here, and I cannot think of many who have taken that sacred obligation to heart more than Becky Shipp. She spent her time in Congress working on welfare and human resource issues. Her dedication and zealousness in defending the less fortunate should serve as an example to all of us. While issues surrounding child welfare, child and family services, and foster care programs are often overlooked, anyone in Washington who knows anything about these issues knows that Becky has played a singular role in the creation and preservation of the safety net we now have in place. Too often, welfare issues become bitterly partisan, but during Becky's time here, she always strove to find common ground no matter the personal sacrifice. Her time on the Hill was extremely productive and impacted far more children and families than most any of us could probably ever count. Still, it was not without moments that, when looking back, seemed pretty lighthearted. One such moment came just a few years ago after many in Congress had become aware of the fact that welfare funds distributed through electronic bank transfers had been used by some to purchase alcohol, food, or other illicit items from strip clubs and other less than savory establishments. Becky quietly began developing a proposal to prevent this type of abuse. Eventually, her idea gained more traction than she thought it would initially. Once members of the Finance Committee and in the House began to realize the nature of this problem, her proposal caught on like wildfire. The problem was that the Social Security Act did not have a definition for these establishments. After quite a bit of wrangling and putting herself in the shoes of some of the more seedy clientele and business owners, Becky developed a definition, more or less, from scratch. Specifically, the bill, now a Federal statute, prohibited the distribution of Federal welfare funds at ``any retail establishment which provides adult-oriented entertainment in which performers disrobe or perform in an unclothed state for entertainment.'' Now, many have chuckled at the specificity of that definition and at the fact that someone, somewhere had to come up with and write down that type of legal terminology, but Becky was not playing a joke or trying to be facetious; she was addressing a legitimate concern. That story, to me, epitomizes the type of person Becky Shipp is and the type of congressional staffer she was when she worked in the Senate. I am quite certain that, even in her new endeavors, Becky will remain committed to promoting the same type of no-nonsense, proper governance, with an equal eye toward helping those in need to find meaningful work, care, and assistance. While Becky's work ethic, persistence, and friendliness have already been missed on the Finance Committee, I am quite certain that she will continue to do many great things and help many more people. I personally thank Becky for her years of service and for all that she has done for me, for others in the Senate, and for those in our country who have been in need of a helping hand. Tribute to Preston Rutledge Finally, Mr. President, I want to say a few words about Preston Rutledge, my former tax counsel who was recently nominated and confirmed to serve as Assistant Secretary of Labor for the Employee Benefits Security Administration. Preston began his career in public service as a teenager when he worked in the national forests. Later, he served honorably as an officer in the U.S Navy. After graduating from law school, he was a law clerk on the Fifth Circuit of the U.S Court of Appeals and spent more than a decade working at the IRS, focusing on tax-exempt organizations and employee benefits. He came to the Finance Committee about 7 years ago. During that time, he worked on a number of issues that many people, quite frankly, consider to be tedious or mundane, but Preston is an expert on these issues, and he has always taken great pleasure in the issues and work before him. As a staffer, Preston was, more than anything, committed to advancing reforms to our Nation's pension and savings programs in order to ensure a stable and reliable retirement savings system. Toward that end, he was a lead [[Page S91]] staffer in the drafting and passage of key pieces of pension and savings legislation, including the Retirement Enhancement and Savings Act, which provided a number of key reforms to our Nation's retirement savings system, and the ABLE Act, which provided savings enhancements for children with disabilities and their families. Preston's knowledge of tax policy and ERISA issues is unsurpassed. I was not the only one to benefit from and rely upon his expertise. Indeed, the entire Finance Committee relied on Preston whenever these types of issues came up because, once again, there just aren't many people in Washington with that particular focus and expertise. I wish Preston good luck in his new position at the Labor Department and thank him for the work he performed on the committee. I am confident his expertise, as well as his open-minded and inclusive approach, will help improve the situations of workers and families across the country. I can think of no one more capable to serve in this important capacity. As you can see, I have been fortunate to have worked with some excellent staffers in recent years--well, really throughout my whole service in the Senate. That has been true of my entire time at the Senate. Of course, I have many great staffers still working in the Senate, both in the Finance Committee and in my personal office. I am grateful for each of them as well. I am very fortunate to have them with me as we have some important work ahead of us. The Finance Committee's current workload is, quite honestly, mind- boggling. There is much to do over the next several months. I will have more to say on that in the coming days. For now, I will simply say, I look forward to working with my colleagues and staff on the vitally important tasks that lie ahead. With that, I yield the floor. I suggest the absence of a quorum. The PRESIDING OFFICER. The clerk will call the roll. The bill clerk proceeded to call the roll. Mr. SANDERS. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded. The PRESIDING OFFICER (Mr. Flake). Without objection, it is so ordered. DACA Mr. SANDERS. Mr. President, I rise today to speak on behalf of nearly 800,000 Dreamers, young people who were brought to this country as children who today are living in fear and uncertainty. As a result of the Trump administration's decision to end the DACA Program, these young people are at risk of losing their legal status and, in fact, face deportation from the only home that most of them have ever known, and that home is the United States of America. This is one of the great moral issues of our time, and it is an issue that must be dealt with now as part of the budget negotiations. It cannot be kicked down the road any longer. We must pass the Dream Act now as part of the current budget negotiations. In the last 6 years since the DACA Program was established, these young people--again, people who were brought to this country as infants, in many cases--were finally able to breathe a sigh of relief. For the first time in their lives, they could walk the streets of this country without fear, without worrying about being arrested, without worrying about being deported. Think about what it means to live in this country every single day knowing that, at any moment, you could be arrested or deported. What DACA finally did is to give these 800,000 young people a legal status and a protection so they could go out and work, so they could go to school, and so they could serve in the U.S military without fear. As we all know, tragically, on September 5, 2017, President Trump announced the end of the DACA Program through Executive order. President Obama had established it through Executive order, and President Trump ended it through Executive order. In his announcement, President Trump noted: I look forward to working with Republicans and Democrats in Congress to finally address all of these issues. As I have said before, we will resolve the DACA issue with heart and compassion, but through the lawful democratic process. It is now time for Congress to act. That is Donald Trump. The President was right. It is time for Congress to act. It is time for Congress to not kick the can down the road. Our Republican President, Mr. Trump, told the Republican-led Congress to get to work on a DACA fix, and I say today to the Republican leadership: Let's do it. Let's do it now. That is what President Trump asked you to do. Listen to him, and let's do it--not next month, not in March, but right now--as part of the budget agreement. People are working on this issue now. We can come to a consensus. We can pass the Dream Act if there is a political will to do it. Let us also be very clear. Despite what some have said, this is an urgent matter that must be addressed now. Since President Trump rescinded the DACA Program in September, more than 15,000 Dreamers have already lost their DACA status and are now subject to deportation. Each day the Congress does not act, 122 people lose their DACA protections, and 851 people each and every week. This is a matter of urgency, and we have to act accordingly. But I want to assure my Republican colleagues that not only is this the right thing to do from a moral perspective and from an economic perspective, but it is also exactly what the American people want. Nobody here is asking anybody in the Senate to rise up and to be extraordinarily brave and courageous. Why don't you just do what the American people want us to do? No profiles in courage are needed now. Poll after poll has shown that the overwhelming majority of the American people want to provide legal status to the Dreamers and to protect them from deportation. From a political perspective, this is not a difficult decision. A Washington Post-ABC poll from September 2017, a few months ago, found that 86 percent of Americans support allowing Dreamers to stay in the United States. So 86 percent of the American people support providing legal status to Dreamers. This is not a tough political decision. Another recent poll conducted by Quinnipiac found that 77 percent of voters and 65 percent of Republicans support legislation to protect Dreamers and provide them an opportunity to work, to go to school, and to pursue a pathway to citizenship. Another poll conducted by CNN last month found that by an 83-percent to 13-percent margin, Americans support efforts to allow Dreamers to remain in the United States instead of facing potential deportation. Only 15 percent believed that Dreamers should be deported. Passing the Dream Act is also in our national security interests. Former Secretary of Defense Robert Gates recently noted: The United States faces extraordinary security challenges that are placing growing pressure on our Armed Forces. That is why we need legislation that will provide a pathway to citizenship for those immigrants who, among other attributes, are serving or have served in the military, whether they are in America legally or were brought here illegally as children. That is former Secretary of Defense Robert Gates. In addition, just last week three former Secretaries of Homeland Security wrote to House and Senate leadership expressing both their strong support for a DACA fix and for the urgency of acting now. Secretaries Chertoff, Napolitano, and Johnson warned of the need for Congress to act immediately and emphasized how the agency needs time to implement a new program. Without it, they caution that the delay will sow uncertainty in the business community and drive undocumented individuals further into the shadows, with immediate deportation looming for tens of thousands every single month. Let us be very clear that when we talk about the DACA Program and when we talk about these young people receiving legal status, these young people are vetted, they pay a fee, and the vast majority of them are now at jobs important to our economy. They are in school or they are in the military. In order to get DACA status, they could not be convicted of a felony or a significant misdemeanor or pose a threat to national security or public safety. As almost everybody recognizes, these [[Page S92]] are fine young people whom we should be very proud of and should not be talking about deporting them. DACA gave these young people a shot at the American dream, and having been given that opportunity, they seized it and they are excelling and contributing to our country--to their country--in so many ways. With 91 percent of DACA recipients in the workforce, they play an important role in our economy. Many hundreds of Dreamers have taken up the call to serve in our Armed Forces. Can my colleagues imagine a young Dreamer now serving in the Armed Forces, putting his or her life on the line to defend this country, and then reading about Members of Congress who think we should deport them? How outrageous is that? Furthermore, there are some 20,000 DACA recipients who are currently teaching in our schools. We desperately need good teachers, and 20,000 DACA recipients are doing just that. Yet, because of President Trump's cruel decision to rescind the DACA Program, as well as the Republican-controlled Congress's failure to act, these young people's lives and livelihoods have been thrown into chaos and uncertainty. It is our job to enact a legislative fix now. The President has called for a fix. The vast majority of the people of this country want to see a fix. A fix is important to our national security. It is the right thing to do. Let us do it. I am, however, very concerned that President Trump is using the 800,000 Dreamers as a bargaining chip to force the taxpayers of this country to pay for an $18 billion wall. Now, some may remember that during his campaign for President, Donald Trump told the American people that it was the Mexican Government that would be paying for the wall. Well, it turns out that it didn't quite work out that way, and now it is the taxpayers of this country who are supposed to pay for a wall. Let me be as clear as I can be. We cannot and we must not hold the lives of 800,000 young Dreamers hostage in order to fund a wall that the vast majority of the American people oppose. We cannot and we must not allow Donald Trump to shut down the government to fund this wall, but that, it appears, may very well be--for whatever reason--what Donald Trump wants. Let me remind my colleagues what Donald Trump said last August at a rally in Arizona, the Presiding Officer's home State: ``Believe me, if we have to close down our government, we're building that wall.'' August 22, 2017, Donald J. Trump. Now, I do not know why Donald Trump may be pushing for a government shutdown. Maybe he thinks it will work well for him or work well for the Republican Party politically. I have no idea, but I do know that the idea of a government shutdown is a very bad idea. Maybe Republicans will gain from it, maybe Democrats will politically gain from it. I do not have a clue. What I do know is, the American people will lose from a government shutdown, and, in a bipartisan manner, we must do everything we can to prevent that shutdown. A shutdown would harm tens of millions of Americans who would be unable to access vital government services; it would disrupt the lives of hundreds of thousands, or more, Federal employees who depend upon a check to provide for their families; and, in fact, it would endanger members of the U.S military who are putting their lives on the line to defend our country. The U.S Congress has a responsibility to the American people to prevent a government shutdown and to work in a bipartisan manner to reach a budget agreement that is fair and that addresses the very serious problems facing not only DACA recipients but the working people of our country. So I say to my Republican colleagues, you control the White House, you control the U.S House, and you control the U.S Senate. You have a responsibility to govern. For President Trump and the Republican leadership to allow DACA to expire without a new program in place is not only a failure to govern, it is an act of extraordinary cruelty. We know President Trump wants to build a wall, I guess somewhat like the Great Wall of China. The problem is, building walls may have made sense in the 14th century, but I would inform the President that technology has somewhat changed since then, and our job is to provide strong border security in the most cost-effective way we can, and that way is not building a wall. Ironically, while the President wants to spend $18 billion to build a wall, he is taking money away from other far more important and effective border security measures. Let me quote from an article that appeared in today's New York Times: The Trump administration would cut or delay funding for border surveillance, radar technology, patrol boats and customs agents in its upcoming spending plan to curb illegal immigration--all proven security measures that officials and experts have said are more effective than building a wall along the Mexican border. The wall also has become a bargaining chip in negotiations with Congress as lawmakers seek to prevent nearly 800,000 young undocumented immigrants from being deported. But security experts said the president's focus on a border wall ignores the constantly evolving nature of terrorism immigration and drug trafficking. In other words, if we want strong border security, if we want to keep people out of this country who should not be coming into this country, if we want to keep drugs out of this country, building a wall is not the most cost-effective way. It may have been a great idea in the 14th century in China when they built their Great Wall, but it is not a great idea in 2018, in the United States of America. So let me just conclude by saying, we are at a very important moment in history. If we do not do the right thing, if we do not do the moral thing, if we allow some 800,000 young people--people who have spent virtually their entire lives in this country, who know no other country, who see the United States of America as their home--if we betray them, if we take away their legal status, if we allow them to be deported, this will be a moral stain on this country that will never ever be wiped out. I yield the floor. The PRESIDING OFFICER. The Senator from Indiana. Healthcare Mr. DONNELLY. Mr. President, for the past decade, health policy, unfortunately, has proven to be one of the most bitterly partisan issues. It doesn't have to be this way. I want to take a few minutes to discuss some health-related issues that Congress left unfinished before the holidays: providing relief from the medical device tax, reauthorizing the Children's Health Insurance Program, funding for community health centers, and doing more to address the opioid crisis. Each has strong bipartisan support and could provide help to our constituents now. First, many of us, on both sides of the aisle, agree on the need to provide relief from the medical device tax, which went back into effect on January 1. The medical device tax is one of these issues that leaves most Hoosiers scratching their heads. First adopted as part of the Affordable Care Act, the device tax was one of the few issues Republicans and Democrats agreed needed to be fixed, and in 2015, with bipartisan support, President Obama enacted a 2-year suspension of the tax. The argument was really pretty simple. The medical device tax was making it harder for innovative companies to invest in the research and development of new technologies, and, in the process, we were stifling job creation. If there was a question as to whether this was the case, the last 2 years provided evidence. When we agreed to suspend the tax in 2016 and 2017, manufacturers used that additional money to hire new workers, invest in research and technologies, and continue producing innovative, lifesaving products in the United States. For example, Zimmer Biomet, headquartered in Warsaw, IN, my home State, used the money from the device tax suspension to invest in new innovation to improve musculoskeletal health across the world. They were also able to upgrade their manufacturing equipment and facilities. Perhaps more importantly, these investments not only supported existing jobs, but they also helped to create new jobs--new, good-paying jobs. Yet, despite this evidence, despite this strong bipartisan support for repeal, and despite a wide-ranging package of changes to the Tax Code becoming law in recent days, Congress has failed to address the medical device [[Page S93]] tax, which went back into place on January 1. As we again discuss the policy priorities that were left unaddressed in 2017, I strongly urge my colleagues to work with me to quickly and meaningfully address the medical device tax. This would allow these innovative companies to make the long-term investments that not only lead to life-changing technologies but support thousands of high-paying jobs across the country, including in my home State of Indiana. Another issue that has garnered bipartisan support is a healthcare program that covers millions of our children. We must reauthorize the Children's Health Insurance Program--also known as CHIP--that expired in September. I have long supported the CHIP program. It provides health coverage for millions of kids, including nearly 115,000 children from Indiana. I am not alone in my support for this program. The fact is, CHIP has had strong bipartisan support for the past 20 years, and Democrats and Republicans in both the Senate and the House have shown they support a 5-year reauthorization of the program. That gives States the certainty they need to plan their budgets and provide high-quality care to these children. Despite this shared commitment for the program and agreement on the need for a long-term reauthorization, we were only able to fund the program through March before Congress departed for the holidays. This short-term extension bought some time, but according to the Centers for Medicare and Medicaid Services--CMS--some States will start running out of money after January 19. This means families and States will very soon face the harmful consequences of congressional inaction. Just last week, the Congressional Budget Office said that funding the CHIP program for the next 5 years will cost significantly less than previous estimates. This program is vital to our families and vital to our children. We should reauthorize the CHIP program right away. Like the CHIP program, community health centers have enjoyed long bipartisan support for the high-quality care they provide to our families. Also, like CHIP, the funding for community health centers expired on September 30, leaving many health centers across Indiana worried about if they will have the resources they need to continue to serve Hoosiers. We have the ability to work together now to ensure that our community health centers can continue to provide cost-effective, high-quality healthcare to people all across the country. Finally, we have demonstrated a common desire to address the needs of the opioid and drug abuse crisis. It is a scourge. It took the lives of 63,000 people just in 2016--63,000 of our brothers and sisters, our husbands and wives, our sons and daughters. It is a heartbreak that is crushing the entire country. I welcomed President Trump's declaration of a public health emergency, and both Republican and Democratic Senators have highlighted the need for Congress to do even more to help those struggling with addiction. Like many other States, the opioid epidemic has been particularly devastating in underserved areas in Indiana that lack adequate treatment providers. Senator Murkowski and I have partnered on a bipartisan bill that would encourage addiction treatment professionals to serve in underserved areas by making addiction treatment facilities eligible for National Health Service Corps student loan repayment and forgiveness. We can show our commitment to increasing access to treatment by reauthorizing the National Health Service Corps program, which expired in September. We also must recognize that a meaningful response to the opioid crisis will require robust and meaningful funding to help our communities as soon as possible. I have often said that most people think Congress can do something to help make life better--to provide working parents with the peace of mind that their children can grow up healthy and to instill confidence in our communities so that they will have the tools they need to respond to this heartbreaking crisis. At the very least, Congress should not make this situation worse. By failing to take action in 2017, medical device companies are once again paying a counterproductive tax that inhibits growth in Indiana. On all of these issues--medical device taxes, our families and our children and this opioid crisis, community health centers--we can work together as Democrats, as Republicans, but more than either of those, as Americans to make sure that our families can get decent healthcare, to make sure that no one else dies because of this terrible opioid scourge we are dealing with. These are critically important issues. These are issues that know no political party, that know no special agenda. What we do know is that we need this Congress, this Senate, to deal with them now. Mr. President, I yield back. The PRESIDING OFFICER (Mr. Johnson). The Senator from North Dakota. Congratulating the North Dakota State University Bison Football Team for Winning the FCS National Championship Mr. HOEVEN. Mr. President, I will be subbmitting a resolution in the U.S Senate honoring the North Dakota State University Bison football team, who just won their sixth national championship in 7 years. Mr. President, I know you are a football fan, so you can truly appreciate what a fantastic achievement that is. What NDSU has accomplished over the last 7 seasons is absolutely extraordinary. With our victory on Saturday, the Bison have now won six national football championship series division I national titles in 7 years. That ties them for the most of all time. Also, in each of the past 7 years, they have won or shared the top spot in the Missouri Valley Football Conference championship. We also want to congratulate the James Madison University Dukes on an outstanding year. We had five championships in a row. The Dukes managed to beat us last year in a semifinal game, and we came back and avenged that loss in a thrilling championship game in Frisco, TX. It went down

to the final play. It was a very, very exciting game. Winning a national championship is not easy, and this success, reflected both on and off the field, is earned through hard work and dedication. We recognize and congratulate all of the incredible players and Coach Klieman and his tremendous coaching staff, who put in countless hours of practice and preparation. We also recognize the importance of good leadership from athletic director Matt Larsen, NDSU president Dean Bresciani, and everyone at NDSU, all the coaches and the staff, team members, and really everybody who is part of Bison Nation. North Dakotans travel with our team. They show up in Bison Nation, and their cheering and supporting our great team is a huge part of our incredible victories. We congratulate Easton Stick, the quarterback, for achieving MVP honors and leading a tremendous offensive effort by the Bison and also Nick DeLuca, middle linebacker, for leading an incredible defensive effort. These were two tremendous defenses--James Madison and North Dakota State Bison--fast, strong, and it was a thrilling game and fun to watch. I want to compliment James Madison not only on their program but on all their fans and supporters--a real class act. I am very impressed with James Madison University--their students, their team, and all of their alumni, who also turned out in force for what was a tremendous game in Frisco, TX. With that, I submit this resolution to the U.S Senate honoring the North Dakota State Bison. Mr. President, I have just one other thing to say: Go Bison. With that, I yield the floor. Mr. MORAN. Mr. President, I ask unanimous consent to speak as in morning business. The PRESIDING OFFICER. Without objection, it is so ordered. American Farm Bureau Federation Convention and NAFTA Mr. MORAN. Mr. President, I was fortunate enough this week to attend the American Farm Bureau Federation's annual convention in Nashville, where I had the opportunity to headline a discussion of the farm bill, along with my colleague from Kansas on the [[Page S94]] Senate Ag Committee and the gentleman from Texas, Congressman Conaway, who is leading on the House Agriculture Committee, during the President's commodity meeting. The American Farm Bureau hosted other farm groups and commodity organizations from across the country to talk about the next farm bill and to try to bring consensus as to what agriculture is looking for in farm policy. In my opportunity to visit with people at the Farm Bureau's annual meeting, in my remarks, I paid particular attention to the farm bill. It is a farm safety net. When we talk about a farm bill, I suppose we ought to highlight that only a small portion of the farm bill is actually related to farm programs. There are a number of titles to the farm bill, and most of the money in a farm bill is spent on nutrition programs and mostly SNAP, but there are other important components of a farm bill--rural development and conservation. In addition to that topic, which I have been on the Senate floor speaking about before, are food aid and support for those who are experiencing famine around the globe. My opportunity to be with farmers and ranchers from across the country gave me an opportunity to not only speak about my views as to what a farm bill should contain but, more importantly, for me to hear what they had to say that was important to them. Farm Bureau members from across the country made it clear to me, first of all, that they would like to see Congress--Republicans and Democrats in the House and the Senate--and the administration work together in a bipartisan fashion to get a farm bill done and, prior to that, to get a disaster relief bill completed, which I hope we will do yet this month on the Senate floor--both the disaster bill that needs to get to the President's desk as soon as possible and also a farm bill that needs to be completed in a timely fashion. The current farm bill under which we are operating expires in 2018. Of the things I want to highlight that I heard from Farm Bureau members while I was there is certainly the importance of crop insurance and the value it provides, particularly for those of us who live and farm and work in places where the weather is not often our friend, as well as just the challenges the current farm bill is creating in Kansas. Particularly, the safety net programs PLC and ARC don't work as well as they should or could. Part of that has to do with timeliness, and part is the inability and the difficulty in farmers having to choose between two programs and to predict for a long period--the life of the farm bill--which makes the most sense to them economically. Whether they are going to have high prices, low prices, good weather, or bad weather is a hard thing to know in the life of a farm bill. Again, because of the issues we have with the current farm bill, timeliness is important because those provisions that are less than satisfactory today will be extended if we aren't successful in completing a farm bill this year. While the topic of conversation generally revolved around the farm bill, I want to indicate to my colleagues that so much of what I heard was about trade, particularly about NAFTA. The reality is, 98 to 99 percent of the mouths to feed are outside of the United States. Farmers and ranchers earn their livings by feeding a hungry world, and exports matter to us. There was a lot of concern expressed to me and among the farmers and ranchers who were gathered there about the potential of the withdrawal by the United States from NAFTA. Kansas is a good example. Our largest importer--the place to which we export the most agricultural commodities--is Mexico. It is not just about commodities. In addition to the commodities, there are manufacturing jobs related to food and food products. There are 36,000 jobs that generate more than $5.7 billion in economic activity, and approximately 14 percent of all jobs and 10 percent of all manufacturing jobs are tied to the food and agricultural sectors. So, when we talk about trade and exports, we are not just talking about shipping a ton of wheat or a carload of wheat to another country; we are also talking about all of the jobs here in the United States. It is not just in growing commodities and not just in raising cattle but all of the jobs that come from taking those commodities, turning them into food, and exporting the food to other countries as well. I have had this conversation with people within the administration and with my colleagues in the U.S Senate. I do believe the tax bill we passed will improve the economy and that farmers, lots of other business men and women, manufacturers, and others will experience greater economic opportunity as a result of the passage of the tax bill. I would highlight that the tax rates are a lot less important if we don't have income. If something would happen in which we would not be exporting--for example, if there would be a withdrawal from NAFTA-- the outcome could be that the tax rates would become semi-irrelevant because the income levels of farmers and ranchers and those who would have jobs in the food sector would be significantly diminished. Less income means tax rates don't matter as much as they otherwise would. Things are really difficult in agriculture today. Commodity prices are at low prices historically. The challenges are great. Weather, as I said earlier when speaking about crop insurance, is not always our friend. Across Kansas, the plea is for rain or snowfall or moisture. It is dry statewide. The challenges the producers in my State but really those across the country face are low commodity prices and weather, which are significant. What that means is, we need every additional market. We cannot afford to lose any market to which we sell those commodities. More markets mean higher prices, and more demand means higher prices. Today, we need every penny we can gain on a bushel of corn or wheat or soybeans or grain sorghum. We need to make certain we don't lose markets but that we gain markets. I commend the President for traveling to Nashville and speaking and meeting with the American Farm Bureau. I believe it has been 30-plus years since a President attended a Farm Bureau annual convention. I know, in my own experience both in the House and the Senate, reporters have often asked me to analyze what I have heard or haven't heard in a President's State of the Union Address. It has always been my practice to listen to a State of the Union Address and hear whether a President speaks about agriculture, about farmers, about ranchers, about rural America. Here we had a President who traveled to Nashville and spent time with those farmers and ranchers of America, and I am pleased the President did so. I continue to encourage the administration to remain mindful of the role agricultural trade plays in our economy. I would indicate that our withdrawal from NAFTA is a high-risk strategy--a negotiating tactic, perhaps. It is true we have the highest quality of agriculture products available in the world, but other countries are very interested in taking our markets, and any indication that our markets are not going to continue gives countries like Argentina, Brazil, and others the opportunity to make the case that they will be stable suppliers. The things we raise in the United States they can sell and provide in those countries as well. My point is, we don't have a corner on the market, and any suggestion that we are not a stable supplier or that the trading relationship is going to diminish or disappear between two countries means that others are eagerly seeking to take those markets away from us. Given the impact on our Nation's economy, I urge those conference attendees, those people I visited with in Nashville, to continue to convey to all of those policymakers the importance of trade and the importance of trade agreements. The administration has a desire to develop bilateral as compared to multilateral trade agreements, and I encourage those negotiations to be ongoing today. We don't have any time to waste when it comes to finding new markets and trading relationships with other countries. Again, I appreciate the President traveling to Nashville and spending time with farmers and ranchers, and I appreciate the agenda he outlined in regard to regulatory relief, as well as the issue of broadband, on which the President spent a significant amount of time, providing technology to a part of [[Page S95]] the country that has, in many instances, been lacking or woefully inadequate. But the bottom line is that rural America needs income. We can do lots of things to improve the quality of life in rural America, but in the absence of farmer success, in the absence of a farmer and rancher earning a living, the ability to attract our children or others to come back to the farm and the ability to retain our young people in the community to work on a farm diminishes greatly. One of the questions I received was from a young lady studying in Texas, and this was her question: What are you doing to make certain that young people have a chance to be farmers? While my answer was less than perfect--it is a hard one to answer--it is an important question. The reality is that the chances of young people having the opportunity in agriculture to earn a living is totally dependent upon the economic success of those individuals in agriculture today and what the future holds. We can find a few programs that might encourage young people to be able to enter agriculture as a profession and as a career, but the reality is that it will only work when they are earning a good living, and that comes, once again, from the safety nets, including crop insurance, which will be included in a farm bill as it works its way through Congress this year, but also in the opportunity to see that every market around the globe is available to the U.S farmer and rancher so that he and she will earn a living and so that they will increase the chances that their sons and daughters have the opportunity to work side by side with them into the future. I especially want to thank a few people from the American Farm Bureau Federation for allowing me to attend and inviting me to attend and to speak--certainly, President Zippy Duvall, the president of the American Farm Bureau Federation, from Georgia; Dale Moore, a Kansan who is at the American Farm Bureau Federation; and Mary Kay Thatcher, their long- time government affairs person. All of those individuals at the American Farm Bureau Federation do their job so well, but I especially want to acknowledge the friendship and support of those three individuals. I am reminded that no matter where we go, farmers and ranchers have a lot in common. In addition to their economic importance to communities across Kansas and around rural America, it is farmers and ranchers that still today provide a sense of what is right in America--an understanding of right and wrong, an understanding of the value of life, integrity, character, and values. It is something that is important not just to rural America but to our entire United States of America. So thank you to the farmers who visited with me. Thank you to the farmers who gave me the opportunity to speak with them and listened to me. Please know that I am happy and will continue to roll up my sleeves to work with my colleagues, Republicans and Democrats--the Senator from Kansas, the chairman of the Ag Committee; and the Senator from Michigan, the ranking member, Ms. Stabenow. Let's get a good farm bill done. Let's get it done on time, and let's all work together to make sure economic activity is alive and well and trade flourishes between the United States and the rest of the world. I yield the floor. I suggest the absence of a quorum. The PRESIDING OFFICER. The clerk will call the roll. The assistant bill clerk proceeded to call the roll. Mr. WHITEHOUSE. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded. The PRESIDING OFFICER. Without objection, it is so ordered. Mr. WHITEHOUSE. Mr. President, I believe that my distinguished colleague and friend, Senator Blumenthal, will be joining me on the floor. I ask unanimous consent that I be allowed to speak as in morning business for such time as I may require and, at the conclusion of my remarks, that Senator Blumenthal be recognized to make his remarks on the same subject. The PRESIDING OFFICER. Without objection, it is so ordered. Safeguarding OUr Elections Mr. WHITEHOUSE. Mr. President, 2018 is going to be an election year. In just 10 months, Americans will go to the polls to exercise their franchise, believing in the integrity of our democratic process. I am here today to discuss a threat to the integrity of that process, which is getting little attention here in Congress--nothing near what it deserves. We really ought to be acting with some expedition to safeguard our elections this November. Yet, instead, the effort is one of chasing down partisan investigative rabbit holes. What ought to be our job? Well, national security, intelligence, election, and law enforcement officials, many of them testifying before us here in Congress, have made what our job is very clear. We must counter Russia's well-established election interference playbook. Russia will hack. Russia will bully. Russia will propagandize. Perhaps more insidiously, Russia will seek to corrupt, particularly by exploiting cracks in our incorporation and campaign finance laws. We are warned: Russia will seek to interfere in 2018's election. I ask unanimous consent that an article entitled ``CIA's Pompeo says Russia and others trying to undermine U.S elections'' be printed in the Record at the conclusion of my remarks. To quote the Center for ***Strategic*** and International Studies' Heather Conley, testifying before Congress last spring, corruption is the ``lubricant'' for Moscow's election interference, so ``the battle of Western democracies to defeat corruption'' must be seen as ``a matter of national security.'' Testifying before our Crime and Terrorism Subcommittee, former Director of National Intelligence, James Clapper, agreed, saying of Russia's 2016 election meddling: I believe [the Russians] are now emboldened to continue such activities in the future, both here and around world, and to do so even more intensely. If there has ever been a clarion call for vigilance and action against a threat to the very foundation of our democratic political system, this episode is it. I hope the American people recognize the severity of this threat and that we collectively counter it before it further erodes the fabric of our democracy. How to counter it? Well, there are two important solutions that witnesses have identified in recent testimony before the Judiciary and other committees here in the Senate. First, guard against the use of phony shell corporations as facilitators of corruption. Ms. Conley, as I said, wrote that corruption is the ``lubricant'' with which the Russians operate their interference schemes. She and her colleagues warn that to fight the corruption that gives Russia this channel of influence--and I quote her here--``enhancing transparency and the effectiveness of the Western democratic tools, instruments, and institutions is critical.'' One central way to cut off this channel of improper influence would be to require companies to disclose who their real owner is so that Russian influence can no longer hide behind anonymous American shell companies. Another would be to crack down on the dark money that is flooding into American elections. It is illegal for foreign nationals to spend money or participate at all in American elections. Yet, post-Citizens United, the same dark money avenues that allow domestic election interference--for instance, that the Koch brothers use to manipulate American elections--are right out there to be used by Vladimir Putin. If they can hide their identity behind 501(c)(4)s and other dark money channels, so can operatives for the Russians. Instead of taking up these important measures or even ensuring a thorough investigation into the 2016 election meddling, we are--to paraphrase the legendary Senator Sam Ervin of Watergate fame--chasing rabbits when we should be on a bear hunt. Let's look at a few rabbits that have distracted us from the task at hand. Remember, when Michael Flynn, the President's former National Security Adviser, illicitly communicated with the Russian Ambassador about sanctions during the transition. Then in the White House, he lied to the FBI about it, which concerned the Justice Department so badly that the Acting Attorney General warned the White House Counsel personally, after which she was fired, but the President then [[Page S96]] waited 18 days until all of this had become public in the media to ask for Michael Flynn's resignation. Out of all of that, the topic for many Republicans was the alleged leaks of classified information that allowed the story to come to light--not the story itself of problems at the highest level of our national security establishment. Off people went after the ``leaks'' rabbit. Republicans then pivoted to talking about the ``unmasking''--remember that word; we heard a lot of it around here--of identities in intelligence reporting and the purported misconduct of Obama administration officials. Trump even publicly suggested that former National Security Adviser Susan Rice may have committed a crime. So off people went after the ``unmasking'' rabbit. Next, the President accused President Obama of wiretapping Trump Tower, an allegation so outrageous that even congressional Republicans have refused to stand by it, but my, what a bright and shiny rabbit it was for the weeks that it was still a distraction. By the spring and summer, Republicans were railing against purported conflicts of interest by FBI Deputy Director Andrew McCabe, a distinguished career public servant. I ask unanimous consent that this article, ``FBI ruled McCabe had no conflict of interest in Clinton probe,'' be printed in the Record at the conclusion of my remarks. So off everybody went after the ``McCabe's wife'' rabbit. After President Trump fired FBI Director James Comey to impede the Russia investigation and then told the Russian Foreign Minister and NBC that was why he had done it, the President launched another leak rabbit: a coordinated effort with his lawyers, congressional Republicans, and the rightwing media to suggest that Comey had leaked classified information by sharing with a friend his own contemporaneous notes of conversations with Trump. Just last week, the President again suggested on Twitter that Comey should be charged with a crime--another bite at the ``leaks'' rabbit. In early July, we learned of the June 2016 meeting at Trump Tower between Russian lawyer and operative Natalia Veselnitskaya and senior Trump campaign leaders seeking dirt on Hillary Clinton. Republicans tried to distract attention from that mess by suggesting that Veselnitskaya was in the country on a visa issued by Obama administration officials, with some rightwing media--aided by some congressional Republicans--even whipping on the ``visa'' rabbit by suggesting there was a setup orchestrated by the Obama administration against the Trump campaign. Then came the ``Fusion'' rabbit. Because Fusion GPS had worked on separate projects--one with Christopher Steele and a separate one with Natalia Veselnitskaya--some Republicans began suggesting either that Russia had been Fusion's client for the Steele dossier or that Steele was the unwitting victim of a Russian disinformation campaign. Then there is the ``Uranium One'' rabbit, which began when a rightwing author suggested, without evidence, that Hillary Clinton may have been responsible for a Russian state company acquiring uranium mines in the United States. This rabbit remains a topic of investigation in Congress and in rightwing media. Then there are the attacks on Bob Mueller, which, like rabbits, multiply by the hour. As the special counsel's investigation started heating up over the late summer and fall, the rightwing began investigating the investigation--alleged conflicts of interest, history of campaign donations, inappropriate text messages, questions about spouses' employment. But the big one was that the FBI was corruptly involved in the procurement of the Steele dossier and that this had launched the ``witch hunt.'' This, of course, is a very shiny rabbit. However, a week ago, reporting by the New York Times confirmed that the FBI did not begin its investigation into Donald Trump's connections to Russia because of the so-called Steele dossier. This should not come as a surprise. We have already been told that U.S allies warned American national security officials about Russian interference in our 2016 elections. In response to a question from Ranking Member Feinstein at our Crime and Terrorism Subcommittee hearing on May 8, former Director of National Intelligence James Clapper confirmed that ``Britain's intelligence service''--Britain's intelligence service--``first became aware in late 2015 of suspicious interactions between Trump advisers and Russian intelligence agents,'' and the Brits passed that information on to U.S intelligence agencies. Clapper confirmed that in ``the spring of 2016, multiple European allies passed on additional information to the United States about contacts between the Trump campaign and Russians.'' Clapper said that these reports were accurate and that ``the specifics are quite sensitive.'' Now we have learned that Trump campaign foreign policy adviser George Papadopoulos, who pled guilty last year to lying to the FBI, apparently told a senior Australian official in the spring of 2016 that Russia had dirt on Hillary Clinton. This is something he said he had been told by an intermediary for the Russians. When hacked emails started showing up that summer, Australia's Government became sufficiently concerned to let U.S officials know about what they had learned from Papadopoulos. So you have the British intelligence community warnings, the European intelligence community warnings, the Australian warnings, and Carter Page's travels to Russia. You have the attribution of the DNC hack, the intrusion into those emails, to Russian hackers. You have the leaking of the stolen emails. You have abundant evidence out of all of that for the FBI that the Trump campaign's links to Russia required further investigation. It would have been a complete failure of their duty to not have looked further based on all of that evidence. That is not to say that Christopher Steele and his work are not taken seriously by U.S intelligence and law enforcement officials. U.S security agencies have relied on Steele's analysis long before any dossier appeared. Steele is a leading Russia expert. Beginning in 1990, as an undercover officer in Moscow, he watched the Soviet Union unravel. He observed Russia's current leaders ascend through the Russian security services during the 1990s and 2000s. He rose to a senior position on MI6's Russia desk in London. Since leaving MI6, his reports on Russia and Ukraine have been shared widely within the U.S Government as credible reporting. A U.S official told the Guardian that Steele's reports were ``consistently reliable, meticulous, and well-informed.'' But you would never know this from listening to congressional Republicans. They have been repeating, in chorus with the White House and conservative media, the disproven claim that the Russians somehow commissioned the Steele dossier or that Steele somehow got suckered by the Russians or that some deep-state FBI set up the whole thing to pressure Trump. They have pushed to discredit Steele. They have pushed to discredit Fusion. As one example, rewind to the Judiciary Committee's hearing on the Foreign Agents Registration Act, or FARA, last July. On the morning of the second day of that hearing, the President tweeted: ``One of the things that has been lost in the politics of this situation is that the Russians collected and spread negative information about then candidate Trump.'' This is Trump tweeting about himself. His tweet came shortly after a segment on FOX News centered on the same question. Other rightwing outlets parroted the same message. That same day, Republicans in Congress spun out the same premise that Russians paid for the dossier and that the dossier was, to use their word, the ``genesis'' of the FBI's inquiry. I hope we have made it clear that this was not the genesis. While the FARA hearing was still going on, that same day, the gop.gov website published this post: [W]e now know a Russian backed, Democrat connected research firm, with a history of smearing individuals and pitching fake information to reporters, was hired by opponents of President Trump to compile a ``dossier'' of supposed Trump ties to Russia. The information that was compiled was taken seriously by the highest level of our intelligence community along with our media, despite obvious signs that the firm behind it was tied to Russia. [[Page S97]] As a reminder, this phony ``dossier'' helped spark the investigation now led by Special Counsel Mueller. That is the rabbit we are chasing now. The uniformity of the rightwing message that day with the White House was telling, but the message--the content of it--is simply not true. In fact, at that hearing, the witness denied any knowledge of any link between Russians and the clients of the Steele dossier. In the months that followed, Fusion GPS's founder, Glenn Simpson, spent over 20 hours speaking with congressional investigators, including investigators from the Senate Judiciary Committee. I ask unanimous consent that his op-ed be printed in the Record as a third and final item at the conclusion of my remarks. During these interviews, he specifically told Democratic and Republican staff alike that the dossier was taken seriously by the FBI because it corroborated reports the Bureau had already received from other sources--remember the British, the European, the Australian we have talked about--and a source inside the Trump campaign. From the Time's recent reporting, we can conclude that that source was George Papadopoulos. This has all been known for months, but the narrative about Fusion GPS and the FBI grinds on, unhinged from fact. The revelation about George Papadopoulos and the Australian Government should serve as a clarifying moment about the rightwing effort to undermine Bob Mueller's investigation of the ties of the Trump campaign and his Presidency to Russia. The FBI investigation did not begin because of ***opposition*** research. It did not begin because researchers or journalists or American national security officials fell victim to Russian disinformation. It did not begin because of fake news or because Democrats needed an explanation for losing an election. It began when multiple allies, friends of the United States, warned us that the Russian Government was interfering in our democratic process-- something many of them knew about from Russia's interference in their own democratic process. We still do not know to what extent that interference may have been facilitated or even simply known to members of the Trump campaign or other Trump associates. We still have done nothing to prevent further interference in our elections in 2018. The special counsel's investigation and the investigations going on in Congress must be allowed to continue until all of the facts are known. Here in the Senate, we should stop looking for new distractions, stop chasing rabbits, and start thinking about how we are going to protect our future elections--our 2018 election--against a repeat performance, which we have been warned about, by the Russians or another foreign adversary, for that matter. As the Center for ***Strategic*** and International Studies warns in its report, ``The Kremlin Playbook,'' we must fight the avenues for corruption that give Russia influence. We must ``enhanc[e] transparency'' in government and build ``resilience against Russian influence'' in our elections and elsewhere in American society. I will conclude by saying that the best measure of our success in Congress will be an America defended against foreign election interference in time to protect our 2018 elections. If we have not achieved that, we have failed at our duty. I do not see us presently on a path to meet that goal. We are less than a year out from election day. We have work to do. Enough with the rabbits. There being no objection, the material was ordered to be printed in the Record, as follows: CIA's Pompeo Says Russia and Others Trying To Undermine U.S Elections (By Susan Cornwell) Washington (Reuters).--The head of the Central Intelligence Agency said on Sunday that Russia and others are trying to undermine elections in the United States, the next major one being in November when Republicans will try to keep control of Congress. U.S intelligence agencies have concluded that Russia interfered in the 2016 presidential election to try to help President Donald Trump ***win***, in part by hacking and releasing emails embarrassing to Democratic presidential candidate Hillary Clinton, and spreading social media propaganda. CIA Director Mike Pompeo told CBS that the Russian interference is longstanding, and continues. Asked on ``Face the Nation'' if Moscow is currently trying to undermine U.S elections, Pompeo responded: ``Yes sir, have been for decades.'' ``Yes, I continue to be concerned, not only about the Russians, but about others' efforts as well,'' Pompeo said, without giving details. ``We have many foes who want to undermine Western democracy.'' Moscow denies any meddling in the 2016 elections to help Republican Trump ***win***. U.S Special Counsel Robert Mueller is investigating whether any crimes were committed. Two Trump associates, former national security adviser Michael Flynn and campaign aide George Papadopoulos have pleaded guilty to lying to FBI agents in the probe. Trump denies any campaign collusion with Russia. Trump has at times suggested that he accepts the U.S intelligence agencies' assessment that Russia sought to interfere in the election but at other times has said he accepts Russian President Vladimir Putin's denials that Moscow meddled. Trump has frequently spoken of wanting to improve relations with Putin, even though Russia has frustrated U.S policy in Syria and Ukraine and done little to help Washington in its standoff with North Korea. Pompeo told CBS that the CIA had an important function as a part of the national security team to keep U.S elections secure and democratic. ``We are working diligently to do that. So we're going to work against the Russians or any others who threaten that very outcome,'' he said. Trump said on Saturday that he planned an active year on the campaign trail on behalf of Republican candidates running in the mid-term elections, in which all of the House of Representatives and one-third of the Senate will be up for election. Republicans hold majorities in both. \_\_\_\_ [From The Hill, Jan. 5, 2018] FBI Ruled McCabe Had No Conflict of Interest in Clinton Probe: Docs (By Julia Manchester) The FBI said in documents released Friday that Deputy Director Andrew McCabe did not have any role in the probe into Hillary Clinton's private email server while his wife ran as a Democrat for state office in Virginia. The documents note that Jill McCabe announced her candidacy for state Senate in Virginia in March 2015, while Andrew McCabe's role as deputy director started in February 2016, three months after his wife lost her electoral bid. Andrew McCabe had asked ethics officials if his wife's candidacy would lead to a potential conflict of interest while he was working as an assistant director at the FBI Field Office in Washington, D.C , the documents show. ``From the first contemplation that his wife would run for office in Virginia, [McCabe] sought out and consulted with ethics officers, which included briefings on the Hatch Act,'' the records state. A ``system of recusal'' was also put in place to prevent any potential conflicts of interests, according to the documents. The release of the documents comes after President Trump and other Republicans have claimed McCabe had a conflict of interest due to his wife's electoral bid, noting that her campaign was supported by a super-PAC associated to Virginia Gov. Terry McAuliffe (D), a Clinton ally. ``How can FBI Deputy Director Andrew McCabe, the man in charge, along with leakin' James Comey, of the Phony Hillary Clinton investigation (including her 33,000 illegally ***deleted*** emails) be given $700,000 for wife's campaign by Clinton Puppets during investigation?'' Trump tweeted last month: ``How can FBI Deputy Director Andrew McCabe, the man in charge, along with leakin' James Comey of the Phony Hillary Clinton investigation (including her 33,000 illegally ***deleted*** emails) be given $700,000 for wife's campaign by Clinton Puppets during investigation?'' 3:27 PM-Dec. 23, 2017 Trump's tweet and others he sent targeting the No. 2 FBI official amid the federal Russia probe came after it was revealed McCabe would be retiring from his post in the coming months. Trump interviewed McCabe to be FBI director in May after he fired James Comey from the top post. The president ultimately tapped Christopher Wray for the bureau's top spot. \_\_\_\_ [From the New York Times, Jan. 2, 2018] The Republicans' Fake Investigations (By Glenn R. Simpson and Peter Fritsch) A generation ago, Republicans sought to protect President Richard Nixon by urging the Senate Watergate committee to look at supposed wrongdoing by Democrats in previous elections. The committee chairman, Sam Ervin, a Democrat, said that would be ``as foolish as the man who went bear hunting and stopped to chase rabbits.'' Today, amid a growing criminal inquiry into Russian meddling in the 2016 election, congressional Republicans are again chasing rabbits. We know because we're their favorite quarry. In the year since the publication of the so-called Steele dossier--the collection of intelligence reports we commissioned about Donald Trump's ties to Russia--the president [[Page S98]] has repeatedly attacked us on Twitter. His allies in Congress have dug through our bank records and sought to tarnish our firm to punish us for highlighting his links to Russia. Conservative news outlets and even our former employer, The Wall Street Journal, have spun a succession of mendacious conspiracy theories about our motives and backers. We are happy to correct the record. In fact, we already have. Three congressional committees have heard over 21 hours of testimony from our firm, Fusion GPS. In those sessions, we toppled the far right's conspiracy theories and explained how The Washington Free Beacon and the Clinton campaign--the Republican and Democratic funders of our Trump research-- separately came to hire us in the first place. We walked investigators through our yearlong effort to decipher Mr. Trump's complex business past, of which the Steele dossier is but one chapter. And we handed over our relevant bank records--while drawing the line at a fishing expedition for the records of companies we work for that have nothing to do with the Trump case. Republicans have refused to release full transcripts of our firm's testimony, even as they selectively leak details to media outlets on the far right. It's time to share what our company told investigators. We don't believe the Steele dossier was the trigger for the F.B.I 's investigation into Russian meddling. As we told the Senate Judiciary Committee in August, our sources said the dossier was taken so seriously because it corroborated reports the bureau had received from other sources, including one inside the Trump camp. The intelligence committees have known for months that credible allegations of collusion between the Trump camp and Russia were pouring in from independent sources during the campaign. Yet lawmakers in the thrall of the president continue to wage a cynical campaign to portray us as the unwitting victims of Kremlin disinformation. We suggested investigators look into the bank records of Deutsche Bank and others that were funding Mr. Trump's businesses. Congress appears uninterested in that tip: Reportedly, ours are the only bank records the House Intelligence Committee has subpoenaed. We told Congress that from Manhattan to Sunny Isles Beach, Fla., and from Toronto to Panama, we found widespread evidence that Mr. Trump and his organization had worked with a wide array of dubious Russians in arrangements that often raised questions about money laundering. Likewise, those deals don't seem to interest Congress. We explained how, from our past journalistic work in Europe, we were deeply familiar with the political operative Paul Manafort's coziness with Moscow and his financial ties to Russian oligarchs close to Vladimir Putin. Finally, we debunked the biggest canard being pushed by the president's men--the notion that we somehow knew of the June 9, 2016, meeting in Trump Tower between some Russians and the Trump brain trust. We first learned of that meeting from news reports last year--and the committees know it. They also know that these Russians were unaware of the former British intelligence officer Christopher Steele's work for us and were not sources for his reports. Yes, we hired Mr. Steele, a highly respected Russia expert. But we did so without informing him whom we were working for and gave him no specific marching orders beyond this basic question: Why did Mr. Trump repeatedly seek to do deals in a notoriously corrupt police state that most serious investors shun? What came back shocked us. Mr. Steele's sources in Russia (who were not paid) reported on an extensive--and now confirmed--effort by the Kremlin to help elect Mr. Trump president. Mr. Steele saw this as a crime in progress and decided he needed to report it to the F.B.I We did not discuss that decision with our clients, or anyone else. Instead, we deferred to Mr. Steele, a trusted friend and intelligence professional with a long history of working with law enforcement. We did not speak to the F.B.I and haven't since. After the election, Mr. Steele decided to share his intelligence with Senator John McCain via an emissary. We helped him do that. The goal was to alert the United States national security community to an attack on our country by a hostile foreign power. We did not, however, share the dossier with BuzzFeed, which to our dismay published it last January. We're extremely proud of our work to highlight Mr. Trump's Russia ties. To have done so is our right under the First Amendment. In is time to stop chasing rabbits. The public still has much to learn about a man with the most troubling business past of any United States president. Congress should release transcripts of our firm's testimony, so that the American people can learn the truth about our work and most important, what happened to our democracy. Mr. WHITEHOUSE. I now yield, per the pending agreement, to my distinguished friend from Connecticut. The PRESIDING OFFICER (Mr. Rubio). The Senator from Connecticut. Mr. BLUMENTHAL. Thank you, Mr. President. I thank my colleague Senator Whitehouse for his very erudite and insightful summary of the bright, shiny toys and rabbits and rabbit holes that a number of our colleagues have attempted to use to distract the Judiciary Committee and this body from what should be its quest for the truth; that is, the truth about the Russian attack on our democracy during the last election and potential collusion in that attack-- specifically, collusion by the Trump campaign--and obstruction of justice. Indeed, obstruction of justice is within the direct purview of the Judiciary Committee. I want to thank my colleague Senator Whitehouse for joining me in a letter that we wrote to the chairman of the Judiciary Committee, Senator Grassley, asking that he very simply make public the transcript of the interview with Glenn Simpson conducted by our staff. Senator Grassley declined. But, earlier today, Senator Feinstein released the interview, advancing the American people's right and need to know the full truth. I want to applaud Senator Feinstein's leadership in using her proper authority as the ranking member to serve this vital public interest. I am grateful to her for her courage and strength in moving forward and disclosing the transcript to prevent its use as a dangerous distraction from the critical work of our committee. I want to thank at least one of our colleagues across the aisle, Senator Cornyn, for apparently supporting that step. The toys and rabbits and rabbit holes are hardly new to efforts by defenders of an administration against an investigation, and perhaps for some amusement as well as enlightenment, I want to cite a satiric column done by Art Buchwald in 1973. Mr. President, I ask unanimous consent that the column be printed in the Record. There being no objection, the material was ordered to be printed in the Record, as follows: Here Are Handy Excuses for Nixon Backers (By Art Buchwald) Washington.--These are difficult times for people who are defending the Nixon administration. No matter where they go they are attacked by pseudo-liberals, McGovern lovers, heterosexual constitutionalists and paranoid John Dean believers. As a public service, I am printing instant responses for loyal Nixonites when they are attacked at a party. Please cut it out and carry it in your pocket. 1--Everyone does it. 2--What about Chappaquiddick? 3--A President can't keep track of everything his staff does. 4--The press is blowing the whole thing up. 5--Whatever Nixon did was for national security. 6--The Democrats are sore because they lost the election. 7--Are you going to believe a rat like John Dean or the President of the United States? 8--Wait till all the facts come out. 9--What about Chappaquiddick? 10--If you impeach Nixon, you get Agnew. 11--The only thing wrong with Watergate is they got caught. 12--What about Daniel Ellsberg stealing the Pentagon Papers? 13--It happens in Europe all the time. 14--People would be against Nixon no matter what he did. 15--I'd rather have a crook in the White House than a fool. 16--L.B.J used to read FBI reports every night. 17--What's the big deal about finding out what your ***opposition*** is up to? 18--The President was too busy running the country to know what was going on. 19--What about Chappaquiddick? 20--People who live in glass houses shouldn't throw stones. 21--McGovern would have lost anyway. 22--Maybe the Committee for the Re-Election of the President went a little too far, but they were just a bunch of eager kids. 23--I'm not for breaking the law, but sometimes you have to do it to save the country. 24--Nixon made a mistake. He's only human. 25--Do you realize what Watergate is doing to the dollar abroad? 26--What about Harry Truman and the deep freeze scandal? 27--Franklin D. Roosevelt did a lot worse things. 28--I'm sick and tired of hearing about Watergate and so is everybody else. 29--This thing should be tried in the courts and not on television. 30--When Nixon gives his explanation of what happened there are going to be a lot of people in this country with egg on their faces. 31--My country right or wrong. 32--What about Chappaquiddick? 33--I think the people who make all this fuss about Watergate should be shot. 34--If the Democrats had the money they would have done the same thing. 35--I never trusted Haldeman and Ehrlichman to start with. [[Page S99]] 36--If you say one more word about Watergate I'll punch you in the nose. A--If the person is bigger than you: ``If you say one more word about Watergate I'm leaving this house.'' B--If it's your own house and the person is bigger than you: ``What about Chappaquiddick? Mr. BLUMENTHAL. Mr. Buchwald wrote a satirical list of tactics Republicans were using to keep Americans from focusing on the Watergate scandal. The list is eerily familiar. The tactics being employed by the Trump supporters today ring of those same tactics used in Watergate. Buchwald suggests focusing on accusations made against prominent Democrats or individuals who had accused Richard Nixon of wrongdoing. He suggests attacking the media. He suggests saying: ``The Democrats are sore because they lost.'' He suggests deflecting blame to a ``bunch of eager kids''--perhaps sounding like the reference to ``coffee boys'' today--and saying that this investigation is ``bad for the dollar,'' much like bad for America abroad. I am very confident--and I want to emphasize this point very emphatically--that the special counsel will be in no way distracted from his investigation and his team will be undeterred by these tactics. But the American people should not be distracted or deterred either and, equally important, the Judiciary Committee, the U.S Senate, and the Congress as a whole has a duty here that is, in fact, vulnerable to that same distraction. We must persevere. What our Republican colleagues are doing at this point is indicated by a recent New York Times article. The article describes President Trump's efforts to persuade congressional allies to drop their investigations, and it says: Another Republican Senator said Mr. Trump had not urged him to help bring the Russia inquiry to a halt. Instead, the Senator said, the President nudged him to begin an investigation into Hillary Clinton's connection with the intelligence-gathering firm Fusion GPS, which produced a dossier of allegations about Mr. Trump's ties to Moscow. The goal was to stop the investigation of Russian meddling, but the implication in the article is that the President knew he could achieve that goal as effectively, or at least more practically, by distracting from those investigations, diverting resources to other issues, and muddying the waters for the American people. That is the playbook from 1973 that is referenced by Art Buchwald in his 1973 column. Here is the danger: Distractions are dangerous, and efforts to discredit law enforcement are equally perilous. Those efforts have included not only the urging for an investigation of Uranium One and Fusion GPS but also attacks on the integrity of some members of the FBI and the FBI as a whole and attacks on individual members of the special counsel's team, on the team as a whole, and on Robert Mueller himself. The effort plainly is to discredit the investigation before it reaches a potentially incriminating conclusion and to stop the investigation, but if not stop it, at least to demean its credibility before charges are brought. It is standard operating procedure. We know as prosecutors. The distinguished Senator from Rhode Island and I served as U.S attorneys and then attorneys general for our States. We know going into the courtroom that we can expect to be attacked and that our teams can be expected to be attacked. That is what defense lawyers do. That is what they do because they hope to demean and discredit and dismantle the credibility of prosecutors before the jury in the courtroom. Here, the courtroom is not a court of law but the court of public opinion. Our Republican friends have launched that preemptive strike, methodically and meticulously, just as the special counsel is engaging in his investigation methodically and meticulously. Now, I referred to Republican colleagues, and I believe strongly and passionately that many, if not most, of our Republican colleagues share our zeal for the rule of law and for a just outcome to this investigation. The reason is very simple. The Russian attack on our democracy imperils not just this administration and not just one election. It imperils our democracy as a whole. The meddling in our elections was perhaps done to advance the Trump candidacy in 2016, but it can be used against the Trump candidacy in 2020. It can be used against another Republican candidate in that year. It could be used in 2018 against other candidates for Congress or for State election. My Republican colleagues have been as eloquent as any of us in defining that threat because there is no doubt in the intelligence community that it is a threat, that the Russians did interfere, and that they sought to advance the Trump candidacy. Whether there was an impact and what the impact was may never be known, but the effort is clear. It involved a massive campaign of disinformation, propaganda, cyber attack, and other means. That is what the FBI learned was happening, not as a result of Christopher Steele but from sources within the Trump campaign, including George Papadopoulos, and from other intelligence sources, and that is what we must make sure is known to the American public. We must make sure that anyone who aided the Russians pays a price and that the Russians themselves pay a price, because if there is no price, it will be done with impunity again. So there should be--and I believe there is--bipartisan apprehension about that threat to our Nation's security. That is the reason that the Judiciary Committee's investigation, along with the special counsel, is so important, because our purview includes obstruction of justice and the integrity of the Department of Justice. Any interference politically with the FBI's investigation into Russian meddling must be prevented in the future as well. Only the Judiciary Committee can frame and craft legislation that will help to protect the FBI. Senator Whitehouse and I, and Senator Feinstein and others on the committee, will be proposing such legislation based on what we know so far. It is legislation that essentially protects the rule of law against such efforts to obstruct justice and politically interfere. The intelligence community's conclusions about Russian meddling did not rely on the credibility of Glenn Simpson or Christopher Steele. The two guilty pleas and convictions that the special counsel has already secured do not rely on the credibility of Simpson or Steele. Without fear of contradiction, I can predict that additional convictions and indictments will be based on fact and law, not on the credibility of Simpson and Steele. The conclusions reached by Simpson, Steele, or anybody else are relevant only insofar as they are supported and backed and proved by facts and consistent with relevant law. Now, in fact, as we know, Christopher Steele tried to blow the whistle on the Russians. He brought to the FBI's attention information that he thought was relevant to protecting the United States of America against Russian interference. As my colleague Senator Whitehouse has outlined in detail, the FBI already knew of it and courteously heard from Christopher Steele and later interviewed him. The effort to undermine the credibility of the FBI by pointing to Christopher Steele completely misses the mark. In fact, I am deeply disappointed that the first major action by our Republican colleagues on the Judiciary Committee was aimed at someone who reported wrongdoing, not committed it, and it was done without any cooperation or even consultation with Democratic colleagues. It is really a betrayal of the spirit that I think should characterize this very serious investigation, because it should be bipartisan. My hope is that these distractions, dangerous as they are, will, in fact, not divert either our committee or the special counsel. The pace of our committee's investigation--again, to be very blunt--has been shamefully slow. I hope that its pace will quicken and that it will intensify and that there will be hearings in public with witnesses under oath and subpoenas of documents. I have said it repeatedly. I hope we will use those tools because only by relying on our powers to investigate effectively and comprehensively will we protect the goals of upholding integrity and justice. As for the special counsel and our law enforcement community, I think they should know that we support them and that we will protect the special counsel against political interference. That is why there is legislation I have proposed, along with my [[Page S100]] colleague Senator Whitehouse and others. It is bipartisan legislation. I thank Senators Tillis and Graham, as well as Senators Coons and Booker, for joining in this legislation. That legislation has already had a hearing. It should be voted to the floor and passed by the Congress so that there is no question that the special counsel will be protected against interference or firing. As that investigation moves closer to the Oval Office, as it tightens its grip on members of the administration, there will be increasing threats and efforts to intimidate. The FBI and the Department of Justice, as well as the special counsel, have a well-earned reputation for integrity and zeal. It is part of our rule of law that a law is enforced. Enforcement of a law depends on thorough and independent investigations that are pursued without fear or favor, without efforts to distract or demean. This body, the U.S Congress, has an obligation to support those kinds of values. They are uniquely American values. They are the underpinning of all of our laws, all that we hold dear, and all that we celebrate in this body and in this country. My hope is that we will be part of the effort to avoid politicizing the pursuit of justice. Politicization of the pursuit of justice diverts energy and attention away from credible criminal investigations. It sends a message to this President and future Presidents--and everybody who occupies any office--that there are no repercussions for diverting and distracting and for the ploys and rabbit holes that may be used to squander resources or undermine credibility. Republicans and Democrats alike should join in the effort to preserve the rule of law. My hope is that we will and will do so without delay because every day that passes when these kinds of false, baseless, and biased innuendos and rumors are raised and given credence is a day that undermines those values that we hold dear. I yield the floor. The PRESIDING OFFICER. The Senator from Ohio. Mr. BROWN. Mr. President, I thank Senators Whitehouse and Blumenthal for their remarks. Children's Health Insurance Program Mr. President, it has been 100 days since this Congress allowed the Children's Health Insurance Program to expire. Congress did nothing in September, October, November, and December, and now we are more than a week into January--100 days of anxiety for parents, 100 days of wondering if their kids will be kicked off their coverage, 100 days of worrying if they will be able to afford their child's prescriptions or worrying whether they can take them to the doctor if they get the flu. Members of Congress--new Members, such as Senators Smith and Jones, Members like Senator Hatch, who has been here for 40 years, and all of us--have healthcare paid for by taxpayers. We remember the discussion of the tax bill written down the hall in the office of Majority Leader McConnell. The Senate found plenty of time in December to pass a massive handout for corporations. The Presiding Officer, the Senator from Florida, has since questioned whether too much of this bill went to corporate interests. More than 80 percent of the tax cut bill went to the richest 1 percent. In addition, we know it was a massive handout for corporations that sent jobs overseas. We are going to see more companies shut down in Mansfield, Lima, Zanesville, Chillicothe, Portsmouth, and in big cities like Columbus, Cleveland, and Cincinnati. We are going to see more plants close and move overseas because this Senate and the House passed a tax bill that encourages more corporations to ship jobs overseas. All the while, this body couldn't be bothered to give families more than a short-term funding Band-Aid for CHIP, which experts have said will not even last the last 3 months they promised. I applaud the Presiding Officer, the Senator from Florida, for his efforts to enlarge at least some of the tax bill to put more money into the pockets of working families, particularly low-income working families. It was not enough, but at least some effort was made. The Centers for Medicare and Medicaid Services are reporting that some States will run out of money by January 19, next week. In my State of Ohio, 209,000 children rely on CHIP. Who are these kids? These are sons and daughters of Ohioans, who are working, in most cases, making $8, $10, or $12 an hour. They are the sons and daughters of parents who don't have insurance not because they aren't working as hard or harder than we do, but they don't have insurance simply because their parents happen to work at a job where they are not provided insurance. There are 209,000 Ohio children who rely on CHIP, a program that has been bipartisan for 20 years. It was without controversy in the past. Families in some States already got letters last year and early this year warning them that their children could lose their healthcare. Think about these families. The parents of some of these millions of children around the country come home from work, working in a $10-an- hour job, not making a lot of money. They are working every bit as hard as we do. They go to the mailbox and see a letter from their State government. I will read one of these letters, a copy of which went to tens of thousands of parents: Because Congress has not acted yet, we need to let you know there is a chance that the CHIP Program may have to be shut down. In other words, there is a chance that your children's health insurance will be cut off. Remember, this is because of the inaction in this body. This is because Senators, who have insurance paid for by taxpayers, would rather vote for tax cuts, would rather do whatever we do all day instead of renewing the Children's Health Insurance Program. This letter goes on: If Congress does not renew Federal funds for CHIP in time, you will get another letter in January telling you your benefits will end. So first, it is a warning. Some parents got this warning right around Christmastime. They are already struggling financially. They are not giving their children nearly as much as they want for Christmas because they are making $8, $10, or $12 an hour. They are just trying to stay above water. They are just trying to raise their kids. They get a letter like this at Christmastime saying: If Congress doesn't act, there is really bad news; your kids are going to lose their insurance. Then the same letter says: If Congress doesn't act, in January you will get another letter saying your insurance is cut off. It is already an expensive time of year. There is record cold in Ohio. Several of our grandchildren live in Columbus, one of them in St. Croix, and two in Providence, RI. When a number of our grandchildren were around, it was too cold to go outside. It was that kind of winter in Ohio. The day after Christmas, temperatures dropped to single digits for 5, 6, or 7 days running. Families are paying more for their heating bill. At Christmastime, of course, it is more expensive. Now their government adds to this list of worries. How do they plan their budget for this year if they don't know whether or not they will have to shell out thousands of dollars more for care for their kids? Remember, 9 million children are at risk because of Republican inaction. Senator Portman, my Republican colleague from Ohio, and I and almost every other Senator on the Finance Committee voted to move forward on CHIP, to renew it for these 9 million children for 5 years. That was a good thing. It passed out of committee, but Senator McConnell, for whatever reason, didn't think this was important enough to actually put it on the floor, move on it, and get it to the President. I have no idea if the President will sign it. I don't think he knows much about the Children's Health Insurance Program, but I assume his advisers will say that it is probably a good idea to sign it. But he hasn't had a chance to sign it because the majority leader doesn't think this bill is important enough--that these 9 million children are important enough--that Congress should take action. These are often families with two working parents. They might make $8, $10, or $12 an hour, but they are working in jobs where they are not lucky enough to have health insurance. They work for companies or many for small businesses that, for whatever reason, can't afford it. Whatever the reason, they are working for companies that don't offer health insurance coverage [[Page S101]] for their families, or they are families with children with special needs. I have introduced to my colleagues before Crystal Lett. This is Crystal's son Noble, a first-grader in Dublin, OH, a small, prosperous suburb west and northwest of Columbus. I met Crystal and Noble last year, when they made the trip from Ohio to Washington to talk to Members of Congress about CHIP. Crystal's life is not easy because she is taking care of a child with a disability whom she so clearly and dearly loves. I could see, watching Noble, how much he loves his mother and how important they are to each other. Noble was born with a rare genetic disorder. He needs three therapy sessions every week. He gets daily hormone injections. His medications cost $1,500 a month. I talked to Crystal when she visited. I talked to her again. We talked about how she and her family are scared to death about what will happen to them if Congress doesn't save CHIP. This is not difficult. Congress has renewed it every year for 20 years. It is bipartisan. It has never had much of any ***opposition***. There are a lot of people like Noble's mother. Crystal said CHIP is ``the difference between living a middle class lifestyle, or being part of the poverty line.'' Congress had time to hand out massive permanent tax cuts to the richest Americans and the biggest corporations that send job overseas, but it could only manage to scrape together just a little short-term 3 months of funding for these families. It is really what is wrong with this city. Folks here listen too much to the lobbyists. I remember--and the Presiding Officer remembers, too--seeing the stream of lobbyists from drug companies, from insurance companies, from the big banks, and from the oil industry, in and out of Senator McConnell's office, writing a tax bill. We remember that from just a couple of months ago. But for some reason, Crystal and Noble couldn't get in that line--the line of lobbyists asking for huge tax breaks, saving billions of dollars for their employers while these lobbyists are paid very well. But, frankly, there was nobody having the political wherewithal to convince the majority leader that we ought to move on the CHIP bill. Healthcare for our kids shouldn't be controversial. It never was until this recent Senate and until this recent President was sworn in. It shouldn't be partisan. It should be easy. It is a program created 20 years ago. It was bipartisan. It has always been bipartisan. It still has bipartisan support today, except that the Speaker of the House down the hall and the majority leader a little closer to us just simply don't want to pass it. We passed the CHIP extension out of the Finance Committee. It is ready to go. Republican leaders could put it on the floor today, and it would pass. I am guessing that it would pass with no more than 5 or 10 ``no'' votes. I want my colleagues to explain to Noble's mother Crystal and to explain to other mothers and fathers like her why corporate tax cuts are more important than their children's health. This is about whose side you are on. Do we work for the corporations that send our jobs overseas, do we work for those companies that line up hungrily for tax breaks, or do we work for families who just want the peace of mind so they can take their kids to the doctor? It is past time for folks in Congress, with taxpayer-funded healthcare, to do their jobs and extend CHIP. I don't want more families to get a letter like this from their capital city, from the Department of Welfare or the Department of Job and Family Services, whatever it is in each community in each State. I don't want any more parents to go to the mailbox, to open this letter, and to have that fear and anxiety hit them in their gut, thinking: Oh, my God, my children's health insurance may be canceled. We can do better than that. I suggest the absence of a quorum. The PRESIDING OFFICER. The clerk will call the roll. The bill clerk proceeded to call the roll. Mr. McCONNELL. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded. The PRESIDING OFFICER. Without objection, it is so ordered.

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**End of Document**



[***Council of the European Union: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the internal market for electricity (recast) ST 10681 2017 INIT***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5R18-T1B1-JDG9-Y33X-00000-00&context=1516831)

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**Body**

Brussels: Council of the European Union has issued the following document:

 10681/17 BL/ns 1 DGE 2B EN Council of the European Union Brussels, 15 September 2017 (OR. en) 10681/17 ENER 308 ENV 646 CLIMA 201 COMPET 516 CONSOM 270 FISC 150 CODEC 1135 Interinstitutional File: 2016/0379 (COD) NOTE From: General Secretariat of the Council To: Delegations No. Cion doc.: 15135/1/16 ENER 418 ENV 758 CLIMA 169 COMPET 637 CONSOM 301 FISC 221 IA 131 CODEC 1809 REV 1 + ADD 1 REV 1 + ADD 2 REV 1 Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the internal market for electricity (recast) Delegations will find attached the Presidency's revised proposal on the draft regulation, amended in light of the discussions in the Energy Working Party and the written comments received. Furthermore, the text includes revisions in line with the opinion of the Consultative Working Party of Legal Services, as set out in doc. 10556/17. New text compared to the Commission proposal is indicated in bold underline. ***Deletions*** are marked by [brackets and strikethrough]. 10681/17 BL/ns 2 ANNEX DGE 2B EN ANNEX 2016/0379 (COD) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the internal market for electricity (recast) (Text with EEA relevance) THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty establishing the European Community,  Treaty on the Functioning of the European Union,  and in particular Article 95  194 (2)  thereof, Having regard to the proposal from the  European  Commission,  After transmission of the draft legislative act to the national parliaments,  Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the  ordinary legislative  procedure, Whereas: 10681/17 BL/ns 3 ANNEX DGE 2B EN  new (1) Regulation (EC) No 714/2009 of the European Parliament and of the Council1 has been substantially amended several times.

Since further amendments are to be made, that Regulation should be recast in the interests of clarity.  714/2009 recital 1 (adapted)  new (2)  The Energy Union aims at providing consumers – household and business – with safe, secure, sustainable, competitive and affordable energy. Historically, the electricity system was dominated by vertically integrated, often publicly owned, monopolies with large centralised nuclear or fossil fuel power plants. The internal market in electricity, which has been progressively implemented since 1999, aims to deliver a real choice for all consumers in the  Union  Community, bothbe they citizens andor businesses, new business opportunities and more cross-border trade, so as to achieve efficiency gains, competitive prices and higher standards of service, and to contribute to security of supply and sustainability.  The internal market in electricity has increased competition, in particular at the wholesale level, and cross-border trade. It remains the foundation of an efficient energy market.  1 Regulation (EC) No 714/2009 of the European Parliament and of the Council of 13 July 2009 on conditions for access to the network for cross-border exchanges in electricity and repealing Regulation (EC) No 1228/2003 (OJ L 211, 14.8.2009, p. 15). 10681/17 BL/ns 4 ANNEX DGE 2B EN  new (3) Europe's energy system is in the middle of its most profound change in decades and the electricity market is at the heart of that change. The common goal to decarbonise the energy system creates new opportunities and challenges for market participants. At the same time, technological developments allow for new forms of consumer participation and cross-border cooperation. (4) State interventions, often designed in an uncoordinated manner, have led to increasing distortions of the wholesale electricity market, with negative consequences for investments and cross-border trade. (5) In the past, electricity customers were purely passive, often buying electricity at regulated prices which had no direct relation to the market. In the future, customers need to be enabled to fully participate in the market on equal footing with other market participants. To integrate growing shares of renewable energy, the future electricity system should make use of all available sources of flexibility, particularly demand response and storage. To achieve effective decarbonisation at lowest cost, it also needs to encourage energy efficiency. (6) More market integration and the change towards a more volatile electricity production requires increased efforts to coordinate national energy policies with neighbours and to use the opportunities of cross-border electricity trade. 10681/17 BL/ns 5 ANNEX DGE 2B EN  714/2009 recitals 2 to 5 (2) Directive 2003/54/EC of the European Parliament and of the Council of 26 June 2003 concerning common rules for the internal market in electricity1 and Regulation (EC) No 1228/2003 of the European Parliament and of the Council of 26 June 2003 on conditions for access to the network for cross-border exchanges in electricity2 have made significant contributions towards the creation of such an internal market in electricity. (3) However, at present, there are obstacles to the sale of electricity on equal terms, without discrimination or disadvantage in the Community. In particular, non-discriminatory network access and an equally effective level of regulatory supervision do not yet exist in each Member State, and isolated markets persist. (4) The Communication of the Commission of 10 January 2007 entitled ‘An Energy Policy for Europe’ highlighted the importance of completing the internal market in electricity and creating a level playing field for all electricity undertakings in the Community. The Communications of the Commission of 10 January 2007 entitled ‘Prospects for the internal gas and electricity market’ and ‘Inquiry pursuant to Article 17 of Regulation (EC) No 1/2003 into the European gas and electricity sectors (Final Report)’ demonstrated that the present rules and measures neither provide the necessary framework nor provide for the creation of interconnection capacities to achieve the objective of a well-functioning, efficient and open internal market. (5) In addition to thoroughly implementing the existing regulatory framework, the regulatory framework for the internal market in electricity set out in Regulation (EC) No 1228/2003 should be adapted in line with those communications. 1 OJ L 176, 15.7.2003, p. 37. 2 OJ L 176, 15.7.2003, p. 1. 10681/17 BL/ns 6 ANNEX DGE 2B EN  new (7) Regulatory frameworks have developed, allowing electricity to be traded across the Union. That development has been supported by the adoption of several network codes and guidelines for the integration of the electricity markets. Those network codes and guidelines contain provisions on market rules, system operation and network connection. To ensure full transparency and increase legal certainty, the main principles of market functioning and capacity allocation in the balancing, intraday, day ahead and forward market timeframes should also be adopted pursuant to the ordinary legislative procedure and incorporated in a single act. (8) Core market principles should set out that electricity prices are to be determined through demand and supply. Those prices should signal when electricity is needed, providing market-based incentives for investments into flexibility sources such as flexible generation, interconnection, demand response or storage. (9) The decarbonisation of the electricity sector, with renewable energy becoming a major part of the market, is a core objective of the Energy Union. As the Union moves towards the decarbonisation of the electricity sector and increasing penetration of renewable energy sources, it is crucial that the market removes existing barriers to cross-border trade and encourages investments into supporting infrastructure, for example, more flexible generation, interconnection, demand response and storage. To support this shift to variable and distributed generation, and to ensure that energy market principles are the basis for the Union's electricity markets of the future, a renewed focus on short-term markets and scarcity pricing is essential. 10681/17 BL/ns 7 ANNEX DGE 2B EN (10) Short-term markets will improve liquidity and competition by enabling more resources to participate fully in the market, especially those that are more flexible. Effective scarcity pricing will encourage market participants to be available when the market most needs it and ensures that they can recover their costs in the wholesale market. It is therefore critical to ensure that, as far as possible, administrative and implicit price caps are removed to allow scarcity prices to increase up to the value of lost load. When fully embedded in the market structure, short-term markets and scarcity pricing will contribute to the removal of other measures, such as capacity mechanisms, to ensure security of supply. At the same time, scarcity pricing without price caps on the wholesale market should not jeopardize the possibility for reliable and stable prices for final customers, in particular households and SMEs. (11) Subject to Union State aid rules pursuant to Articles 107, 108 and 109 derogations to fundamental market principles such as balancing responsibility, market-based dispatch, or [curtailment and] redispatch reduce flexibility signals and act as barriers to the development of solutions such as storage, demand response or aggregation. While derogations are still necessary to avoid unnecessary administrative burden for certain actors, in particular households and SMEs, broad derogations covering entire technologies are not consistent with the objective of achieving market-based and efficient decarbonisation and should thus be replaced by more targeted measures. 10681/17 BL/ns 8 ANNEX DGE 2B EN  714/2009 recital 16 (12) The precondition for effective competition in the internal market in electricity is non-discriminatory and transparent charges for network use including interconnecting lines in the transmission system. The available capacity of those lines should be set at the maximum levels consistent with the safety standards of secure network operation.  714/2009 recital 17 (13) It is important to avoid distortion of competition resulting from the differing safety, operational and planning standards used by transmission system operators in Member States. Moreover, there should be transparency for market participants concerning available transfer capacities and the security, planning and operational standards that affect the available transfer capacities.  new (14) To efficiently steer necessary investments, prices also need to provide signals where electricity is most needed. In a zonal electricity system, correct locational signals require a coherent, objective and reliable determination of bidding zones via a transparent process. In order to ensure efficient operation and planning of the Union electricity network and to provide effective price signals for new generation capacity, demand response or transmission infrastructure, bidding zones should reflect structural congestion. In particular, cross-zonal capacity should not be reduced in order to resolve internal congestion. 10681/17 BL/ns 9 ANNEX DGE 2B EN (15) Efficient decarbonisation of the electricity system via market integration requires systematically abolishing barriers to cross-border trade to overcome market fragmentation and to allow Union energy customers to fully benefit from the advantages of integrated electricity markets and competition.  714/2009 recital 10 (16) This Regulation should lay down basic principles with regard to tarification and capacity allocation, whilst providing for the adoption of gGuidelines detailing further relevant principles and methodologies, in order to allow rapid adaptation to changed circumstances.  714/2009 recital 22 (17) The management of congestion problems should provide correct economic signals to transmission system operators and market participants and should be based on market mechanisms.  714/2009 recital 11 (18) In an open, competitive market, transmission system operators should be compensated for costs incurred as a result of hosting cross-border flows of electricity on their networks by the operators of the transmission systems from which cross-border flows originate and the systems where those flows end. 10681/17 BL/ns 10 ANNEX DGE 2B EN  714/2009 recital 12 (19) Payments and receipts resulting from compensation between transmission system operators should be taken into account when setting national network tariffs.  714/2009 recital 13 (20) The actual amount payable for cross-border access to the system can vary considerably, depending on the transmission system operator involved and as a result of differences in the structure of the tarification systems applied in Member States. A certain degree of harmonisation is therefore necessary in order to avoid distortions of trade.  714/2009 recital 21 (21) There should be rules on the use of revenues flowing from congestion-management procedures, unless the specific nature of the interconnector concerned justifies an exemption from those rules.  new (22) To provide for a level playing field between all market participants, network tariffs should be applied in a way which does not discriminate between production connected at the distribution-level with regard to the production connected at the transmission level, either positively or negatively. They should not discriminate against energy storage, and should not create disincentives for participation in demand response or represent an obstacle to improvements in energy efficiency. 10681/17 BL/ns 11 ANNEX DGE 2B EN (23) In order to increase transparency and comparability in tariff-setting where binding harmonization is not seen as adequate, recommendations on tariff methodologies should be issued by the European Agency for the Cooperation of Energy Regulators established by [recast of Regulation (EC) No 713/2009 as proposed by COM(2016) 863/2] ('the Agency'). (24) To better ensure optimum investment in the trans-European grid and address the challenge where viable interconnection projects cannot be built for lack of prioritisation at national level, the use of congestion rents should be reconsidered and only allowed in order to guarantee availability and maintain or increase interconnection capacities.  714/2009 recital 7 (adapted) (25) In order to ensure optimal management of the electricity transmission network and to allow trading and supplying electricity across borders in the  Union  Community, a European Network of Transmission System Operators for Electricity (the ENTSO for Electricity), should be established. The tasks of the ENTSO for Electricity should be carried out in compliance with  Union's  Community competition rules which remain applicable to the decisions of the ENTSO for Electricity. The tasks of the ENTSO for Electricity should be well-defined and its working method should ensure efficiency, transparency and the representative nature of the ENTSO for Electricity. The network codes prepared by the ENTSO for Electricity are not intended to replace the necessary national network codes for non-cross-border issues. Given that more effective progress may be achieved through an approach at regional level, transmission system operators should set up regional structures within the overall cooperation structure, whilst ensuring that results at regional level are compatible with network codes and non-binding ten-year network development plans at  Union  Community level. Member States should promote cooperation and monitor the effectiveness of the network at regional level. Cooperation at regional level should be compatible with progress towards a competitive and efficient internal market in electricity. 10681/17 BL/ns 12 ANNEX DGE 2B EN  new (26) A robust medium to long-term Union level resource adequacy assessment should be carried out by the ENTSO for Electricity to provide an objective basis for the assessment of adequacy concerns. The resource adequacy concern that capacity mechanisms address should be based on the EU assessment. (27) The medium to long-term resource adequacy assessment (from 10 year-ahead to year-ahead) set out in this regulation has a different purpose than the seasonal outlooks (six months ahead) as set out in Article 9 [Regulation on risk preparedness as proposed by COM(2016) 862]. Medium- to long-term assessments are mainly used to assess the need for capacity mechanisms whereas seasonal outlooks are used to alert to risks that might occur in the following six months that are likely to result in a significant deterioration of the electricity supply situation. In addition, [Regional Operational Centres] Regional Security Coordinators [+] also carry out regional adequacy assessments as defined in European legislation on electricity transmission system operation. These are very short-term adequacy assessments (from weak-ahead to day-ahead) used in the context of system operation. (28) Prior to introducing capacity mechanisms, Member States should assess regulatory distortions contributing to the related resource adequacy concern. They should be required to adopt measures to eliminate the identified distortions including a timeline for their implementation. Capacity mechanisms should only be introduced for the residual concerns that cannot be addressed through removing such distortions. 10681/17 BL/ns 13 ANNEX DGE 2B EN (29) Member States intending to introduce capacity mechanisms should derive resource adequacy targets following a transparent and verifiable process. Member States should have the freedom to set their own desired level of security of supply. (30) Main principles of capacity mechanisms should be laid down, building on the environmental and energy State aid principles and the findings of DG Competition's Sector Inquiry on capacity mechanisms. Capacity mechanisms already in place should be reviewed in light of these principles. In case the European resource adequacy assessment reveals the absence of any adequacy concern, no new capacity mechanism should be established and no new capacity commitments under mechanisms already in place should be made. The application of the State aid control rules pursuant to Articles 107 to 109 TFUE must be complied with at all times. (31) Detailed rules for facilitating effective cross-border participation in capacity mechanisms other than reserve schemes should be laid down. Transmission system operators across the borders should facilitate interested generators wanting to participate in capacity mechanisms in other Member States. Therefore, they should calculate capacities up to which cross-border participation would be possible, enable participation and check availabilities. National regulatory authorities should enforce the cross-border rules in the Member States. (32) In view of differences in national energy systems and technical limitations of existing electricity networks, the best approach to achieving progress in market integration will often be at a regional level. Regional cooperation of transmission system operators should thus be strengthened. In order to ensure efficient cooperation, a new regulatory framework should foresee stronger regional governance and regulatory oversight, including by strengthening the decision-making power of the Agency for cross-border issues. Closer cooperation of Member States could be needed also in crisis situations, to increase security of supply and limit market distortions. 10681/17 BL/ns 14 ANNEX DGE 2B EN (33) The coordination between transmission system operators at regional level has been formalised with the mandatory participation of transmission system operators in regional security coordinators, which should be complemented by an enhanced institutional framework via the establishment of [Regional Operational Centres] Regional Security Coordinators [+]. The creation of [Regional Operational Centres] Regional Security Coordinators [+] should take into account existing regional coordination initiatives and support the increasingly integrated operation of electricity systems across the Union, ensuring their efficient and secure performance. (34) The ***geographical*** scope of [Regional Operational Centres] Regional Security Coordinators [+] should allow them to play an effective coordination role by optimising the operations of transmission system operators over larger regions. (35) [Regional Operational Centres] Regional Security Coordinators [+] should carry out functions where their regionalisation brings added value compared to functions performed at national level. The functions of [Regional Operational Centres] Regional Security Coordinators [+] should cover the functions carried out by regional security coordinators as well as additional system operation, market operation and risk preparedness functions. The functions carried out by [Regional Operational Centres] Regional Security Coordinators [+] should exclude real time operation of the electricity system. (36) [Regional Operational Centres] Regional Security Coordinators [+]should primarily act in the interest of system and market operation of the region over the interests of any single entity. Hence, [Regional Operational Centres] Regional Security Coordinators [+]should be entrusted with decision-making powers to act and to direct actions to be taken by transmission system operators of the system operation region for certain functions and with an enhanced advisory role for the remaining functions. 10681/17 BL/ns 15 ANNEX DGE 2B EN (37) ENTSO for Electricity should ensure that the actions of [Regional Operational Centres] Regional Security Coordinators [+] are coordinated across the regions' boundaries. (38) In order to raise efficiencies in the electricity distribution networks in the Union and ensure close cooperation with transmission system operators and ENTSO for electricity, a European entity of distribution system operators in the Union ('EU DSO entity') should be established. The tasks of the EU DSO entity should be well-defined and its working method should ensure efficiency, transparency and representativeness amongst the Union distribution system operators. The EU DSO Entity should closely cooperate with ENTSO for Electricity on the preparation and implementation of the network codes where applicable and should work on providing guidance on the integration inter alia of distributed generation and storage in distribution networks or other areas which relate to the management of distribution networks. 10681/17 BL/ns 16 ANNEX DGE 2B EN  714/2009 recital 6 (adapted) (39) In particular, iIncreased cooperation and coordination among transmission system operators is required to create network codes for providing and managing effective and transparent access to the transmission networks across borders, and to ensure coordinated and sufficiently forward-looking planning and sound technical evolution of the transmission system in the  Union  Community, including the creation of interconnection capacities, with due regard to the environment. Those network codes should be in line with framework guidelines, which are non-binding in nature (framework guidelines) and which are developed by the Agency for the Cooperation of Energy Regulators established by Regulation (EC) No 713/2009 of the European Parliament and of the Council of 13 July 2009 establishing an Agency for the Cooperation of Energy Regulators1 (the Agency). The Agency should have a role in reviewing, based on matters of fact, draft network codes, including their compliance with the framework guidelines, and it should be enabled to recommend them for adoption by the Commission. The Agency should assess proposed amendments to the network codes and it should be enabled to recommend them for adoption by the Commission. Transmission system operators should operate their networks in accordance with those network codes. 1 See page 1 of this Official Journal. 10681/17 BL/ns 17 ANNEX DGE 2B EN  714/2009 recital 24 (40) To ensure the smooth functioning of the internal market in electricity, provision should be made for procedures which allow the adoption of decisions and gGuidelines with regard, inter alia, to tarification and capacity allocation by the Commission whilst ensuring the involvement of Member States’ regulatory authorities in that process, where appropriate through their European association. Regulatory authorities, together with other relevant authorities in the Member States, have an important role to play in contributing to the proper functioning of the internal market in electricity.  714/2009 recital 8 (adapted) (41) All market participants have an interest in the work expected of the ENTSO for Electricity. An effective consultation process is therefore essential and existing structures that are set up to facilitate and streamline the consultation process, such as the Union for the Coordination of Transmission of Electricity,  via  national regulators or the Agency, should play an important role. 10681/17 BL/ns 18 ANNEX DGE 2B EN  714/2009 recital 9 (adapted) (42) In order to ensure greater transparency regarding the entire electricity transmission network in the  Union  Community, the ENTSO for Electricity should draw up, publish and regularly update a non-binding  Union  Community-wide ten-year network development plan ( Union  Community-wide network development plan). Viable electricity transmission networks and necessary regional interconnections, relevant from a commercial or security of supply point of view, should be included in that network development plan.  new (43) Experience with the development and adoption of network codes has shown that it is useful to streamline the development procedure by clarifying that the Agency has the right to revise draft electricity network codes before submitting them to the Commission.  714/2009 recital 14 A proper system of long-term locational signals is necessary, based on the principle that the level of the network access charges should reflect the balance between generation and consumption of the region concerned, on the basis of a differentiation of the network access charges on producers and/or consumers. 10681/17 BL/ns 19 ANNEX DGE 2B EN  714/2009 recital 15 It would not be appropriate to apply distance-related tariffs or, provided appropriate locational signals are in place, a specific tariff to be paid only by exporters or importers in addition to the general charge for access to the national network.  714/2009 recital 18 Market monitoring undertaken over recent years by the national regulatory authorities and by the Commission has shown that current transparency requirements and rules on access to infrastructure are not sufficient to secure a genuine, well-functioning, open and efficient internal market in electricity.  714/2009 recital 19 Equal access to information on the physical status and efficiency of the system is necessary to enable all market participants to assess the overall demand and supply situation and identify the reasons for movements in the wholesale price. This includes more precise information on electricity generation, supply and demand including forecasts, network and interconnection capacity, flows and maintenance, balancing and reserve capacity. 10681/17 BL/ns 20 ANNEX DGE 2B EN  714/2009 recital 23 (44) Investments in major new infrastructure should be promoted strongly while ensuring the proper functioning of the internal market in electricity. In order to enhance the positive effect of exempted direct current interconnectors on competition and security of supply, market interest during the project-planning phase should be tested and congestion-management rules should be adopted. Where direct current interconnectors are located in the territory of more than one Member State, the Agency should handle as a last resort the exemption request in order to take better account of its cross-border implications and to facilitate its administrative handling. Moreover, given the exceptional risk profile of constructing those exempt major infrastructure projects, undertakings with supply and production interests should be able to benefit from a temporary derogation from the full unbundling rules for the projects concerned. Exemptions granted under Regulation (EC) No 1228/20031 continue to apply until the scheduled expiry date as decided in the granted exemption decision.  714/2009 recital 25 National regulatory authorities should ensure compliance with the rules contained in this Regulation and the Guidelines adopted pursuant thereto. 1 Regulation (EC) No 1228/2003 of the European Parliament and of the Council of 26 June 2003 on conditions for access to the network for cross-border exchanges in electricity (OJ L 176, 15.7.2003, p. 1). 10681/17 BL/ns 21 ANNEX DGE 2B EN  714/2009 recital 20 (45) To enhance trust in the market, its participants need to be sure that those engaging in abusive behaviour can be subject to effective, proportionate and dissuasive penalties. The competent authorities should be given the competence to investigate effectively allegations of market abuse. To that end, it is necessary that competent authorities have access to data that provides information on operational decisions made by supply undertakings. In the electricity market, many relevant decisions are made by the generators, which should keep information in relation thereto available to and easily accessible by the competent authorities for a fixed period of time. The competent authorities should, furthermore, regularly monitor the compliance of the transmission system operators with the rules. Small generators with no real ability to distort the market should be exempt from that obligation.  714/2009 recital 26 (46) The Member States and the competent national authorities should be required to provide relevant information to the Commission. Such information should be treated confidentially by the Commission. Where necessary, the Commission should have an opportunity to request relevant information directly from undertakings concerned, provided that the competent national authorities are informed. 10681/17 BL/ns 22 ANNEX DGE 2B EN  714/2009 recital 27 (47) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.  714/2009 recital 28 The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission1.  714/2009 recital 29 In particular, the Commission should be empowered to establish or adopt the Guidelines necessary for providing the minimum degree of harmonisation required to achieve the aims of this Regulation. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC. 1 OJ L 184, 17.7.1999, p. 23. 10681/17 BL/ns 23 ANNEX DGE 2B EN  new (48) Member States and the Energy Community Contracting Parties should closely cooperate on all matters concerning the development of an integrated electricity trading region and should take no measures that endanger the further integration of electricity markets or security of supply of Member States and Contracting Parties. (49) In order to ensure the minimum degree of harmonization required for effective market functioning, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be [delegated] to the Commission in respect of areas which are fundamental for market integration. These should include the ***geographical*** area for regional cooperation of transmission system operators, the amount of compensation payments between transmission system operators, the adoption and amendment of network codes and guidelines, as well as the application of exemption

provisions for new interconnectors. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 20161. In particular, to ensure equal participation in the preparation of [delegated] acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of [delegated] acts. 1 OJ L 123, 12.5.2016, p. 1. 10681/17 BL/ns 24 ANNEX DGE 2B EN  714/2009 recital 30 (adapted) (50) Since the objective of this Regulation, namely the provision of a harmonised framework for cross-border exchanges of electricity, cannot be sufficiently achieved by the Member States and can therefore be better achieved at  Union  Community level, the  Union  Community may adopt measures, in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty  on European Union  . In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective. (51) Market rules should enable the integration of electricity from renewable energy sources and provide incentives for increasing energy efficiency; (52) Market rules should deliver appropriate investment incentives for generation, storage, energy efficiency and demand response to meet market needs and thus ensure security of supply while reflecting both the real internal and external costs as well as the principle of sustainable development; (53) Market rules should allow for progress in research and development to be realized and used to the benefit of society; (54) With regard to balancing markets, efficient and non-distrotive price formation in the procurement of balacing capacity and balancing energy requires that balacing capacity does not set the price for balancing energy. This is without prejudice for the disptaching systems using an integrated scheduling process according to the [Commission Regulation XXX on establishing a guideline on electricity balancing]. 10681/17 BL/ns 25 ANNEX DGE 2B EN  714/2009 recital 31 Given the scope of the amendments that are being made herein to Regulation (EC) No 1228/2003, it is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast by bringing them all together in a single text in a new Regulation, 10681/17 BL/ns 26 ANNEX DGE 2B EN  714/2009 (adapted) HAVE ADOPTED THIS REGULATION: Chapter I  Subject matter, scope and definitions  Article 1 Subject-matter and scope This Regulation aims at:  new (a) setting the basis for an efficient achievement of the objectives of the European Energy Union and in particular the climate and energy framework for 20301 by enabling market signals to be delivered for increased flexibility, sustainability, decarbonisation and innovation; 1 COM/2014/015 final. 10681/17 BL/ns 27 ANNEX DGE 2B EN (b) setting fundamental principles for well-functioning, integrated electricity markets, which allow non-discriminatory market access for all resource providers and electricity customers, empower consumers, enable demand response and energy efficiency, facilitate aggregation of distributed demand and supply, and contribute to the decarbonisation of the economy by enabling market integration and market-based remuneration of electricity generated from renewable sources;  714/2009 (adapted)  new (ca) setting fair rules for cross-border exchanges in electricity, thus enhancing competition within the internal market in electricity, taking into account the particular characteristics of national and regional markets. This  includes  will involve the establishment of a compensation mechanism for cross-border flows of electricity and the setting of harmonised principles on cross-border transmission charges and the allocation of available capacities of interconnections between national transmission systems; (db)facilitating the emergence of a well-functioning and transparent wholesale market with a high level of security of supply in electricity. It provides for mechanisms to harmonise the rules for cross-border exchanges in electricity. 10681/17 BL/ns 28 ANNEX DGE 2B EN Article 2 Definitions 1. For the purpose of this Regulation, the definitions contained in Article 2 of Directive 2009/72/EC [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2] of the European Parliament and of the Council of 13 July 2009concerning common rules for the internal market in electricity , in Article 2 of Regulation (EU) No 1227/2011 of the European Parliament and of the Council1, in Article 2 of Commission Regulation (EU) No 543/20132 and in Article 2 of [Recast Renewable Energies Directive] apply, with the exception of the definition of ‘interconnector’ which shall be replaced by the following:— ‘interconnector’ means a transmission line which crosses or spans a border between Member States and which connects the national transmission systems of the Member States. 2.  In addition,  tThe following definitions shall apply: (a) ‘regulatory authorities’ means the regulatory authorities referred to in Article 5735(1) of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2] Directive 2009/72/EC; (b) ‘cross-border flow’ means a physical flow of electricity on a transmission network of a Member State that results from the impact of the activity of producers and/or  customers  consumers outside that Member State on its transmission network; 1 Regulation (EU) No 1227/2011 of the European Parliament and of the Council of 25 October 2011 on wholesale energy market integrity and transparency (OJ L 326, 8.12.2011, p. 1). 2 Commission Regulation (EU) No 543/2013 of 14 June 2013 on submission and publication of data in electricity markets and amending Annex I to Regulation (EC) No 714/2009 of the European Parliament and of the Council (OJ L 163, 15.6.2013, p. 1). 10681/17 BL/ns 29 ANNEX DGE 2B EN (c) ‘congestion’ means a situation in which  all requests from market participants to trade between [two bidding zones] network areas cannot be accommodated because they would significantly affect the physical flows on network elements which cannot accommodate those flows  an interconnection linking national transmission networks cannot accommodate all physical flows resulting from international trade requested by market participants, because of a lack of capacity of the interconnectors and/or the national transmission systems concerned; (d) ‘declared export’ means the dispatch of electricity in one Member State on the basis of an underlying contractual arrangement to the effect that the simultaneous corresponding take-up (declared import) of electricity will take place in another Member State or a third country; (e) ‘declared transit’ means a circumstance where a declared export of electricity occurs and where the nominated path for the transaction involves a country in which neither the dispatch nor the simultaneous corresponding take-up of the electricity will take place; (f) ‘declared import’ means the take-up of electricity in a Member State or a third country simultaneously with the dispatch of electricity (declared export) in another Member State; (g)(d) ‘new interconnector’ means an interconnector not completed by 4 August 2003;.  new (e) 'structural congestion' means congestion in the transmission system that is predictable, is ***geographically*** stable over time, and is frequently reoccurring under normal power system conditions; 10681/17 BL/ns 30 ANNEX DGE 2B EN (f) 'market operator' means an entity that provides a service whereby the offers to sell electricity are matched with bids to buy electricity; (g) 'nominated electricity market operator' or 'NEMO’ means a market operator designated by the competent authority to perform tasks related to single day-ahead or single intraday coupling; (h) 'value of lost load' means an estimation in €/MWh, of the maximum electricity price that customers are willing to pay to avoid an outage; (i) 'balancing' means all actions and processes, in all timelines, through which transmission system operators ensure, in a continuous way, maintenance of the system frequency within a predefined stability range and compliance with the amount of reserves needed with respect to the required quality; (j) 'balancing energy' means energy used by transmission system operators to perform balancing; (k) 'balancing service provider' means a market participant providing either or both balancing energy and balancing capacity to transmission system operators; (l) 'balancing capacity' means a volume of capacity that a balancing service provider has agreed to hold to and in respect to which the balancing service provider has agreed to submit bids for a corresponding volume of balancing energy to the transmission system operator for the duration of the contract; 10681/17 BL/ns 31 ANNEX DGE 2B EN (m) 'balance responsible party' means a market participant or its chosen representative responsible for its imbalances in the electricity market; (n) 'imbalance settlement period' means the time unit for which the imbalance of the balance responsible parties is calculated; (o) 'imbalance price' means the price, be it positive, zero or negative, in each imbalance settlement period for an imbalance in each direction; (p) 'imbalance price area' means the area in which an imbalance price is calculated; (q) 'prequalification process' means the process to verify the compliance of a provider of balancing capacity with the requirements set by the transmission system operators; (r) 'reserve capacity' means the amount of frequency containment reserves, frequency restoration reserves or replacement reserves that needs to be available to the transmission system operator; (s) 'priority dispatch' means in self-dispatch model systems the dispatch of power plants on the basis of criteria different from the economic order of bids and, in central dispatch model systems, also from network constraints, giving priority to the dispatch of particular generation technologies; 10681/17 BL/ns 32 ANNEX DGE 2B EN (t) 'capacity calculation region' means the geographic area in which the coordinated capacity calculation is applied; (u) 'capacity mechanism' means an administrative measure to ensure the achievement of the desired level of resource adequacy [security of supply] by remunerating resources for their availability not including measures relating to ancillary services; [(v) '***strategic*** reserve' means a capacity mechanism in which resources are only dispatched in case day-ahead and intraday markets have failed to clear, transmission system operators have exhausted their balancing resources to establish an equilibrium between demand and supply, and imbalances in the market during periods where the reserves were dispatched are settled at the value of lost load;] (w) ‘high-efficiency cogeneration’ means cogeneration meeting the criteria laid down in Annex II of Directive 2012/27/EU of the European Parliament and of the Council1; (x) ‘demonstration project’ means a project demonstrating a technology as a first of its kind in the Union and representing a significant innovation that goes well beyond the state of the art. 1 Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC (OJ L 315, 14.11.2012, p. 1). 10681/17 BL/ns 33 ANNEX DGE 2B EN (y) 'market participant' means a natural or legal person, who is buying or selling electricity, demand response or storage services, including the placing of orders to trade, in one or more electricity markets including balancing energy markets. (z) 'redispatching1' means a measure activated by one or several system operators by altering the generation and/or load pattern in order to change physical flows in the transmission system and relieve a physical congestion. (aa) 'countertrading' means a exchange initiated by system operators between two network areas to relieve physical congestion. (bb) 'power generating facility' means a facility that converts primary energy into electrical energy and which consists of one or more power generating modules connected to a network at one or more connection points. (cc) 'central dispatching model' means a scheduling and dispatching model where the generation schedules and consumption schedules as well as dispatching of power generating facilities and demand facilities, in reference to dispatchable facilities, are determined by a TSO within the integrated scheduling process. 1 Definition included in Commission Regulation (EU) No 543/2013 10681/17 BL/ns 34 ANNEX DGE 2B EN Chapter II General rules for the electricity market Article 3 Principles regarding the operation of electricity markets 1. Member States, national regulatory authorities, transmission system operators, distribution system operators, and market operators shall ensure that electricity markets are operated in accordance with the following principles: (a) prices shall be formed based on demand and supply; (b) actions which prevent price formation on the basis of demand and supply or constitute a disincentive to the development of more flexible generation, low carbon generation, or more flexible demand shall be avoided; (c) customers shall be enabled to benefit from market opportunities and increased competition on retail markets; (d) market participation of consumers and small businesses shall be enabled by aggregation of generation from multiple generation facilities or load from multiple demand facilities to provide joint offers on the electricity market and be jointly operated in the electricity system, subject to compliance with EU treaty rules on competition; 10681/17 BL/ns 35 ANNEX DGE 2B EN [(e) market rules shall support the decarbonisation of the economy by enabling the integration of electricity from renewable energy sources and providing incentives for energy efficiency;] [(f) market rules shall deliver appropriate investment incentives for generation, storage, energy efficiency and demand response to meet market needs and thus ensure security of supply;] (g) barriers to cross-border electricity flows and cross-border transactions on electricity markets and related services markets shall be avoided; (h) market rules shall provide for regional cooperation where effective; (i) all generation, storage and demand resources shall participate on equal footing in the market, unless otherwise provided for in the EU law; (j) all producers shall be directly or indirectly responsible for selling the electricity they generate; [(k) market rules shall allow for progress in research and development to be realized and used to the benefit of society;] (l) market rules shall enable the efficient dispatch of generation assets and demand response; (m) market rules shall allow for entry and exit of electricity generation and electricity supply undertakings based on their assessment of the economic and financial viability of their operations; 10681/17 BL/ns 36 ANNEX DGE 2B EN (n) long-term hedging opportunities, which allow market participants to hedge against price volatility risks on a market basis, and [eliminate] mitigate uncertainty on future returns on investment shall be tradable on exchanges in a transparent manner subject to compliance with EU treaty rules on competition. (o) market participants have a right to obtain access to the transmissin and distribution networks on objective, transparent and non-discriminatory terms. Article 4 Balancinge responsibility 1. All market participants [shall aim for system balance and] shall be financially responsible for the imbalances they cause in the system. They shall either be balance responsible parties or contractually delegate their responsibility to a balance responsible party of their choice. Market rules shall incentivise all market participants to aim for system balance. 2. Member States may provide for derogation from the financial responsibility of imbalances [balance responsibility] in respect of: (a) demonstration projects for emerging technologies as defined in Article 66 and 67 of the Commission Regulation (EU) 2016/631; (b) power generating facility, using renewable energy sources or high-efficiency cogeneration with an total installed electricity capacity of less than [500 ]250 kW; 10681/17 BL/ns 37 ANNEX DGE 2B EN (c) installations benefitting from support approved by the Commission under Union State aid rules pursuant to Articles 107 to 109 TFEU, and commissioned prior to [OP: entry into force]. Member States may, subject to Union state aid rules, incentivize market participants which are fully or partly exempted from balancing responsibility to accept full balancing responsibility. [against appropriate compensation.] 2a. When a Member State chooses to provide a derogation according to Article 4 (2), they need to ensure that the financial responsibilities of imbalances are fulfilled by another party. 3. For power generating facilities comissioned after 1 January 2026, point (b) of paragraph 2 shall apply only to renewable energy sources or high-efficiency cogeneration with an total installed electricity capacity of less than [250] 501 kW. Article 5 Balancing market [1. All market participants shall have access to the balancing market be it individually or through aggregation. Balancing market rules and products shall respect the need to accommodate increasing shares of variable generation as well as increased demand responsiveness and the advent of new technologies.] 1 RES directive Art 17 to be checked for consistiency 10681/17 BL/ns 38 ANNEX DGE 2B EN 2. Balancing markets, including prequalification processes, shall be organised in such a way as to: (a) ensure effective non-discrimination between market participants taking account of the different technical needs of the system, a transparent and technologically neutral definition of services and their transparent, market based procurement [capability of generation from variable renewable sources and demand side response and storage]; (b) ensure access to all prequalified market participants, be it individual or through aggregation; (c) respect the need to accommodate increasing shares of variable generation as well as increased demand responsiveness and the advent of new technologies. 3. Balancing energy shall be procured separately from balancing capacity except in case of a central dispatching model. The price of balancing energy shall not be pre-determined in a contract of balancing except where an exemption is applied in accordance with paragraph 6 of Article 16 of the [Commission Regulation XXX on establishing a guideline on electricity balancing]. Procurement processes shall be transparent while at the same time respecting confidentiality. 4. Balancing markets shall ensure operational security whilst allowing for maximum use and efficient allocation of cross-zonal capacity across timeframes in accordance with Article 15. 10681/17 BL/ns 39 ANNEX DGE 2B EN 5. [Marginal pricing shall be used for] Tthe settlement of balancing energy shall be based on marginal pricing. Market participants shall be allowed to bid as close to real time as possible, and [at least after] balancing energy gate closure times shall not be before the intraday cross-zonal gate closure time determined in accordance with Article 59 of Commission Regulation (EU) 2015/12221. Transmission system operator applying a central dispatching model may define additional rules in accordance with paragraph six Article 24 of the [Commission Regulation (EU) 2017/XXX on establishing a guideline on electricity balancing] 6. The imbalances shall be settled at a price that reflects the real time value of energy and shall be calculated in accordance with Title V [Commission Regulation (EU) 2017/XXX on establishing a guideline on electricity balancing]. 6a. Each imbalance price area should be equal to a bidding zone, except for central dispatching model. 7. The sizing of reserve capacity shall be performed at regional level in accordance with point 7 of Annex I. [Regional Operational Centres] Regional Security Coordinators [+] shall support transmission system operators in determining the amount of balancing capacity that needs to be procured in accordance with point 8 of Annex I. 1 Commission Regulation (EU) 2015/1222 of 24 July 2015 establishing a guideline on capacity allocation and congestion management (OJ L 197, 25.7.2015, p. 24). 10681/17 BL/ns 40 ANNEX DGE 2B EN 8. The procurement of balancing capacity shall be performed by the transmission system operators and facilitated on a regional level in accordance with point 8 of Annex I. The procurement shall be based on a primary market and organised in such a way as to be non-discriminatory between market participants in the prequalification process individually or through aggregation. The allocation of cross-zonal capacity for the exchange of balancing capacity or sharing of reserve shall be limited to 5% of the available capacity for the exchange of energy of the previous relevant calendar year between the respective bidding zones. 9. The procurement of upward balancing capacity and downward balancing capacity shall be carried out separately, exept in cases defined in paragraph three of Article 32 of the [Commission Regulation (EU) 2017/XXX on establishing a guideline on electricity balancing]. To the extent possible, and at least for a minimum of [75] % of the balancing capacity, Tthe contracting of balancing capacity shall be performed for not longer than one day before the provision of the balancing capacity and the contracting period shall have a maximum of one day. The contracting of the remaining part of the balancing capacity shall be performed for a maximum of one month in advance of the provision of balancing capacity and the contracting period of the remaining part of balancing capacity shall have a maximum period of one month. 9a. On the request of the transmission system operator the national regulatory authority may lower the threshold refered to in paragraph 9 to [60]% provided that such decision will be limited in time, and the posititve effects in terms of lowering of costs for consumers will exceed the negative impacts on the market. The request shall include: 10681/17 BL/ns 41 ANNEX DGE 2B EN (a) specification of the time period during which the exemption would apply; (b) specification of the volume of balancing capacity for which the exemption would apply; (c) analysis of the impact of such an exemption on the participation of balancing resources; and (d) justification for the exemption demonstrating that such an exemption would lead to lower costs for consumers. 10. Transmission system operators shall publish, as soon as possible but not later than 30 minutes after [close to ] real-time, the information on the current system balance [balancing state] of their [control] scheduling areas and the estimated [imbalance price] balancing energy prices. 10681/17 BL/ns 42 ANNEX DGE 2B EN Article 6 Day-ahead and intraday markets 1. Transmission system operators and nominated electricity market operators shall jointly organise the management of the integrated day-ahead and intraday markets based on market coupling as set out in Regulation (EU) 2015/1222. Transmission system operators and nominated electricity market operators shall cooperate at Union level or, where more appropriate, on a regional basis in order to maximise the efficiency and effectiveness of Union electricity day-ahead and intraday trading. The obligation to cooperate shall be without prejudice to the application of the provisions of Union competition law. In their functions relating to electricity trading, transmission system operators and nominated electricity market operators shall be subject to regulatory oversight by regulators and the Agency pursuant to Article 59 of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2] and Articles 4 and 9 of [recast of Regulation (EC) No 713/2009 as proposed by COM(2016) 863/2]. 2. Day-ahead and intraday markets shall (a) be organised in such a way as to be non-discriminatory; (b) maximise the ability of all market participants to [contribute to avoid system] manage their imbalances; 10681/17 BL/ns 43 ANNEX DGE 2B EN (c) maximise the opportunities for all market participants to participate in cross-[border] zonal trade as close as possible to real time across all bidding zones; (d) provide prices that reflect market fundamentals, including the real time value of energy, and that market participants can rely on when agreeing on longer-term hedging products; (e) ensure operational security whilst allowing for maximum use of transmission capacity; (f) be transparent while at the same time respecting confidentiality and ensuring trading occurs in an anonymous manner; and; [(g) ensure trades are anonymous; and] (h) make no distinction between trades made within a bidding zone and across bidding zones. [3. Market operators shall be free to develop products and trading opportunities that suit market participants' demand and needs and ensure that all market participants are able to access the market individually or through aggregation. They shall respect the need to accommodate increasing shares of variable generation as well as increased demand responsiveness and the advent of new technologies.] 10681/17 BL/ns 44 ANNEX DGE 2B EN Article 7 Trade on day-ahead and intraday markets 1. Nominated electricity Mmarket operators shall allow market participants to trade energy as close to real time as possible and at least up to the intraday cross-zonal gate closure time determined in accordance with Article 59 of Regulation (EU) 2015/1222. 2. Nominated electricity Mmarket operators shall provide market participants with the opportunity to trade in energy in time intervals at least as short as the imbalance settlement period in both day-ahead and intraday markets. 3. Nominated electricity Mmarket operators shall provide products for trading in day-ahead and intraday markets which are sufficiently small in size, with minimum bid sizes of 1 Megawatt [or less], to allow for the effective participation of demand-side response, energy storage and small-scale renewables. 4. By 1 January 20251, the imbalance settlement period shall be 15 minutes in all control areas unless a derogation has been granted by a regulatory authority in accordance with Article 62(2)(d) of Commission Regulation (EU) 2017/XXX [Balancing]. No derogation shall apply after 1 January 2025. 10681/17 BL/ns 45 ANNEX DGE 2B EN Article 8 Forward markets 1. In line with Regulation (EU) 2016/1719, transmission system operators shall issue long-term transmission rights or have equivalent measures in place to allow for market participants, [in particular] including owners of generation facilities using renewable energy sources, to hedge price risks across bidding zone borders, unless an assessment of the forward market performed by the competent regulatory authorities on the bidding zone borders shows sufficient hedging opportunities in the concerned bidding zones in accordance with Article 30 of Commission Regulation (EU) 2016/1719. 2. Long-term transmission rights shall be allocated in a transparent, market based and non-discriminatory manner through a single allocation platform according to the provisions of the Regulation (EU) 2016/1719. [Long-term transmission rights shall be firm and be transferable between market participants.] 3. Subject to compliance with treaty rules on competition, market operators shall be free to develop forward hedging products including for the long-term to provide market participants, in particular owners of generation facilities using renewable energy sources, with appropriate possibilities to hedge financial risks from price fluctuations. Member States shall not restrict such hedging activity to trades within a Member State or bidding zone. 10681/17 BL/ns 46 ANNEX DGE 2B EN Article 9 [Price Restrictions] Technical bidding limits 1. Balancing energy prices, including bidding and clearing prices, shall not be subject to a minimum limit. Theyre shall also be not subject to a maximum limit [of the wholesale electricity price ] unless it is set at the value of lost load as determined in accordance with Article 10. [There shall be no minimum limit of the wholesale electricity price unless it is set at a value of minus 2000 € or less and, in the event that it is or anticipated to be reached, set at a lower value for the following day. This provision shall apply, inter alia, to bidding and clearing in all timeframes and include balancing energy and imbalance prices.] 2. [By way of derogation from paragraph 1, until [OP: two years after entry into]] Nominated electricity market operators may apply limits on maximum and minimum clearing prices for day-ahead and intraday timeframes in accordance with Articles 41 and 54 of Regulation (EU) 2015/1222. These limits shall take into account the value of lost load. In the event that the set limits are, or are anticipated to be, reached, they shall be raised for the following day. 3. Transmission system operators shall not take any measures with the aim of changing the wholesale prices. [All dispatch orders shall be reported to the national regulatory authority within one day.] 4. National regulatory authorities or other competent authorities designated by Member States shall identify policies and measures applied within their territory that could contribute to indirectly restrict price formation, including limiting bids relating to the activation of balancing energy, capacity mechanisms, measures by the transmission system operators, measures intended to challenge market results or to prevent abuse of dominant positions or inefficiently defined bidding zones. 10681/17 BL/ns 47 ANNEX DGE 2B EN 5. Where a national regulatory authority or other competent authority designated by Member State has identified a policy or measure which could serve to restrict price formation it shall take all appropriate actions to eliminate or, if not possible, mitigate the impact on bidding behaviour. Member States shall provide a report to the Commission by [OP: six months after entry into force] detailing the measures and actions they have taken or intend to take. Article 10 Value of lost load 1. By [OP: one year after entry into force] national regulatory authorities or other competent authorities designated by Member States shall establish a single estimate of the Value of Lost Load (VoLL) for their territory, expressed in €/MWh. That estimate shall be [reported to the Commission and] made publically available. National regulatory authorities or other competent authorities designated by Member States may establish different estimates individually[ VoLL] per bidding zone if they have several bidding zones in their territory. In case a bidding zone consists of territories of more than one member state, the concerned Member States shall establish a single VoLL for that bidding zone. In establishing VoLL, national regulatory authorities or other competent authorities designated by Member States shall apply the methodology developed pursuant to Article 19(5). 2. Member States shall update their estimate at least every five years. 10681/17 BL/ns 48 ANNEX DGE 2B EN Article 11 Dispatching of generation and demand response 1. Dispatching of power generation facilities and demand response shall be non-discriminatory, transparent and, unless otherwise provided under Article 11 (2) to Article 11 (4), market based. [unless otherwise provided under paragraphs 2 to 4.] 2. [When dispatching electricity generating installations, transmission system operators give priority to] Without prejudice to Union State aid rules pursuant to Articles 107 to 109 TFEU Member States may provide for electricty generated [installations] using renewable energy sources or high-efficiency cogeneration from small [generating installations or generating installations] power generating facility or power generating facility using emerging technologies to be granted priority dispatch to the following extent: (a) [generating installations] power generating facility using renewable energy sources or high-efficiency cogeneration with an installed electricity capacity of less than [500] 250 kW; or (b) demonstration projects for emerging [innovative] technologies as defined in Article 66 and 67 of the Commission Regulation (EU) 2016/631. 10681/17 BL/ns 49 ANNEX DGE 2B EN 3. Where the total [capacity] annual energy production of [generating installations] power generating facility subject to priority dispatch under paragraph 2 is higher than 15 % of the total [installed generating capacity] annual electricity production in a Member State, [point (a) of paragraph 2 shall apply only to additional generating installations using renewable energy sources or high-efficiency cogeneration with an installed electricity capacity of less than 250 kW. ] this Member State may decide not to apply point (a) of paragraph 2 to power generating facilities commissioned after 31 December of the second year after the year in which the threshold has been reached. (Second paragraph of 3, moved as 3a below) 3a. For power generating facility commissioned as fFrom 1 January 2026, point (a) of paragraph 2 shall apply only to power generating facilities [generating installations] using renewable energy sources or high-efficiency cogeneration with an installed electricity capacity of less than 250 kW[ or, if the threshold under the first sentence of this paragraph has been reached, of less than 125 kW]. 4. [Generating installations] power generating facility using renewable energy sources or high-efficiency cogeneration which have been commissioned prior to [OP: entry into force] and have, when commissioned, been subject to priority dispatch under Article 15(5) of Directive 2012/27/EU of the European Parliament and of the Council or Article 16(2) of Directive 2009/28/EC of the European Parliament and of the Council1 shall [remain subject to] continue to benefit from priority dispatch. Priority dispatch shall no longer be applicable from the date where the [generating installation] power generating facility is subject to significant modifications, which shall be the case at least where a new connection agreement is required or the generation capacity is increased. 1 Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16). 10681/17 BL/ns 50 ANNEX DGE 2B EN 5. Priority dispatch shall not endanger the secure operation of the electricity system, shall not be used as a justification for curtailment of cross-border capacities beyond what is provided for in Article 14 and shall be based on transparent and non-discriminatory criteria. Article 12 Redispatching [and curtailment]1 1. [Curtailment or ] Rredispatching of generation and redispatching of demand response shall be based on objective, transparent and non-discriminatory criteria. It shall be open to all generation technologies, storage and demand response, including operators located in other Member States unless technically not feasible. 2. The resources [curtailed or] redispatched shall be selected amongst generation, storage or demand facilities [submitting offers for curtailment or redispatching] using market-based mechanisms and be financially compensated. Bids used for redispatching shall be excluded from setting the price in other timeframes. (Parts of 2, moved as 2a below) 1 Definition of redispatching includes curtailment 10681/17 BL/ns 51 ANNEX DGE 2B EN 2a. Without prejudice to Union State aid rules pursuant to Articles 107 to 109 TFEU non-market-based [curtailment or] redispatching of generation or redispatching of demand response shall only be used where,: (a) no market-based alternative is available, (b) [where] that all available market-based resources have been used, or (c) [where] that the number of generation or demand facilities available in the area where suitable generation or demand facilities for the provision of the service are located is too low to ensure effective competition. [The provision of market-based resources shall be open to all generation technologies, storage and demand response, including operators located in other Member States unless technically not feasible.] 3. The responsible system operators shall report at least once per year to the competent regulatory authority on [curtailment or] downward redispatching of power generating facility generating installations using renewable energy sources or high-efficiency cogeneration and on measures taken to reduce the need for such [curtailment or] downward redispatching in the future. [Curtailment or redispatching of generating installations using renewable energy sources or high-efficiency cogeneration shall be subject to compensation pursuant to paragraph 6.] 4. Subject to requirements relating to the maintenance of the reliability and safety of the grid, based on transparent and non-discriminatory criteria defined by the competent national authorities, transmission system operators and distribution system operators shall: 10681/17 BL/ns 52 ANNEX DGE 2B EN (a) guarantee the capability of transmission and distribution networks to transmit electricity produced from renewable energy sources or high-efficiency cogeneration with minimum possible [curtailment or] redispatching. That shall not prevent network planning from taking into account limited [curtailment or] redispatching where this is shown to be more economically efficient and unless otherwise provided by a Member State in which electricity from power generating facility using renewable energy sources or high-efficiency cogeneration represents more than 50 % of annual gross final consumption of electricity, does not exceed 5 % of installed capacities using renewable energy sources or high-efficiency cogeneration in their area; (b) take appropriate grid and market-related operational measures in order to minimise the [curtailment or] downward redispatching of electricity produced from renewable energy sources or high-efficiency cogeneration. 5. Where non-market-based downward redispatching or curtailment is used, the following principles shall apply: (a) [generating installations] power generating facility using renewable energy sources shall only be subject to downward redispatching or curtailment if no other alternative exists or if other solutions would result in disproportionate costs or severe risks to network security; (b) electricity generated in a [generating installations using] high-efficiency cogeneration shall only be subject to downward redispatching or curtailment if, other than [curtailment or] downward redispatching of generating installations power generating facility using renewable energy sources, no other alternative exists or if other solutions would result in disproportionate costs or severe risks to network security; 10681/17 BL/ns 53 ANNEX DGE 2B EN [(c) self-generated electricity from generating installations using renewable energy sources or high-efficiency cogeneration which is not fed into the transmission or distribution network shall not be curtailed unless no other solution would resolve network security issues;] (d) downward redispatching [or curtailment] under letters a [to] and b [c] shall be duly and transparently justified. The justification shall be included in the report under paragraph 3. 6. Where non-market based [curtailment or ] redispatching is used, it shall be subject to financial compensation by the system operator requesting the [curtailment or] redispatching to the [owner ] operator of the [curtailed or] redispatched generation or demand facility except in the case of generators accepting non-firm connections. Financial compensation shall at least be equal to the highest of the following elements: (a) additional operating cost caused by the [curtailment or] redispatching, such as additional fuel costs in case of upward redispatching, or backup heat provision in case of downward redispatching or curtailment of [generating installations] power generating facility using high-efficiency cogeneration; [90 % of the n] Net revenues from the sale of electricity on the day-ahead market that the generating or demand facility would have generated without the [curtailment or] redispatching request. Where financial support is granted to generating or demand facilities based on the electricity volume generated or consumed, lost financial support shall be deemed part of the net revenues. 10681/17 BL/ns 54 ANNEX DGE 2B EN Chapter III Network access and congestion management SECTION 1 CAPACITY ALLOCATION Article 13 Definition of bidding zones 1. Bidding zone borders shall be based on [long-term], structural congestions in the transmission network and bidding zones shall not contain such congestions. The configuration of bidding zones in the Union shall be designed in such a way as to maximise economic efficiency and cross-border trading opportunities while maintaining security of supply. [2. Each bidding zone should be equal to an imbalance price area. ] 10681/17 BL/ns 55 ANNEX DGE 2B EN 3. In order to ensure an optimal bidding zone definition in [closely interconnected areas], a bidding zone review shall be carried out. That review shall include analysis of the different configurations of bidding zones in a coordinated manner with the involvement of affected stakeholders from all affected Member States, following the process in accordance with Articles 32 to 34 of Regulation (EU) 2015/1222. Based on the proposal from the concerned transmission system operators, tThe Agency shall [approve and may request amendments to] decide on the methodology and assumptions that will be used in the bidding zone review process as well as the alternative bidding zone configurations considered. 4. The transmission system operators participating in the bidding zone review shall submit a proposal to the Commission regarding whether to amend or maintain the bidding zone configuration. Based on that proposal, the Commission shall for a maximum of three months consult with all affected Member States. Following the consultation, the Commission shall adopt a decision whether to amend or maintain the bidding zone configuration, [no later than 6 months after entry into force of this Regulation, specific date to be inserted by OP] or by [six] nine months after the conclusion of the bidding zone [configuration ] review launched in accordance with points (a), (b) or (c) of Article 32(1) of Regulation (EU) 2015/1222, whichever comes later. 5. The decision referred to in paragraph 4 shall be based on the result of the bidding zone review and the transmission system operators' proposal concerning its maintenance or amendment and the views of the affected member States and Capacity Calculation Region. The decision shall be justified, in particular as regards possible deviations from the result of the bidding zone review. 6. Where further bidding zone reviews are launched under Article 32(1)(a), (b) or (c) of Regulation (EU) 2015/1222 the Commission shall follow the procedure outlined in Article 34 of Regulation (EU) 2015/1222 and may adopt a decision within [six] nine months of the conclusion of that bidding zone review. 10681/17 BL/ns 56 ANNEX DGE 2B EN 7. The Commission shall consult relevant stakeholders on its decisions under this Article before they are adopted. 8. The Commission decision shall specify the date of implementation of a change. That implementation date shall balance the need for expediency with practical considerations, including forward trade of electricity and shall not be less than 12 months after the decision is published unless otherwise agreed with the relevant Member States. The Commission may define appropriate transitional and/or arrangements as part of its decision.  714/2009 (adapted)  new Article 1416 General principles of  capacity allocation and  congestion management 1. Network congestion problems shall be addressed with non-discriminatory market-based solutions which give efficient economic signals to the market participants and transmission system operators involved. Network congestion problems shall preferentially be solved with non-transaction based methods, i.e methods that do not involve a selection between the contracts of individual market participants.  When taking operational measures to ensure that its transmission system remains in the normal state, the transmission system operator shall take into account the effect of those measures on neighbouring control areas and coordinate such measures with other affected transmission system operators as provided for in Regulation (EU) 1222/2015.  10681/17 BL/ns 57 ANNEX DGE 2B EN 2. Transaction curtailment procedures shall only be used in emergency situations where the transmission system operator must act in an expeditious manner and re-dispatching or countertrading is not possible. Any such procedure shall be applied in a non-discriminatory manner. Except in cases of force majeure, market participants who have been allocated capacity shall be compensated for any curtailment. 3. Unless otherwise provided in paragraphs 7, 7a and 8, tThe maximum capacity of the interconnections and/or the transmission networks affectinged by cross-border [flows] transactions shall be made available to market participants, complying with safety standards of secure network operation.  After implementation of redispatching and countertrading cost sharing methodology in accordance with Article 74 of Commission Regulation (EU) 2015/1222 and Article 76 of Commission Regulation (EU) 2017/XYZZ cCounter-trading and redispatch, including cross-border redispatch, shall be used to maximise available capacities [unless it is demonstrated that it is not beneficial to economic efficiency at Union level.]   new 4. Capacity shall be allocated only by means of explicit capacity auctions or implicit auctions including both capacity and energy. Both methods may coexist on the same interconnection. For intra-day trade continuous trading shall be used which may be complemented by auctions. 10681/17 BL/ns 58 ANNEX DGE 2B EN 5. In case of congestion, tThe valid highest value bids for network capacity, whether implicit or explicit, offering the highest value for the (scarce) transmission capacity in a given timeframe, shall be successful. Other than in the case of new interconnectors which benefit from an exemption under Article 7 of Regulation (EC) No 1228/2003, Article 17 Regulation 714/2009 or Article 59, establishing reserve prices in capacity-allocation methods shall not be allowed. 6. Capacity shall be freely tradable on a secondary basis, provided that the transmission system operator is informed sufficiently in advance. Where a transmission system operator refuses any secondary trade (transaction), this shall be clearly and transparently communicated and explained to all the market participants by that transmission system operator and notified to the regulatory authority. 7. Transmission system operators shall not limit the volume of interconnection capacity to be made available to [other] market participants in order to solve congestion inside their own bidding zone [control area] or as a means of managing flows [on a border between two control areas observed even without any transaction, that is to say flows over control areas caused by origin and destination within one control area] leaving and re-entering a bidding zone without being scheduled. (Part of 7, moved as 7a below) 10681/17 BL/ns 59 ANNEX DGE 2B EN 7a. Upon request by a transmission system operator and subject to the coordination procedure set out in this paragraph, the relevant regulatory authority may grant a derogation from [the first subparagraph] paragraph 7 where it is necessary for maintaining operational security or where a socio-economic cost benefit analysis, including cross-border effects, shows that the related costs are expected to be higher than benefits . Such a derogation, which may not relate to curtailment of already allocated capacities pursuant to paragraph 5, shall be limited in time, strictly limited to what is necessary, and avoid discrimination between internal and cross-zonal exchanges. Before granting a derogation, the relevant regulatory authority shall consult the regulatory authorities of other Member States forming part of an affected capacity calculation region. In case a regulatory authority disagrees with the proposed derogation, the Agency shall decide on the derogation pursuant to Article 6(8)(a) [recast of Regulation (EC) No 713/2009 as proposed by COM(2016) 863/2]. The justification and reasons for the derogation shall be published. Where a derogation is granted, the relevant transmission system operators shall develop and publish a methodology and projects that shall provide a long-term solution to the issue that the derogation seeks to address. The derogation shall expire when the time limit is reached or, once the solution is applied, whichever is earlier.  714/2009 4.8 Market participants shall inform the transmission system operators concerned a reasonable time in advance of the relevant operational period whether they intend to use allocated capacity. Any allocated capacity that will not be used shall be reattributed to the market, in an open, transparent and non-discriminatory manner. 10681/17 BL/ns 60 ANNEX DGE 2B EN 5.9 Transmission system operators shall, as far as technically possible, net the capacity requirements of any power flows in ***opposite*** direction over the congested interconnection line in order to use that line to its maximum capacity. Having full regard to network security, transactions that relieve the congestion shall never be denied.  new 10. The financial consequences of failure to honour obligations associated with the allocation of capacity shall be attributed to those who are responsible for such a failure. Where market participants fail to use the capacity that they have committed to use, or, in the case of explicitly auctioned capacity, fail to trade on a secondary basis or give the capacity back in due time, they shall lose the rights to such capacity and pay a cost-reflective charge. Any cost-reflective charges for the non-use of capacity shall be justified and proportionate. If a transmission system operator does not fulfil its obligation, it shall be liable to compensate the market participant for the loss of capacity rights. Consequential losses shall not be taken into account for that purpose. The key concepts and methods for the determination of liabilities that accrue upon failure to honour obligations shall be set out in advance in respect of the financial consequences, and shall be subject to review by the relevant national regulatory authority or authorities. 11. When allocating costs of remedial actions between transmission system operators, regulators shall analyse to what extent flows leaving and re-entering a bidding zone without being scheduled contribute to the congestion between two bidding zones observed, and allocate the costs in proportion to the contribution to the congestion. 10681/17 BL/ns 61 ANNEX DGE 2B EN Article 15 Allocation of cross-zonal capacity across timeframes 1. Transmission system operators shall recalculate available cross-zonal capacity at least after day-ahead and after intraday cross-zonal gate closure times. Transmission system operators shall allocate the available cross-zonal capacity plus any remaining cross-zonal capacity not previously allocated and any cross-zonal capacity released by physical transmission right holders from previous allocations in the next cross-zonal capacity allocation process. 2. When cross-zonal capacity is available after the intraday cross-zonal gate closure time, transmission system operators shall use the cross-zonal capacity for the exchange of balancing energy or for operating the imbalance netting process. 3. Transmission system operators shall use the methodologies developed in network codes and guidelines on balancing, where applicable, to allocate cross-zonal capacity for the exchange of balancing capacity or sharing of reserves pursuant to Article 5(4) and (7). 4. Transmission system operators shall not increase the reliability margin calculated pursuant to Regulation (EU) 2015/1222 due to the exchange of balancing capacity or sharing of reserves. 10681/17 BL/ns 62 ANNEX DGE 2B EN  714/2009 (adapted)  new SECTION 2  NETWORK CHARGES AND CONGESTION INCOME  Article 1614 Charges for connection and access to networks 1. Charges applied by network operators for access to networks  , including charges for connection to the networks, charges for use of networks, and, where applicable, charges for related network reinforcements,  shall be transparent, take into account the need for network security  and flexibility  and reflect actual costs incurred insofar as they correspond to those of an efficient and structurally comparable network operator and are applied in a non-discriminatory manner.  [In particular,] Without prejudice to Article 15(1) and (6) and the criteria in Annex XI of Directive 2012/27/EU they shall in particular be applied in a way which does not discriminate between production connected at the distribution level and production connected at the transmission level, either positively or negatively. They shall not unduly discriminate either positively or negatively against energy storage and shall not create disincentives for participation in demand response. Without prejudice to paragraph 3,  tThose charges shall not be distance-related. 10681/17 BL/ns 63 ANNEX DGE 2B EN  new 2. Tariffs methodologies shall [grant] reflect appropriate incentives to transmission and distribution system operators, The allowed revenues to be recovered through distribution and transmission tariffs shall reflect appropriate incentives to transmission and distribution system operators over both the short and long term, to increase efficiencies, including energy efficiency, foster market integration [and] security of supply, and support investments and [the related research activities] facilitate innovation.  714/2009 (adapted)  new 2.3 Where appropriate, the level of the tariffs applied to producers and/or consumers shall provide locational signals at  Union  Community level, and take into account the amount of network losses and congestion caused, and investment costs for infrastructure. 3.4 When setting the charges for network access, the following shall be taken into account: (a) payments and receipts resulting from the inter-transmission system operator compensation mechanism; (b) actual payments made and received as well as payments expected for future periods of time, estimated on the basis of past periods. 10681/17 BL/ns 64 ANNEX DGE 2B EN 4.5 Setting the charges for network access under this Article shall be without prejudice to charges on declared exports and declared imports resulting from congestion management referred to in Article 1416. 5.6 There shall be no specific network charge on individual transactions for  cross-[border] zonal trade  declared transits of electricity.  new 7. Distribution tariffs shall reflect the cost of use of the distribution network by system users including active customers, and may be differentiated based on system users' consumption or generation profiles. Where Member States have implemented the deployment of smart metering systems, [regulatory authorities may introduce] time differentiated network tariffs may be introduced, reflecting the use of the network, in a transparent and foreseeable way for the consumer. 8. [Regulatory authorities shall provide incentives to distribution system operators to procure services for the operation and development of their networks and integrate innovative solutions in the distribution systems. For that purpose authorities shall recognise as eligible and include all relevant costs in distribution tariffs and introduce] Distribution tarrifs may include performance targets in order to incentivise distribution system operators [to raise efficiencies, including energy efficiency, in their networks] to operate their networks as efficiently as possible. [9. By [OP: please add specific date – three months after entry into force] the Agency shall provide a best practice report [recommendation addressed to regulatory authorities ] on the progressive convergence of transmission and distribution tariff methodologies. That recommendation shall address at least: 10681/17 BL/ns 65 ANNEX DGE 2B EN (a) the ratio of tariffs applied to producers and to consumers; (b) the costs to be recovered by tariffs; (c) time differentiated network tariffs; (d) locational signals; (e) the relationship between transmission and distribution tariffs, including principles relating to non-discrimination; (f) methods to ensure transparency in the setting and structure of tariffs; (g) groups of network users subject to tariffs, including tariff exemptions.] The Agency shall update its report at least once every two years. [10. Without prejudice to further harmonisation by way of [delegated] acts pursuant to Article 55(1)(k), regulatory authorities shall take the Agency's recommendation duly into consideration when approving or fixing transmission tariffs or their methodologies in accordance with Article 59(6)(a) of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2]. [11. The Agency shall monitor the implementation of its recommendation and provide a report to the Commission by 31st January each year. It shall update the recommendation at least once every two years.] 10681/17 BL/ns 66 ANNEX DGE 2B EN Article 17 Congestion income 1. Congestion-management procedures associated with a pre-specified timeframe may generate revenue only in the event of congestion which arises for that timeframe, except in the case of new interconnectors which benefit from an exemption under Article 7 of Regulation (EC) No 1228/2003, Article 17 of Regulation (EC) No 714/2009 or Article 59. The procedure for the distribution of those revenues shall be subject to review by the regulatory authorities and shall neither distort the allocation process in favour of any party requesting capacity or energy nor provide a disincentive to reduce congestion.  714/2009 (adapted)  new 2.6 Any revenues resulting from the allocation of interconnection  capacity  shall be used for the following purposes: (a) guaranteeing the actual availability of the allocated capacity including firmness compensation; and/or (b) maintaining or increasing interconnection capacities through network investments, in particular in new interconnectors and internal lines which are listed in Ten Years Network Development Plan of ENTSOE as being relevant to reduce interconnector congestion, as well as cross-border remedial actions such as redispatch and counter-trading. (Part of 2(b), moved as 2a below) 10681/17 BL/ns 67 ANNEX DGE 2B EN 2a. If a socio-economic cost-benefit analysis demonstrates that the revenues cannot be efficiently used for the purposes set out in points (a) and/or (b) of [the first sub]paragraph 2,  they shall be placed on a separate internal account line for future use on these purposes or may be used, subject to approval by the regulatory authorities of the Member States concerned, as income to be taken into account by the regulatory authorities when approving the methodology for calculating network tariffs and/or fixing network tariffs. they may be used, subject to approval by the regulatory authorities of the Member States concerned, up to a maximum amount to be decided by those regulatory authorities, as income to be taken into account by the regulatory authorities when approving the methodology for calculating network tariffs and/or fixing network tariffs. The rest of revenues shall be placed on a separate internal account line until such time as it can be spent on the purposes set out in points (a) and/or (b) of the first subparagraph. The regulatory authority shall inform the Agency of the approval referred to in the second subparagraph.  new 3. The use of revenues in accordance with points (a) and (b) of paragraph 2 shall be subject to a methodology proposed by the tranmission system operators [the Agency] and approved by the Agency [the Commission. The Agency's proposal shall be submitted to the Commission by [OP: 12 months after entry into force] and be approved within six months.] The tranmission system operators shall submit the proposal to the Agency by [OP: 12 months after entry into force] and the Agency shall decide on it within six months . 10681/17 BL/ns 68 ANNEX DGE 2B EN [The Agency may, at its own initiative or upon a request from the Commission update the methodology and the Commission shall approve the updated methodology not later than six months from its submission.] [Before submission to the Commission, the Agency shall consult on the methodology pursuant to Article 15 [recast of Regulation (EC) No 713/2009 as proposed by COM(2016) 863/2]]. (Part of 3, moved as 3a below) 3a. The methodology shall detail as a minimum the conditions under which the revenues [can be used for ] are deemed to have fulfilled the objectives expressed in points (a) and (b) of paragraph 2, the main elements to cover in a cost benefit analysis of the social welfare benefits of further interconnection, [and] the conditions under which, and for how long, they may be placed on a separate internal account line for future use on those purposes or taken into account for calculation of network tariffs. 10681/17 BL/ns 69 ANNEX DGE 2B EN . Transmission system operators shall clearly establish beforehand how any congestion income will be used, and report on the actual use of that income. On an annual basis, and by 31 [July] January each year, the national regulatory authorities shall publish a report setting out the amount of revenue collected for the 12-month period ending on 301 [June] December of the [same ] previous calendar year and how that revenue was used, including the specific projects the income has been used for or the amount placed on a separate account line or the amount that has been used when calculating network tariffs, together with verification that that use complies with this Regulation and the methodology developed pursuant to paragraph 3. In such cases where some of the congestion revenues are used when calculating network tariffs, the report shall set out how the TSOs fulfilled the priority objectives in Article 2. 10681/17 BL/ns 70 ANNEX DGE 2B EN Chapter IV Resource adequacy Article 18 Resource adequacy 1. Member States shall monitor resource adequacy within their territory and contribute to [based on] the European resource adequacy assessment pursuant to Article 19 2. Where the European resource adequacy assessments identifiesy a resource adequacy concern Member States shall identify any regulatory distortions or system bottlenecks that caused or contributed to the emergence of the concern. 3. Member States shall publish roadmap with a concrete a timeline for adopting measures to eliminate any identified [regulatory distortions] issues. When addressing resource adequacy concerns Member States shall in particular take into account the principles defined in Article 3 and consider removing regulatory distortions, enabling scarcity pricing via free price formation, developing interconnection, allowing for undistorted market access for all market participants including energy storage, and demand side measures and energy efficiency. 10681/17 BL/ns 71 ANNEX DGE 2B EN  714/2009 (adapted)  new Article 19  European resource adequacy assessment  4.1 The European  resource adequacy assessment  generation adequacy outlook referred to in point (b) of paragraph 3 shall cover the overall adequacy of the electricity system to supply current and projected demands for electricity  for a ten-year period from the date of that assessment, in a yearly resolution and taking into account the national contributions under paragraph one of Article 18.  for the next five-year period as well as for the period between five and 15 years from the date of that outlook. The European generation adequacy outlook shall build on national generation adequacy outlooks prepared by each individual transmission system operator.  new 2. By [OP: six months after entry into force of this Regulation], the ENTSO for Electricity shall submit to the Agency a draft methodology for the European resource adequacy assessment based on the principles provided for in paragraph 4. 3. Transmission system operators shall provide the ENTSO for Electricity with the data it needs to carry out, [every year,] the European resource adequacy assessment. The ENTSO for Electricity shall carry out the assessment every year. Generators and other market participants shall provide transmission system operators with data regarding expected utilization of the generation resources, considering the availability of primary resources and appropriate scenarios of projected demand and supply. 10681/17 BL/ns 72 ANNEX DGE 2B EN 4. The European resource adequacy assessment shall be based on a methodology which shall ensure that the assessment: (a) is carried out on each respective bidding zone level covering at least all Member States and taking appropriately into account the conditions and specificities at the Member State level; (b) is based on appropriate scenarios of projected demand and supply including an economic assessment of the likelihood of retirement, new-build of generation assets and measures to reach energy efficiency targets and appropriate sensitivities on wholesale prices and carbon price developments; (c) appropriately takes account of the contribution of all resources including existing and future generation, energy storage, demand response, and import and export possibilities and their contribution to flexible system operation; (d) anticipates the likely impact of the measures referred in Article 18(3); (e) includes scenarios without and with existing or planned capacity mechanisms; (f) is based on a market model using, where applicable, the flow-based approach; (g) applies probabilistic calculations; (h) applies at least the following indicators: – 'expected energy not served', and – 'loss of load expectation'; 10681/17 BL/ns 73 ANNEX DGE 2B EN (i) identifies the sources of possible resource adequacy concerns, in particular whether it is a network or a resource constraint, or both. (j) Ensuring that national properties of resources (e.g generation, demand flexibility, storage), including the availability of primary resources, are properly taken into consideration 5. By [OP: six months after entry into force of this Regulation], the ENTSO for Electricity shall submit to the Agency a draft methodology for calculating: (a) the value of lost load; (b) the 'cost of new entry' for generation, or demand response; and (c) the reliability standard refered to in Article 20 [ expressed as 'expected energy not served' the 'loss of load expectation'.] 6. The proposals under paragraphs 2 and 5 for the draft methodology [and the results of the European resource adequacy assessment under paragraph 3] shall be subject to prior consultation and approval by the Agency under the procedure set out in Article 22. Article 20 Reliability standard 1. When applying capacity mechanisms Member States shall have a reliability standard in place indicating their desired level of security of supply in a transparent manner. 2. The reliability standard shall be set by the [national regulatory authority] Member State or a competent authority designated by the Member State based on the methodology pursuant to Article 19(5). 10681/17 BL/ns 74 ANNEX DGE 2B EN 3. The reliability standard shall be calculated using at least the value of lost load and the cost of new entry over a given timeframe and be expressed as 'expected energy not served' and the 'loss of load expectation'. 4. The parameters determining the amount of capacity procured in the capacity mechanism shall be approved by the Member State or another competent authority designated by the Member State.[ national regulatory authority.] Article 21 Cross-border participation in capacity mechanisms 1. Mechanisms other than ***strategic*** reserves shall be open to direct participation of capacity providers located in another Member State [provided there is a network connection between that Member State and the bidding zone applying the mechanism] pursuant to the provisions of paragraph 2 of this Article. 2. Member States shall ensure that foreign capacity capable of providing [equivalent technical performance] contribution to the desired level of adequacy on the same conditions as [to] domestic capacities has the opportunity to participate in the same competitive process as domestic capacity. Member States may apply following requirements to the foreign capacity: (a) the capacity is located in a bidding zone with a direct network connection between that bidding zone and the bidding zone applying the mechanism, (b) the capacity is not participating in another capacity mechanism for which the capacity needs to be available. 10681/17 BL/ns 75 ANNEX DGE 2B EN 3. Member States shall not restrict capacity which is located in their territory from participating in capacity mechanisms of other Member States. 4. Cross-border participation in market-wide capacity mechanisms shall not change, alter or otherwise impact cross-zonal schedules and physical flows between Member States which shall be determined solely by the outcome of capacity allocation pursuant to Article 14. 5. Capacity providers shall be subject to non-availability payments in case of non-availability. In case capacity providers [shall be able to ] participate in more than one mechanism for the same delivery period,. Tthey shall be subject to [ non-availability payments in case of non-availability, and subject to] two or more non-availability payments where there is concurrent scarcity in two or more bidding zones where the capacity provider is contracted. 6. [Regional Operational Centres] Regional Security Coordinators [+] established pursuant to Article 32 shall annually calculate the maximum entry capacity available for the participation of foreign capacity taking into account the expected availability of interconnection and the likely concurrence of system stress between the system where the mechanism is applied and the system in which the foreign capacity is located. A calculation is required for each bidding zone border. 7. Member States shall ensure that the entry capacity referred to in paragraph 6 is allocated to eligible capacity providers in a transparent, non-discriminatory and market-based manner. 8. Any difference in the cost of foreign capacity and domestic capacity arising through the allocation referred to in paragraph 7 shall accrue to transmission system operators and be shared between them according to the methodology referred in point (b) of paragraph 10 . Transmission system operators shall use such revenues for the purposes set out in Article 17(2). 10681/17 BL/ns 76 ANNEX DGE 2B EN 9. The transmission system operator where the foreign capacity is located shall: (a) establish whether interested capacity providers can provide the technical performance as required by the capacity mechanism in which the capacity provider intends to participate and register the capacity provider in the registry as eligible capacity providers. (b) carry out availability checks [as appropriate.] (c) be notified by the respective capacity provider without delay about its participation in foreign capacity mechanism 10. By [OP: twelve months after entry into force of this Regulation] the ENTSO for Electricity shall submit to the Agency: (a) a methodology for calculating the maximum entry capacity for cross-border participation as referred to in paragraph 6; (b) a methodology for sharing the revenues referred to in paragraph 8; (c) common rules to carry out availability checks referred to in point (b) of paragraph 9; (d) common rules to determine when a non-availability payment is due; (e) terms of the operation of the registry as referred to in point (a) of paragraph 9; (f) common rules to identify capacity eligible to participate as referred to in point (a) of paragraph 9. The proposal shall be subject to prior consultation and approval by the Agency under the procedure set out in Article 22. 10681/17 BL/ns 77 ANNEX DGE 2B EN 11. The [Agency] national regulatory authorities concerned shall verify whether the capacities have been calculated in line with the methodology as referred to in point (a) of paragraph 10. 12. National regulatory authorities shall ensure that cross-border participation in capacity mechanisms is organised in an effective and non-discriminatory manner. They shall in particular provide for adequate administrative arrangements for the enforcement of non-availability payments across borders. 13. Allocated capacities as referred to in paragraph 7 shall be transferable between eligible capacity providers. Eligible capacity providers shall notify any transfer to the registry as referred to in point (a) of paragraph 9. 14. No later than [OP: two years after the entry into force of this Regulation] the ENTSO for Electricity shall set up and operate the registry as referred to in point (a) of paragraph 9. The registry shall be open to all eligible capacity providers, the systems applying the mechanisms and their transmission system operators. Article 22 Approval procedure 1. Where reference is made to this Article, the procedure set out in paragraphs 2 to 4 shall be applicable to the approval of a proposal submitted by the ENTSO for Electricity. 2. Prior to submitting the proposal, the ENTSO for Electricity shall conduct a consultation process involving all relevant stakeholders, national regulatory authorities and other national authorities and shall take the results of a consultation process duly into consideration. 10681/17 BL/ns 78 ANNEX DGE 2B EN 3. Within three months from the date of receipt, the Agency shall either approve the proposal or amend it. In the latter case, the Agency shall consult the ENTSO for Electricity before adopting the amended proposal. The adopted proposal shall be published on the Agency's website at the latest three months after the date of receipt of the proposed documents. 4. The Agency may request changes to the approved proposal at any time. Within six months from the request, the ENTSO for Electricity shall submit to the Agency a draft of the proposed changes. Within a period of three months from the date of receipt of the draft, the Agency shall amend or approve the changes and publish it on its website. Article 23 Design principles for capacity mechanisms 1. To address residual concerns that cannot be eliminated by the measures pursuant to Article 18(3), Member States may introduce capacity mechanisms, subject to the provisions of this Article and [to] without prejudice to the Union State aid rules. 2. Where a Member State wishes to implement a capacity mechanism, it shall consult on the proposed mechanism at least with its electrically connected neighbouring Member States, based on a comprehensive study on the possible effects on those Member States. 2a. When a capacity mechanism is designed as a ***strategic*** reserve, resources in the ***strategic*** reserve shall only be dispatched in case transmission system operators have exhausted their balancing resources to establish an equilibrium between demand and supply. During periods where resources in the ***strategic*** reserve were dispatched imbalances in the market shall be settled at least at the value of lost load. 10681/17 BL/ns 79 ANNEX DGE 2B EN 3. Capacity mechanisms shall: (a) not create unnecessary market distortions and not limit cross[- border]zonal trade; (b) be market-based; (c) be open to participation of all resources in a technology neutral manner, including participation of storage and demand response, that are capable of providing the required technical performance; (d) be temporary; (e) [The amount of capacity committed in the mechanism shall] not go beyond what is necessary to address the concern. 4. Generation capacity for which a final investment decision has been made after [OP: entry into force] operating for more than [X] hours per year shall only be eligible to participate in a capacity mechanism if its emissions are below 550 gr CO2/kWh. Generation capacity operating for more than [X] hours per year emitting 550 gr CO2/kWh or more shall not be committed in capacity mechanisms 5 7 years after the entry into force of this Regulation. 5. Where the European resource adequacy assessment has not identified a resource adequacy concern, Member States shall not apply capacity mechanisms. 5a. When designing capacity mechanisms, Member States shall include a provision allowing for efficient phase-out of a capacity mechanism in case the European resource adequaecy assessment proves that the adequacy concern is not present anymore. 10681/17 BL/ns 80 ANNEX DGE 2B EN Article 24 Existing mechanisms Member States applying capacity mechanisms on [OP: entry into force of this Regulation] shall adapt their mechanisms to comply with Articles 18, 21 and 23 of this Regulation within [7] years after entry into force of this Regulation. 10681/17 BL/ns 81 ANNEX DGE 2B EN  714/2009 (adapted) Chapter V  Transmission system operation  Article 254 European network of transmission system operators for electricity 1. TAll transmission system operators shall cooperate at  Union  Community level through the ENTSO for Electricity, in order to promote the completion and functioning of the internal market in electricity and cross[- border]zonal trade and to ensure the optimal management, coordinated operation and sound technical evolution of the European electricity transmission network.  new 2. In performing its functions under EU law, the ENTSO for Electricity shall [act for the European good and independent from individual national interests or the national interests of transmission system operators, and shall] contribute to the efficient and sustainable achievement of the objectives set out in the policy framework for climate and energy covering the period from 2020 to 2030, in particular by contributing to the efficient integration of electricity generated from renewable energy sources and to increases in energy efficiency while maintaining system security. 10681/17 BL/ns 82 ANNEX DGE 2B EN  714/2009  new Article 265 Establishment of the ENTSO for Electricity 1. By 3 March 2011, Tthe transmission system operators for electricity shall submit to the Commission and to the Agency the draft statutes, a list of members and draft rules of procedure, including the rules of procedures on the consultation of other stakeholders, of the ENTSO for Electricity to be established. 2. Within two months of the day of the receipt, the Agency, after formally consulting the organisations representing all stakeholders, in particular the system users, including customers, shall provide an opinion to the Commission on the draft statutes, list of members and draft rules of procedure. 3. The Commission shall deliver an opinion on the draft statutes, list of members and draft rules of procedures taking into account the opinion of the Agency provided for in paragraph 2 and within three months of the day of the receipt of the opinion of the Agency. 4. Within three months of the day of receipt of the Commission's  favourable  opinion, the transmission system operators shall establish the ENTSO for Electricity and adopt and publish its statutes and rules of procedure. 10681/17 BL/ns 83 ANNEX DGE 2B EN  new 5. The documents referred to in paragraph 1 shall be submitted to the Commission and to the Agency in case of changes thereof or upon reasoned request of the Commission or of the Agency. The Agency and the Commission shall deliver an opinion in accordance with paragraphs 2 to 4.  714/2009 (adapted)  new Article 278 Tasks of the ENTSO for Electricity 1. The ENTSO for Electricity shall elaborate network codes in the areas referred to in paragraph 6 of this Article upon a request addressed to it by the Commission in accordance with Article 6(6). 2.1 The ENTSO for Electricity may  shall  : (a) elaborate network codes in the areas set out in paragraph 6 Article 55(1) with a view to achieving the objectives set out in Article 254 where those network codes do not relate to areas covered by a request addressed to it by the Commission. Those network codes shall be submitted to the Agency for an opinion. That opinion shall be duly taken into account by the ENTSO for Electricity. 10681/17 BL/ns 84 ANNEX DGE 2B EN 3. The ENTSO for Electricity shall adopt: (b)  adopt and publish  a non-binding  Union  Community-wide ten-year network development plan, ( Union  Community-wide network development plan), including a European generation adequacy outlook, every two years;  new (c) prepare and adopt proposals related to the European resource adequacy assessment pursuant to Article 19(2), (3) and (5) and for the technical specifications for cross-border participation in capacity mechanisms pursuant to Article 21(10);  714/2009 (adapted) (c) (d)  adopt  recommendations relating to the coordination of technical cooperation between  Union  Community and third-country transmission system operators;  new (e) adopt a framework for the cooperation and coordination between regional security coordinators; (f) adopt a proposal defining the security coordinated [system operation] region covered by each regional security coordinator [operational centre]; (f1) cooperate with distribution system operators. 10681/17 BL/ns 85 ANNEX DGE 2B EN  347/2013 (adapted)  new (a) (g)  adopt  common network operation tools to ensure coordination of network operation in normal and emergency conditions, including a common incidents classification scale, and research plans , including the deployment of these plans through an efficient research programme . These tools shall specify inter alia: (i) the information, including appropriate day ahead, intra-day and real-time information, useful for improving operational coordination, as well as the optimal frequency for the collection and sharing of such information; (ii) the technological platform for the exchange of information in real time and where appropriate, the technological platforms for the collection, processing and transmission of the other information referred to in point (i), as well as for the implementation of the procedures capable of increasing operational coordination between transmission system operators with a view to such coordination becoming Union-wide; (iii) how transmission system operators make available the operational information to other transmission system operators or any entity duly mandated to support them to achieve operational coordination, and to the Agency; and 10681/17 BL/ns 86 ANNEX DGE 2B EN (iv) that transmission system operators designate a contact point in charge of answering inquiries from other transmission system operators or from any entity duly mandated as referred to in point (iii), or from the Agency concerning such information. The ENTSO for Electricity shall submit the adopted specifications on points (i) to (iv) above to the Agency and to the Commission by 16 May 2015. Within 12 months of the adoption of the specifications, the Agency shall issue an opinion in which it considers whether they sufficiently contribute to the promotion of cross-border trade and to ensuring the optimal management, coordinated operation, efficient use and sound technical evolution of the European electricity transmission network.  714/2009 (adapted)  new (d) (h)  adopt  an annual work programme; (e) (i)  adopt  an annual report; (j)(f)  carry out and adopt  annual summer and winter generation  seasonal  adequacy outlooks  pursuant to Article 9(2) [Regulation on risk preparedness as proposed by COM(2016) 862]  .; 4. The European generation adequacy outlook referred to in point (b) of paragraph 3 shall cover the overall adequacy of the electricity system to supply current and projected demands for electricity for the next five-year period as well as for the period between five and 15 years from the date of that outlook. The European generation adequacy outlook shall build on national generation adequacy outlooks prepared by each individual transmission system operator. 10681/17 BL/ns 87 ANNEX DGE 2B EN  new 2. The ENTSO for Electricity shall report to the Agency on shortcomings identified regarding the establishment and performance of [Regional Operational Centres] Regional Security Coordinators [+]. 3. The ENTSO for Electricity shall publish the minutes of its Assembly, Board and Committees meetings and provide the public with regular information on its decision-making and activities.  714/2009 (adapted)  new 5. 4. The annual work programme referred to in (d) (h) of paragraph 3 1 shall contain a list and description of the network codes to be prepared, a plan on coordination of operation of the network, and research and development activities, to be realised in that year, and an indicative calendar. 9.5 The ENTSO for Electricity shall make available all information required by the Agency to fulfil its tasks under Article 299(1).  Transmission system operators shall make available all information required for the ENTSO for Electricity to fulfil its task under sentence 1.  612. Upon request of the Commission, the ENTSO for Electricity shall give its views to the Commission on the adoption of the gGuidelines as laid down in Article 5718. 7. The network codes shall be developed for cross-border network issues and market integration issues and shall be without prejudice to the Member States’ right to establish national network codes which do not affect cross-border trade. 10681/17 BL/ns 88 ANNEX DGE 2B EN 8. The ENTSO for Electricity shall monitor and analyse the implementation of the network codes and the Guidelines adopted by the Commission in accordance with Article 6(11), and their effect on the harmonisation of applicable rules aimed at facilitating market integration. The ENTSO for Electricity shall report its findings to the Agency and shall include the results of the analysis in the annual report referred to in point (e) of paragraph 3 of this Article. Article 2810 Consultations 1. While preparing the  proposals pursuant to the tasks referred to in Article 27(1)  network codes, the draft Community-wide network development plan and the annual work programme referred to in Article 8(1), (2) and (3), the ENTSO for Electricity shall conduct an extensive consultation process, at an early stage and in an open and transparent manner, involving all relevant  stakeholders  market participants, and, in particular, the organisations representing all stakeholders, in accordance with the rules of procedure referred to in Article 26 5(1). That consultation shall also involve national regulatory authorities and other national authorities, supply and generation undertakings, system users including customers, distribution system operators, including relevant industry associations, technical bodies and stakeholder platforms. It shall aim at identifying the views and proposals of all relevant parties during the decision-making process. 10681/17 BL/ns 89 ANNEX DGE 2B EN 2. All documents and minutes of meetings related to the consultations referred to in paragraph 1 shall be made public. 3. Before adopting the  proposals pursuant to Article 27(1)  annual work programme and the network codes referred to in Article 8(1), (2) and (3), the ENTSO for Electricity shall indicate how the observations received during the consultation have been taken into consideration. It shall provide reasons where observations have not been taken into account. Article 299 Monitoring by the Agency 1. The Agency shall monitor the execution of the tasks referred to in Article 278(1), (2) and (3) of the ENTSO for Electricity and report to the Commission. The Agency shall monitor the implementation by the ENTSO for Electricity of network codes elaborated under Article 55(14) 8(2) and network codes which have been developed in accordance with Article 6(1) to (10) but which have not been adopted by the Commission under Article 6(11). Where the ENTSO for Electricity has failed to implement such network codes, the Agency shall request the ENTSO for Electricity to provide a duly reasoned explanation as to why it has failed to do so. The Agency shall inform the Commission of that explanation and provide its opinion thereon. The Agency shall monitor and analyse the implementation of the network codes and the gGuidelines adopted by the Commission as laid down in Article 54(1) 6(11), and their effect on the harmonisation of applicable rules aimed at facilitating market integration as well as on non-discrimination, effective competition and the efficient functioning of the market, and report to the Commission. 10681/17 BL/ns 90 ANNEX DGE 2B EN 2. The ENTSO for Electricity shall submit the draft  Union  Community-wide network development plan, the draft annual work programme, including the information regarding the consultation process, and the other documents referred to in Article 27(1) 8(3) to the Agency for its opinion. Within two months from the day of receipt, the Agency shall provide a duly reasoned opinion as well as recommendations to the ENTSO for Electricity and to the Commission where it considers that the draft annual work programme or the draft  Union  Community-wide network development plan submitted by the ENTSO for Electricity do not contribute to non-discrimination, effective competition, the efficient functioning of the market or a sufficient level of cross-border interconnection open to third-party access.  347/2013 Article 3011 Costs The costs related to the activities of the ENTSO for Electricity referred to in Articles 25 to 29 and 54 to 57 4 to 12 of this Regulation, and in Article 11 of Regulation (EU) No 347/2013 shall be borne by the transmission system operators and shall be taken into account in the calculation of tariffs. Regulatory authorities shall approve those costs only if they are reasonable and appropriate. 10681/17 BL/ns 91 ANNEX DGE 2B EN  714/2009  new Article 3112 Regional cooperation of transmission system operators 1. Transmission system operators shall establish regional cooperation within the ENTSO for Electricity to contribute to the activities referred to in Article 278(1), (2) and (3). In particular, they shall publish a regional investment plan every two years, and may take investment decisions based on that regional investment plan.  The ENTSO for Electricity shall promote cooperation between transmission system operators at regional level ensuring interoperability, communication and monitoring of regional performance in those areas which are not yet harmonised at Union level.  2. Transmission system operators shall promote operational arrangements in order to ensure the optimum management of the network and shall promote the development of energy exchanges, the coordinated allocation of cross-border capacity through non-discriminatory market-based solutions, paying due attention to the specific merits of implicit auctions for short-term allocations, and the integration of balancing and reserve power mechanisms. 10681/17 BL/ns 92 ANNEX DGE 2B EN 3. For the purposes of achieving the goals set in paragraphs 1 and 2 of this Article, the ***geographical*** area covered by each regional cooperation structure may be defined by the Commission, taking into account existing regional cooperation structures. Each Member State shall be allowed to promote cooperation in more than one ***geographical*** area.  The Commission is empowered to adopt [delegated] acts in accordance with Article 63 concerning the ***geographical*** area covered by each regional cooperation structure.  The measure referred to in the first sentence, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23 (2). For that purpose, the Commission shall consult the Agency and the ENTSO for Electricity.  new Article 32 Establishment and mission of [Regional Operational Centres] Regional Security Coordinators [+] 1. By [OP: twelve months after entry into force], all transmission system operators of a system operation region shall [ establish [Regional Operational Centres] in accordance with the criteria set out in this chapter. [Regional Operational Centres] shall be established in the territory of one of the Member States of the region where it will operate.] submit a proposal for the establishment of Regional Security Coordinators [+] for approval by the respective regulatory authorities. 10681/17 BL/ns 93 ANNEX DGE 2B EN 2. [Regional Operational Centres] Regional Security Coordinators [+]shall be organised in a legal form as referred to in Article 1 of Directive 2009/101/EC of the European Parliament and of the Council.1 3. [Regional Operational Centres ] Transmission system operators shall manage electricity flows and ensure a secure, reliable and efficient electricity system in accordance with applicable Union and national legislation. Regional Security Coordinators [+] shall complement the role of transmission system operators by performing [functions] tasks of regional relevance assigned to them in accordance with Article 34. [They shall establish operational arrangements in order to ensure the efficient, secure and reliable operation of the interconnected transmission system.] Regional Security Coordinators [+] shall take up their activities by 1 January 2025. Article 33 [ ***Geographical*** scope of regional operational centres 1. By [OP: six months after entry into force of this Regulation] the ENTSO for Electricity shall submit to the Agency a proposal defining system operation regions covered by regional operational centres, taking into account existing regional security coordinators, on the basis of the following criteria: (a) The grid topology, including the degree of interconnection and of interdependency of the power systems in terms of flows; 1 Directive 2009/101/EC of the European Parliament and of the Council of 16 September 2009 on coordination of safeguards which, for the protection of the interests of members and third parties, are required by Member States of companies within the meaning of the second paragraph of Article 48 of the Treaty, with a view to making such safeguards equivalent (OJ L 258, 1.10.2009, p. 11). 10681/17 BL/ns 94 ANNEX DGE 2B EN (b) the synchronous connection of the systems; (c) the size of the region, which shall cover at least one capacity calculation region; (d) the ***geographical*** optimization of balancing reserves. 2. Within three months of receipt, the Agency shall either approve the proposal defining the system operation regions or propose amendments. In the latter case, the Agency shall consult the ENTSO for Electricity before adopting the amendments. The adopted proposal shall be published on the Agency's website.] Article 34 Tasks of [Regional Operational Centres] Regional Security Coordinators [+] 1. Each [regional operational centre] regional security coordinator shall perform all the following [functions] tasks towards transmisison system operators in the system operation region [where established. and Regional Operational Centres shall perform at least the following tasks functions], set out in more detail in Annex I: (a) coordinated capacity calculation in accordance with the methodologies developed pursuant to Articles 21, 26, 29, and 30 of [Commission Regulation XXX establishing a guideline on capacity allocation and congestion management]; (b) coordinated security analysis in accordance with the methodologies developed pursuant to Articles 75 and 76 of [Commission Regulation XXX establishing a guideline on electricity transmission system operation]; 10681/17 BL/ns 95 ANNEX DGE 2B EN (c) creation of common system models in accordance with the methodologies and procedures developed pursuant to Articles 67, 70 and 79 of [Commission Regulation establishing a guideline on electricity transmission system operation]; (d) consistency assessment of transmission system operators' defense plans and restoration plans in accordance with the procedure set out in Article 6 of [Commission Regulation establishing a network code on electricity emergency and restoration]; (da) regional week ahead to intraday system adequacy forecasts and preparation of risk reducing actions in accordance with the procedures set out in Article 81 of [Commission Regulation XXX establishing a guideline on electricity transmission system operation] (db) outage planning coordination in accordance with the procedures set out in Article 80 of [Commission Regulation XXX establishing a guideline on electricity transmission system operation] (dc) short-term adequacy assessment pursuant to Article 9(2) of [Regulation on risk preparedness as proposed by COM(2016) 862] (dd) training and certification of staff working for Regional Security Coordinators[+] 10681/17 BL/ns 96 ANNEX DGE 2B EN [additional functions to be discussed: where Regional Security Coordinators[+] will issue only Recommendations subject to Article 38: [(e) coordination and optimization of regional restoration;] [(f) post-operation and post-disturbances analysis and reporting;] (g) was moved below [(h) facilitate the regional procurement of balancing capacity;] [(i) regional week ahead to intraday system adequacy forecasts and preparation of risk reducing actions;] [(j) outage planning coordination;] [(k) optimisation of compensation mechanisms between transmission system operators] [(l) training and certification;] [(m) identification of regional crisis scenarios if and to the extent they are requested pursuant to Article 6(1) of [Regulation on risk preparedness as proposed by COM(2016) 862] [(n) preparation and carrying out of yearly crisis simulations in cooperation with competent authorities pursuant to Article 12(3) of [Regulation on risk preparedness as proposed by COM(2016) 862];] 10681/17 BL/ns 97 ANNEX DGE 2B EN [(o) tasks related to the identification of regional crisis scenarios if and to the extent they are [delegated] to the Regional Operational Centres pursuant to Article 6(1) of [Regulation on risk preparedness as proposed by COM(2016) 862];] [(p) tasks related to the seasonal adequacy outlooks if and to the extent they are requested pursuant to Article 9(2) of [Regulation on risk preparedness as proposed by COM(2016) 862]; with possible oversight by NRAs and/or Member States: [(g) regional sizing of reserve capacity;] [(q) calculate the maximum entry capacity available for the participation of foreign capacity in capacity mechanisms pursuant to Article 21(6).] ] 2. [The Commission may add other functions to the Regional Operational Centres not involving decision making power, pursuant to Chapter VII of this Regulation.]. 3. Transmission system operators shall provide their [Regional Operational Centres] Regional Security Coordinators [+]with the information necessary to carry out its functions. 4. [Regional Operational Centres] Regional Security Coordinators [+]shall provide transmission system operators of the system operation region with all the information necessary to implement the decisions proposals for coordinated remedial actions and recommendations proposed by the [Regional Operational Centres] Regional Security Coordinators [+] 10681/17 BL/ns 98 ANNEX DGE 2B EN Article 35 Cooperation within [Regional Operational Centres] and between Regional Security Coordinators [+] 1. The day-to-day [operation of Regional Operational Centres] coordination within Regional Security Coordinators [+] shall be managed through cooperative decision-making process. [The cooperative-decision making process shall be] based on: (a) working arrangements to address planning and operational aspects [related to the functions, in accordance with Article 36 ]relevant for the services referred to in Article 34(1); (b) a procedure for sharing analysis and consulting Regional Security Coordinators proposals with the transmission system operators [of the system operation region in the exercise of its operational duties and tasks,] in accordance with Article 37; (c) a procedure for the adoption of decisions and recommendations in accordance with Article 38; (d) a procedure for the revision of [decisions] coordinated actions and recommendations [adopted by Regional Operational Centres] issued by Regional Security Coordinators [+] in accordance with Article 39. 10681/17 BL/ns 99 ANNEX DGE 2B EN Article 36 Working arrangements 1. [Regional Operational Centres] Regional Security Coordinators [+] shall develop working arrangements to address planning and operational aspects related to the functions to be performed, taking into account, in particular, the specificities and requirements of those functions as specified in Annex I. 2. [Regional Operational Centres] Regional Security Coordinators [+] shall ensure that the working arrangements contain rules for the notification of parties concerned. Article 37 Consultation procedure [Regional Operational Centres] Regional Security Coordinators [+] shall develop a procedure to organise, in the exercise of their daily operational duties and tasks, the appropriate and regular consultation of transmission system operators other Regional Security Coordinators [+] and of relevant stakeholders. In order to ensure that regulatory issues can be addressed, regulatory authorities shall be involved when required. 10681/17 BL/ns 100 ANNEX DGE 2B EN Article 38 [Adoption of decisions] Coordinated actions and recommendations 1. [Regional Operational Centres] Regional Security Coordinators [+] shall develop a procedure for the adoption of [decisions] coordinated actions and recommendations. 2. [Regional Operational Centres] Regional Security Coordinators [+] shall [adopt binding decisions] set-out coordinated actions addressed to the transmission system operators in respect of the functions referred to in points (a), (b), [(g) and (q)] [additional functions to be discussed] of Article 34(1). Transmission system operators may not [ shall ] implement the coordinated actions [binding decisions] issued by the Regional Security Coordinators [+] where the impementation of the coordinated actions would result in a violation of the operational security limits defined by each transmission system operator in accordance with Article 25 of [Commission Regulation XXX establishing a guideline on electricity transmission system operation] [ Regional Operational Centres except in cases when the safety of the system will be negatively affected.] 2a. Where a transmission system operator decides not to implement a coordinated action for the reasons set out in paragraph 2, it shall notify it to the Regional Security Coordinator [+] with the shortest delay possible. In such cases, the Regional Security Coordinator [+] shall assess the impact on the other transmission system operators of the system operation region and may propose a different set of coordinated actions subject to a procedure in paragraph 2. 3. [Regional Operational Centres] Regional Security Coordinators [+] shall adopt recommendations addressed to the transmission system operators for the functions referred to in points (c) to [ additional functions to be discussed] [(f) and (h) to (p)] of Article 34(1). 10681/17 BL/ns 101 ANNEX DGE 2B EN 4. The regulatory authorities of a system operation region may jointly decide to grant binding decision-making powers to the [regional operational centre] Regional Security Coordinators [+] for one or more of the functions provided for in [points (c) to (f) and (h) to (l) of] Article 34(1). Article 39 Revision of [decisions] coordinated actions and recommendations 1. [Regional Operational Centres] Regional Security Coordinators [+] shall develop a procedure for the revision of [decisions] coordinated actions and recommendations refered to tasks described in Article 34. 2. The procedure shall be triggered at the request of one or more of the transmission system operators of the system operation region. Following the revision of the [decisions] coordinated action or recommendation, [Regional Operational Centres] Regional Security Coordinators [+] shall confirm or modify the measure. 3. Where the measure subject to revision is a [binding decisions] coordinated actions in accordance with Article 38(2), the request for revision shall not suspend the [decisions] coordinated action except in cases [when the safety of the system will be negatively affected.] where the impementation of the coordinated actions would result in a violation of the operational security limits defined by each transmission system operator in accordance with Article 25 of [Commission Regulation XXX establishing a guideline on electricity transmission system operation] 10681/17 BL/ns 102 ANNEX DGE 2B EN 4. Where the measure subject to revision is a recommendation in accordance with Article 38(3) and following its revision a transmission system operator decides to deviate from the recommendation, the transmission system operator shall submit a [detailed] justification to the [Regional Operational Centres] Regional Security Coordinators [+] and to the other transmission system operators of the system operation region. Article 40 Management board of [Regional Operational Centres] Regional Security Coordinators [+] 1. In order to adopt measures related to their governance and to monitor their performance, the [Regional Operational Centres] Regional Security Coordinators [+] shall establish a management board. 2. The management board shall be composed of members representing the transmission system operators[ and of observers representing the regulatory authorities of the system operation region. The representatives of the regulatory authorities shall have no voting rights. ] 3. The management board shall be responsible for: (a) drafting and endorsing the statutes and rules of procedure of the [Regional Operational Centres] Regional Security Coordinators [+]; (a) deciding upon and implementing the organisational structure; (b) preparing and endorsing the annual budget; 10681/17 BL/ns 103 ANNEX DGE 2B EN (c) developing and endorsing the cooperative decision-making processes in accordance with Article 35. 4. The competences of the management board shall exclude those that are related to the day-to-day activities of [Regional Operational Centres] Regional Security Coordinators [+] and the performance of its functions. Article 41 Organisational structure 1. Transmission system operators shall establish the necessary arrangements for Regional security coordinators [operational centres shall set up and] to manage their organisation according to a structure that supports the safety of their tasks [functions]. Their organisational structure shall specify: (a) the authority, duties and responsibilities of the management personnel; (b) the relationship and reporting lines between different parts and processes of the organisation. 2. [Regional Operational Centres] Regional Security Coordinators [+]may set up regional desks to address [local] sub-regional specificities or back-up regional security coordinators for the efficient and reliable exercise of their functions. 10681/17 BL/ns 104 ANNEX DGE 2B EN Article 42 Equipment and staff [Regional Operational Centres] Regional Security Coordinators [+] shall be equipped with all the human, technical, physical and financial resources necessary for fulfilling their obligations under this Regulation and carrying out their functions. Article 43 Monitoring and reporting 1. [Regional Operational Centres] Regional Security Coordinators [+]shall establish a process for the continuous monitoring of at least: (a) their operational performance; (b) the [decisions] coordinated actions and recommendations issued and the outcome achieved; (c) the effectiveness and efficiency of each of the [functions] tasks for which they are responsible. 2. Regional Operational Centres shall submit to the Agency and to the regulatory authorities of the system operation region the data resulting from their continuous monitoring at least annually. 10681/17 BL/ns 105 ANNEX DGE 2B EN 3. [Regional Operational Centres] Regional Security Coordinators [+]shall establish their costs in a transparent manner and report them to the Agency and to the regulatory authorities of the system operation region. 4. [Regional Operational Centres] Regional Security Coordinators [+]shall submit an annual report concerning their performance to ENTSO for Electricity, the Agency, the regulatory authorities of the system operation region and the Electricity Coordination Group established pursuant to Article 1 of Commission Decision 2012/C 353/021. 5. [Regional Operational Centres] Regional Security Coordinators [+]shall report shortcomings identified in the monitoring process under paragraph 1 to ENTSO for electricity, the regulatory authorities of the system [operational] security coordinators, the Agency and the competent authorities of Member States responsible for the prevention and management of crisis situations. Article 44 Liability [Regional Operational Centres In the proposal for the establishment of regional security coordinators in accordance with Article 32, the transmission system operators of the system operation region shall take the necessary steps to cover liability related to the execution of their tasks, [in particular, where they adopt decisions on transmission system operators]. The method employed to provide the cover shall take into account the legal status of the [regional operational centre] Regional Security Coordinators [+] and the level of commercial insurance cover available. 1 Commission Decision of 15 November 2012 setting up the Electricity Coordination Group (OJ C 353, 17.11.2012, p.2). 10681/17 BL/ns 106 ANNEX DGE 2B EN  714/2009 (adapted) Article 458  Ten-year network development plan  1. 10. The ENTSO for Electricity shall adopt and publish a Community-wide network development plan every two years. The  Union  Community-wide network development plan  referred to under Article 27(1)(b)  shall include the modelling of the integrated network, scenario development, a European generation adequacy outlook and an assessment of the resilience of the system. The  Union  Community-wide network development plan shall, in particular:  347/2013 (a) build on national investment plans, taking into account regional investment plans as referred to in Article 12(1), and, if appropriate, Union aspects of network planning as set out in Regulation (EU) No 347/2013 of the European Parliament and of the Council of 17 April 2013 on guidelines for trans-European energy infrastructure1; it shall be subject to a cost-benefit analysis using the methodology established as set out in Article 11 of that Regulation; 1 Regulation (EU) No 347/2013 of the European Parliament and of the Council of 17 April 2013 on guidelines for trans-European energy infrastructure (OJ L 115, 25.4.2013, p. 39). 10681/17 BL/ns 107 ANNEX DGE 2B EN  714/2009 (adapted) (b) regarding cross-border interconnections, also build on the reasonable needs of different system users and integrate long-term commitments from investors referred to in Article 8 and Articles 4413 and 5122 of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2] Directive 2009/72/EC; and (c) identify investment gaps, notably with respect to cross-border capacities. In regard to point (c) of the second subparagraph, a review of barriers to the increase of cross-border capacity of the network arising from different approval procedures or practices may be annexed to the  Union  Community-wide network development plan. 112. The Agency shall provide an opinion on the national ten-year network development plans to assess their consistency with the  Union  Community-wide network development plan. If the Agency identifies inconsistencies between a national ten-year network development plan and the  Union  Community-wide network development plan, it shall recommend amending the national ten-year network development plan or the  Union  Community-wide network development plan as appropriate. If such national ten-year network development plan is elaborated in accordance with Article 5122 of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2]Directive 2009/72/EC, the Agency shall recommend that the competent national regulatory authority amend the national ten-year network development plan in accordance with Article 5122(7) of that Directive and inform the Commission thereof. 10681/17 BL/ns 108 ANNEX DGE 2B EN  714/2009 (adapted)  new Article 4613 Inter-transmission system operator compensation mechanism 1. Transmission system operators shall receive compensation for costs incurred as a result of hosting cross-border flows of electricity on their networks. 2. The compensation referred to in paragraph 1 shall be paid by the operators of national transmission systems from which cross-border flows originate and the systems where those flows end. 3. Compensation payments shall be made on a regular basis with regard to a given period of time in the past. Ex-post adjustments of compensation paid shall be made where necessary, to reflect costs actually incurred. The first period of time for which compensation payments shall be made shall be determined in the gGuidelines referred to in Article 5718. 4. The Commission shall decide on  adopt [delegated] acts in accordance with [Article 63] concerning  the amounts of compensation payments payable. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(2). 10681/17 BL/ns 109 ANNEX DGE 2B EN 5. The magnitude of cross-border flows hosted and the magnitude of cross-border flows designated as originating and/or ending in national transmission systems shall be determined on the basis of the physical flows of electricity actually measured during a given period of time. 6. The costs incurred as a result of hosting cross-border flows shall be established on the basis of the forward-looking long-run average incremental costs, taking into account losses, investment in new infrastructure, and an appropriate proportion of the cost of existing infrastructure, in so far as such infrastructure is used for the transmission of cross-border flows, in particular taking into account the need to guarantee security of supply. When establishing the costs incurred, recognised standard-costing methodologies shall be used. Benefits that a network incurs as a result of hosting cross-border flows shall be taken into account to reduce the compensation received. 7. For the purpose of the inter-transmission system operator compensation mechanism referred to in Article 13 only, where transmission networks of two or more Member States form part, in whole or in part, of a single control block, the control block as a whole shall be considered as forming part of the transmission network of one of the Member States concerned, in order to avoid flows within control blocks being considered as cross-border flows under point Article 2(2)(b) of the first subparagraph of this paragraph and giving rise to compensation payments under paragraph 1 of this Article 13. The regulatory authorities of the Member States concerned may decide which of the Member States concerned shall be that of which the control block as a whole is to be considered to form part. 10681/17 BL/ns 110 ANNEX DGE 2B EN  714/2009  new Article 4715 Provision of information 1. Transmission system operators shall put in place coordination and information exchange mechanisms to ensure the security of the networks in the context of congestion management. 2. The safety, operational and planning standards used by transmission system operators shall be made public. The information published shall include a general scheme for the calculation of the total transfer capacity and the transmission reliability margin based upon the electrical and physical features of the network. Such schemes shall be subject to the approval of the regulatory authorities. 3. Transmission system operators shall publish estimates of available transfer capacity for each day, indicating any available transfer capacity already reserved. Those publications shall be made at specified intervals before the day of transport and shall include, in any event, week-ahead and month-ahead estimates, as well as a quantitative indication of the expected reliability of the available capacity. 10681/17 BL/ns 111 ANNEX DGE 2B EN 4. Transmission system operators shall publish relevant data on aggregated forecast and actual demand, on availability and actual use of generation and load assets, on availability and use of the networks and interconnections, and on balancing power and reserve capacity. For availability and actual use of small generation and load units, aggregated estimate data may be used. 5. The market participants concerned shall provide the transmission system operators with the relevant data. 6. Generation undertakings which own or operate generation assets, where at least one generation asset has an installed capacity of at least 250 MW,  or which have a portfolio comprising at least 400 MW of generation assets,  shall keep at the disposal of the national regulatory authority, the national competition authority and the Commission, for five years all hourly data per plant that is necessary to verify all operational dispatching decisions and the bidding behaviour at power exchanges, interconnection auctions, reserve markets and over-the-counter-markets. The per-plant and per hour information to be stored shall include, but shall not be limited to, data on available generation capacity and committed reserves, including allocation of those committed reserves on a per-plant level, at the times the bidding is carried out and when production takes place.  new 7. Transmission system operators shall exchange regularly a set of sufficiently accurate network and load flow data in order to enable load flow calculations for each transmission system operator in their relevant area. The same set of data shall be made available to the regulatory authorities and to the Commission and Member States upon request. The regulatory authorities, Member States and the Commission shall treat that set of data confidentially, and shall ensure that confidential treament is also given by any consultant carrying out analytical work on their request, on the basis of those data. 10681/17 BL/ns 112 ANNEX DGE 2B EN  714/2009 Article 483 Certification of transmission system operators 1. The Commission shall examine any notification of a decision on the certification of a transmission system operator as laid down in Article 5210(6) of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2] Directive 2009/72/EC as soon as it is received. Within two months of the day of receipt of such notification, the Commission shall deliver its opinion to the relevant national regulatory authority as to its compatibility with Article 5210(2) or Article 5311, and Article 439 of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2] Directive 2009/72/EC. When preparing the opinion referred to in the first subparagraph, the Commission may request the Agency to provide its opinion on the national regulatory authority’s decision. In such a case, the two-month period referred to in the first subparagraph shall be extended by two further months. In the absence of an opinion by the Commission within the periods referred to in the first and second subparagraphs, the Commission shall be deemed not to raise objections to the regulatory authority’s decision. 10681/17 BL/ns 113 ANNEX DGE 2B EN 2. Within two months of receiving an opinion of the Commission, the national regulatory authority shall adopt its final decision regarding the certification of the transmission system operator, taking the utmost account of that opinion. The regulatory authority's decision and the Commission's opinion shall be published together. 3. At any time during the procedure, regulatory authorities and/or the Commission may request from a transmission system operator and/or an undertaking performing any of the functions of generation or supply any information relevant to the fulfilment of their tasks under this Article. 4. Regulatory authorities and the Commission shall preserve the confidentiality of commercially sensitive information. 5. The Commission may adopt Guidelines setting out the details of the procedure to be followed for the application of paragraphs 1 and 2 of this Article. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(2). 5.6.Where the Commission has received notification of the certification of a transmission system operator under Article 439(910) of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2] Directive 2009/72/EC, the Commission shall take a decision relating to certification. The regulatory authority shall comply with the Commission decision. 10681/17 BL/ns 114 ANNEX DGE 2B EN  new Chapter VI Distribution system operation Article 49 European entity for distribution system operators 1. Distribution system operators which are not part of a vertically integrated undertaking or which are unbundled according to the provisions of Article 35 [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2], shall cooperate at Union level through a European Entity for Distribution system operators ('EU DSO entity'), in order to promote the completion and functioning of the internal market in electricity, and to promote optimal management and a coordinated operation of distribution and transmission systems. Distribution system operators who wish to participate in the EU DSO entity shall become registered members of the entity. Article 50 Establishment of the EU DSO entity for electricity 1. By [OP: twelve months after entry into force], the distribution system operators and country representatives as defined in Article 49 (2) with the administrative support of the Agency, shall submit to the Commission and to the Agency the draft statutes, a list of registered members, the draft rules of procedure, including the rules of procedures on the consultation with ENTSO for Electricity and other stakeholders rules on a fair voting procedure and the financing rules, of the EU DSO entity to be established. 10681/17 BL/ns 115 ANNEX DGE 2B EN 1a. Where non-consensus is reached among DSOs for decisions with regard to their tasks pursuant to Article 51, they shall decide by qualified majority. A qualified majority shall require a majority of: (a) DSOs representing at least 55% of the Member States; and (b) DSOs representing Member States comprising at least 65% of the population of the Union. 1b. A blocking minority for decisions with regard to the tasks of the EU DSO entity pursuant to Article 51 must include DSOs representing at least four Member States, , failing of which the qualified majority shall be deemed attained. 2. Within two months of receipt, the Agency, after formally consulting the organisations representing all stakeholders, in particular distribution system users, shall provide an opinion to the Commission on the draft statutes, the list of members and the draft rules of procedure. 3. The Commission shall deliver an opinion on the draft statutes, the list of members and the draft rules of procedure taking into account the opinion of the Agency provided for in paragraph 2, within three months of receipt of the opinion of the Agency. 4. Within three months of the day of receipt of the Commission’s positive opinion, the distribution system operators shall establish the EU DSO entity and adopt and publish its statutes and rules of procedure. 5. The documents referred to in paragraph 1 shall be submitted to the Commission and to the Agency in case of changes thereof or upon their reasoned request. The Agency and the Commission shall deliver an opinion in line with the process set out in paragraphs 2 to 4. 10681/17 BL/ns 116 ANNEX DGE 2B EN 6. The costs related to the activities of the EU DSO entity shall be borne by distribution system operators who are registered members and shall be taken into account in the calculation of tariffs. Regulatory authorities shall approve those costs only if they are reasonable and proportionate. Article 51 Tasks of the EU DSO entity 1. The tasks of the EU DSO entity shall be the following: (a) coordinated operation and planning of transmission and distribution networks; (b) integration of renewable energy resources, distributed generation and other resources embedded in the distribution network such as energy storage; (c) development of demand response; (d) digitalisation of distribution networks including deployment of smart grids and intelligent metering systems; (e) data management, cyber security and data protection; (f) participation in the elaboration of network codes which are relevant to the operation and planning of distribution grids and the coordinated operation of the transmission and distribution networks pursuant to Article 55. 10681/17 BL/ns 117 ANNEX DGE 2B EN 2. In addition the EU DSO entity shall: (a) cooperate with ENTSO for electricity on the monitoring of implementation of the network codes and guidelines which are relevant to the operation and planning of distribution grids and the coordinated operation of the transmission and distribution networks and which are adopted pursuant to this Regulation; (b) cooperate with ENTSO for electricity and adopt best practices on the coordinated operation and planning of transmission and distribution systems including issues such as exchange of data between operators and coordination of distributed energy resources; (c) work on identifying best practices on the areas identified in paragraph 1 and for the introduction of energy efficiency improvements in the distribution network; (d) adopt an annual work programme and an annual report; (e) operate in full compliance with competition rules. Article 52 Consultations in the network code development process 1. While preparing possible network codes pursuant to Article 55, the EU DSO entity shall conduct an extensive consultation process, at an early stage and in an open and transparent manner, involving all relevant stakeholders, and, in particular, the organisations representing all stakeholders, in accordance with the rules of procedure referred to in Article 50. That consultation shall also involve national regulatory authorities and other national authorities, supply and generation undertakings, system users including customers, distribution system operators, including relevant industry associations, technical bodies and stakeholder platforms. It shall aim at identifying the views and proposals of all relevant parties during the decision-making process. 10681/17 BL/ns 118 ANNEX DGE 2B EN 2. All documents and minutes of meetings related to the consultations referred to in paragraph 1 shall be made public. 3. The EU DSO entity shall take into consideration the views provided during the consultations. Before adopting proposals for network codes referred to in Article 55 the EU DSO entity shall indicate how the observations received during the consultation have been taken into consideration. It shall provide reasons where observations have not been taken into account. Article 53 Cooperation between distribution system operators and transmission system operators 1. Distribution system operators and transmission system operators shall cooperate with each other [transmission system operators] in planning and operating their networks. In particular, transmission and distribution system operators shall exchange all necessary information and data regarding, the performance of generation assets and demand side response, the daily operation of their networks and the long-term planning of network investments, with the view to ensure the cost-efficient, secure and reliable development and operation of their networks. 2. Transmission and distribution system operators shall cooperate with each other in order to achieve coordinated access to resources such as distributed generation, energy storage or demand response that may support particular needs of both the distribution system and the transmission system. 10681/17 BL/ns 119 ANNEX DGE 2B EN Chapter VII Network codes and guidelines Article 54 Adoption of network codes and guidelines 1. The Commission may, subject to the empowerments in Articles 55 and 57, adopt [delegated] acts. Such [delegated] acts can either be adopted as network codes on the basis of text proposals developed by the ENTSO for Electricity, or, where so decided in the priority list pursuant to Article 55 paragraph 2, by the EU DSO entity in cooperation with the ENTSO for Electricity and the Agency pursuant to the procedure in Article 55 or as guidelines pursuant to the procedure in Article 57. 2. The network codes and guidelines shall (a) ensure that they provide the minimum degree of harmonisation required to achieve the aims of this Regulation; (b) take into account, where appropriate, regional specificities; (c) not go beyond what is necessary for that purpose; and (d) be without prejudice to the Member States’ right to establish national network codes which do not affect cross[- border] zonal trade. 10681/17 BL/ns 120 ANNEX DGE 2B EN  714/2009 (adapted)  new Article 556 Establishment of network codes 61.  The Commission is empowered to adopt [delegated] acts in accordance with [Article 63] concerning the establishment of network codes in  The network codes referred to in paragraphs 1 and 2 shall cover the following areas, taking into account, if appropriate, regional specificities: (a) network security and reliability rules including rules for technical transmission reserve capacity for operational network security; (b) network connection rules; (c) third-party access rules; (d) data exchange and settlement rules; (e) interoperability rules; (f) operational procedures in an emergency; (g) capacity-allocation and congestion-management rules  [including curtailment of generation and redispatch of generation and demand ]; 10681/17 BL/ns 121 ANNEX DGE 2B EN (h) rules for trading related to technical and operational provision of network access services and system balancing; (i) transparency rules; (j) balancing rules including network-related reserve power rules; (k) rules regarding harmonised transmission  and distribution  tariff structures  as referred to in Article 16[and connection charges ] including locational signals and inter-transmission system operator compensation rules; and (l) energy efficiency regarding electricity networks;.  new (m) rules for non-discriminatory, transparent provision of non-frequency ancillary services, including steady state voltage control, inertia, fast reactive current injection, black-start capability; (n) demand response as covered in Article 17 and 32 of the [Electricty Directive XXX], [including aggregation, energy storage, and demand curtailment rules;] (o) cyber security rules; and [(p) rules concerning Regional Operational Centres] 10681/17 BL/ns 122 ANNEX DGE 2B EN  714/2009  new 1.2 The Commission shall, after consulting the Agency, the ENTSO for Electricity, the EU DSO Entity and the other relevant stakeholders, establish an annual priority list  every three years,  identifying the areas set out in paragraph 1 Article 8(6)to be included in the development of network codes.  If the subject-matter of the network code is directly related to the operation of the distribution system and not primarily [less] relevant for the transmission, the Commission may require the EU DSO entity for electricity [instead of] in cooperation with of the ENTSO for Electricity to convene a drafting committee and submit a proposal for a network code to the agency.  2.3 The Commission shall request the Agency to submit to it within a reasonable period of time not exceeding six months a non-binding framework guideline (framework guideline) setting out clear and objective principles, in accordance with Article 8(7), for the development of network codes relating to the areas identified in the priority list.  The request of the Commission may include conditions which the framework guideline shall address.  Each framework guideline shall contribute to  market integration,  non-discrimination, effective competition, and the efficient functioning of the market. Upon a reasoned request from the Agency, the Commission may extend that period. 3.4 The Agency shall formally consult the ENTSO for Electricity  , the EU DSO entity,  and the other relevant stakeholders in regard to the framework guideline, during a period of no less than two months, in an open and transparent manner. 10681/17 BL/ns 123 ANNEX DGE 2B EN  new 5. The Agency shall submit a non-binding framework guideline to the Commission where requested to do so under paragraph 3. The Agency shall review the non-binding framework guideline and re-submit it to the Commission where requested to do so under paragraph 6.  714/2009  new 4.6 If the Commission considers that the framework guideline does not contribute to  market integration , non-discrimination, effective competition and the efficient functioning of the market, it may request the Agency to review the framework guideline within a reasonable period of time and re-submit it to the Commission. 5.7 If the Agency fails to submit or re-submit a framework guideline within the period set by the Commission under paragraphs 32 or 64, the Commission shall elaborate the framework guideline in question. 6.8 The Commission shall request the ENTSO for Electricity  or, where so decided in the priority list pursuant to paragraph 2, the EU DSO entity for Electricity in co-operation with the ENTSO for Electricity , to submit a  proposal for a  network code which is in line with the relevant framework guideline, to the Agency within a reasonable period of time not exceeding 12 months. 7. Within a period of three months of the day of the receipt of a network code, during which the Agency may formally consult the relevant stakeholders, the Agency shall provide a reasoned opinion to the ENTSO for Electricity on the network code. 10681/17 BL/ns 124 ANNEX DGE 2B EN 8. The ENTSO for Electricity may amend the network code in the light of the opinion of the Agency and re-submit it to the Agency.  714/2009 (adapted)  new 1.9  The ENTSO for Electricity, or where so decided in the priority list pursuant to paragraph 2, the EU DSO entity, shall convene a drafting committee to support it in the network code development process. The drafting committee shall consist of representatives of the ENTSO for Electricity, the Agency, where appropriate of the EU DSO entity, where appropriate of nominated electricity market operators and a limited number of the main affected stakeholders. The ENTSO for Electricity or where so decided in the priority list pursuant to paragraph 2 the EU DSO entity, in co-operation with the ENTSO for Electricity shall elaborate  proposals for  network codes in the areas referred to in paragraph 6 Article paragraph 1 upon a request addressed to it by the Commission in accordance with paragraph 8Article 6(6). 9.10 When tThe Agency  shall revise the network code and ensure  is satisfied that the network code is in line with the relevant framework guideline  and contributes to market integration, non-discrimination, effective competition, and the efficient functioning of the market and  , the Agency shall submit the  revised  network code to the Commission and may recommend that it be adopted within  six months of the day of the receipt of the proposal  a reasonable time period. The Commission shall provide reasons in the event that it does not adopt that network code.  In the proposal submitted to the Commission, the Agency shall take into account the views provided by all involved parties during the drafting of the proposal led by the ENTSO for Electricity or the EU DSO entity and shall formally consult the relevant stakeholders on the version to be submitted to the Commission.  10681/17 BL/ns 125 ANNEX DGE 2B EN 10.11 Where the ENTSO for Electricity  or the EU DSO entity  havehas failed to develop a network code within the period of time set by the Commission under paragraph 86, the Commission may request the Agency to prepare a draft network code on the basis of the relevant framework guideline. The Agency may launch a further consultation in the course of preparing a draft network code under this paragraph. The Agency shall submit a draft network code prepared under this paragraph to the Commission and may recommend that it be adopted. 11.12 The Commission may adopt, on its own initiative, where the ENTSO for Electricity  or the EU DSO entity have  has failed to develop a network code, or the Agency has failed to develop a draft network code as referred to in paragraph 1110 of this Article, or upon recommendation of the Agency under paragraph 109 of this Article, one or more network codes in the areas listed in paragraph 1Article 8(6). 13. Where the Commission proposes to adopt a network code on its own initiative, the Commission shall consult the Agency, the ENTSO for Electricity and all relevant stakeholders in regard to the draft network code during a period of no less than two months. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(2). 12.14 This Article shall be without prejudice to the Commission's right to adopt and amend the gGuidelines as laid down in Article 5718.  It shall be without prejudice to the possibility for the ENTSO for Electricity to develop non-binding guidance in the areas set out in paragraph 1 where this does not relate to areas covered by a request addressed to it by the Commission. This guidance shall be submitted to the Agency for an opinion. This opinion shall be taken duly into account by the ENTSO for Electricity.  10681/17 BL/ns 126 ANNEX DGE 2B EN Article 567 Amendments of network codes  new 1. The Commission is empowered to adopt [delegated] acts in accordance with [Article 63] concerning the amendment of network codes following the procedure under Article 55. Amendments can also be proposed by the Agency under the procedure set out in paragraphs 2 to 4 of this Article.  714/2009 (adapted)  new 1.2 Draft amendments to any network code adopted under Article 556 may be proposed to the Agency by persons who are likely to have an interest in that network code, including the ENTSO for Electricity,  the EU DSO entity,  transmission system operators, system users and consumers. The Agency may also propose amendments on its own initiative in close cooperation with ENTSO-E. 23. The Agency shall consult all stakeholders in accordance with Article 10 of Regulation (EC) No 713/2009. Following that process, tThe Agency may make reasoned proposals for amendments to the Commission in close cooperation with ENTSO-E, explaining how such proposals are consistent with the objectives of the network codes set out in Article 6 55(2).  Where it deems an amendment proposal admissible and on amendments on its own initiative,   the Agency shall consult all stakeholders in accordance with Article 15 [recast of Regulation (EC) No 713/2009 as proposed by COM(2016) 863/2].  10681/17 BL/ns 127 ANNEX DGE 2B EN 3.4 The Commission is empowered to may adopt, taking account of the Agency's proposals, amendments to any network code adopted under Article 55 6. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted  as [delegated] acts  in accordance with The Commission is empowered to adopt [delegated] acts in accordance with Article 63 the regulatory procedure with scrutiny referred to in Article 23(2) 4.5 Consideration of proposed amendments under the procedure set out in Article 63 23(2) shall be limited to consideration of the aspects related to the proposed amendment. Those proposed amendments are without prejudice to other amendments which the Commission may propose. Article 5718 Guidelines  new 1. The Commission may adopt binding guidelines in the areas listed below. 2. The Commission may adopt a [delegated] act as a Guideline in the areas where such acts could also be developed under the network code procedure pursuant to Article 55 (1). 10681/17 BL/ns 128 ANNEX DGE 2B EN  714/2009 (adapted)  new 1.3.Where appropriate, Guidelines  may be adopted  relating to the inter-transmission system operator compensation mechanism.  They  shall specify, in accordance with the principles set out in Articles 4613 and 1614: (a) details of the procedure for determining which transmission system operators are liable to pay compensation for cross-border flows including as regards the split between the operators of national transmission systems from which cross-border flows originate and the systems where those flows end, in accordance with Article 4613(2); (b) details of the payment procedure to be followed, including the determination of the first period for which compensation is to be paid, in accordance with the second subparagraph of Article 4613(3); (c) details of methodologies for determining the cross-border flows hosted for which compensation is to be paid under Article 4613, in terms of both quantity and type of flows, and the designation of the magnitudes of such flows as originating and/or ending in transmission systems of individual Member States, in accordance with Article 4613(5); (d) details of the methodology for determining the costs and benefits incurred as a result of hosting cross-border flows, in accordance with Article 4613(6); (e) details of the treatment in the context of the inter-transmission system operator compensation mechanism of electricity flows originating or ending in countries outside the European Economic Area; and 10681/17 BL/ns 129 ANNEX DGE 2B EN (f) the participation of national systems which are interconnected through direct current lines, in accordance with Article 4613. 2.4 Guidelines may also determine appropriate rules leading to a progressive harmonisation of the underlying principles for the setting of  relating to  charges applied to producers,  energy storage  and  customers  consumers (load) under national  distribution and transmission  tariff systems  and connection regimes  , including the reflection of the inter-transmission system operator compensation mechanism in national network charges and the provision of appropriate and efficient locational signals, in accordance with the principles set out in Article 1614. The gGuidelines  may  shall make provision for appropriate and efficient harmonised locational signals at  Union  Community level. Any such harmonisation shall not prevent Member States from applying mechanisms to ensure that network access charges borne by  customers  consumers (load) are comparable throughout their territory. 3.5 Where appropriate, gGuidelines providing the minimum degree of harmonisation required to achieve the aim of this Regulation shall  may  also specify: (a) details relating to provision of information, in accordance with the principles set out in Article 15; (ab) details of rules for the trading of electricity; (bc) details of investment incentive rules for interconnector capacity including locational signals; 10681/17 BL/ns 130 ANNEX DGE 2B EN (b) details of the areas listed in Article 8(6). For that purpose, the Commission shall consult the Agency, the ENTSO for Electricity. 4. Guidelines on the management and allocation of available transmission capacity of interconnections between national systems are laid down in Annex I.  347/2013 (adapted) 4a.6 The Commission may adopt guidelines on the implementation of operational coordination between transmission system operators at Union level. Those guidelines shall be consistent with and build upon the network codes referred to in Article 556 of this Regulation and build upon the adopted specifications and the Agency opinion referred to in Article 27(1)(g)8(3)(a) of this Regulation. When adopting those guidelines, the Commission shall take into account differing regional and national operational requirements. Those guidelines shall be adopted in accordance with the examination procedure referred to in Article 23 (3) 62(2). 10681/17 BL/ns 131 ANNEX DGE 2B EN  714/2009 (adapted)  new 75. The Commission may adopt Guidelines on the issues listed in paragraphs 1, 2 and 3 of this Article. It may amend the Guidelines referred to in paragraph 4 of this Article, in accordance with the principles set out in Articles 15 and 16, in particular so as to include detailed Guidelines on all capacity-allocation methodologies applied in practice and to ensure that congestion-management mechanisms evolve in a manner compatible with the objectives of the internal market. Where appropriate, in the course of such amendments common rules on minimum safety and operational standards for the use and operation of the network, as referred to in Article 15(2) shall be established. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(2). When adopting or amending gGuidelines, the Commission shall:  consult the Agency, the ENTSO for Electricity and other stakeholders where relevant.  (a) ensure that the Guidelines provide the minimum degree of harmonisation required to achieve the aims of this Regulation and do not go beyond what is necessary for that purpose; and (b) indicate what actions it has taken with respect to the conformity of rules in third countries, which form part of the Community electricity system, with the Guidelines in question. 10681/17 BL/ns 132 ANNEX DGE 2B EN When adopting Guidelines under this Article for the first time, the Commission shall ensure that they cover in a single draft measure at least the issues referred to in points (a) and (d) of paragraph 1 and in paragraph 2. Article 5821 Right of Member States to provide for more detailed measures This Regulation shall be without prejudice to the rights of Member States to maintain or introduce measures that contain more detailed provisions than those set out in this Regulation, herein,or in the gGuidelines referred to in Article 5718  or in the network codes referred to in Article 55, provided those measures do not endanger the effectiveness of Union legislation. 10681/17 BL/ns 133 ANNEX DGE 2B EN Chapter VIII  Final provisions  Article 5917 New interconnectors 1. New direct current interconnectors may, upon request, be exempted, for a limited period of time, from the provisions of Article 17(2)16(6) of this Regulation and Articles 69, 4332, and Article 5937(6) and 60(1)(10) of [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2]Directive 2009/72/EC under the following conditions: (a) the investment must enhance competition in electricity supply; (b) the level of risk attached to the investment is such that the investment would not take place unless an exemption is granted; (c) the interconnector must be owned by a natural or legal person which is separate at least in terms of its legal form from the system operators in whose systems that interconnector will be built; (d) charges are levied on users of that interconnector; 10681/17 BL/ns 134 ANNEX DGE 2B EN (e) since the partial market opening referred to in Article 19 of Directive 96/92/EC of the European Parliament and of the Council of 19 December 1996 concerning common rules for the internal market in electricity1, no part of the capital or operating costs of the interconnector has been recovered from any component of charges made for the use of transmission or distribution systems linked by the interconnector; and (f) the exemption must not be to the detriment of competition or the effective functioning of the internal market in electricity, or the efficient functioning of the regulated system to which the interconnector is linked. 2. Paragraph 1 shall also apply, in exceptional cases, to alternating current interconnectors provided that the costs and risks of the investment in question are particularly high when compared with the costs and risks normally incurred when connecting two neighbouring national transmission systems by an alternating current interconnector. 3. Paragraph 1 shall also apply to significant increases of capacity in existing interconnectors. 4. The decision on the exemption under paragraphs 1, 2 and 3 shall be taken on a case-by-case basis by the regulatory authorities of the Member States concerned. An exemption may cover all or part of the capacity of the new interconnector, or of the existing interconnector with significantly increased capacity. Within two months from the date on which the request for exemption was received by the last of the regulatory authorities concerned, the Agency may submit an advisory opinion to those regulatory authorities which could provide a basis for their decision. 1 Directive 96/92/EC of the European Parliament and of the Council of 19 December 1996 concerning common rules for the internal market in electricity (OJ L 27, 30.1.1997, p. 20). 10681/17 BL/ns 135 ANNEX DGE 2B EN In deciding to grant an exemption, consideration shall be given, on a case-by-case basis, to the need to impose conditions regarding the duration of the exemption and non-discriminatory access to the interconnector. When deciding those conditions, account shall, in particular, be taken of additional capacity to be built or the modification of existing capacity, the time-frame of the project and national circumstances. Before granting an exemption, the regulatory authorities of the Member States concerned shall decide upon the rules and mechanisms for management and allocation of capacity. Congestion-management rules shall include the obligation to offer unused capacity on the market and users of the facility shall be entitled to trade their contracted capacities on the secondary market. In the assessment of the criteria referred to in points (a), (b) and (f) of paragraph 1, the results of the capacity-allocation procedure shall be taken into account. Where all the regulatory authorities concerned have reached agreement on the exemption decision within six months, they shall inform the Agency of that decision. The exemption decision, including any conditions referred to in the second subparagraph of this paragraph, shall be duly reasoned and published. 5. The decision referred to in paragraph 4 shall be taken by the Agency: (a) where all the regulatory authorities concerned have not been able to reach an agreement within six months from the date the exemption was requested before the last of those regulatory authorities; or (b) upon a joint request from the regulatory authorities concerned. Before taking such a decision, the Agency shall consult the regulatory authorities concerned and the applicants. 10681/17 BL/ns 136 ANNEX DGE 2B EN 6. Notwithstanding paragraphs 4 and 5, Member States may provide for the regulatory authority or the Agency, as the case may be, to submit, for formal decision, to the relevant body in the Member State, its opinion on the request for an exemption. That opinion shall be published together with the decision. 7. A copy of every request for exemption shall be transmitted for information without delay by the regulatory authorities to the Agency and to the Commission on receipt. The decision shall be notified, without delay, by the regulatory authorities concerned or by the Agency (notifying bodies), to the Commission, together with all the relevant information with respect to the decision. That information may be submitted to the Commission in aggregate form, enabling the Commission to reach a well-founded decision. In particular, the information shall contain: (a) the detailed reasons on the basis of which the exemption was granted or refused, including the financial information justifying the need for the exemption; (b) the analysis undertaken of the effect on competition and the effective functioning of the internal market in electricity resulting from the grant of the exemption; (c) the reasons for the time period and the share of the total capacity of the interconnector in question for which the exemption is granted; and (d) the result of the consultation of the regulatory authorities concerned. 8. Within a period of  50 working days  two months from the day following receipt of notification under paragraph 7, the Commission may take a decision requesting the notifying bodies to amend or withdraw the decision to grant an exemption. That two-month period  of 50 working days  may be extended by an additional period of  50 working days  two months where further information is sought by the Commission. That additional period shall begin on the day following receipt of the complete information. The initial two-month period may also be extended by consent of both the Commission and the notifying bodies. 10681/17 BL/ns 137 ANNEX DGE 2B EN When the requested information is not provided within the period set out in the request, the notification shall be deemed to be withdrawn unless, before the expiry of that period, either the period is extended by consent of both the Commission and the notifying bodies, or the notifying bodies, in a duly reasoned statement, inform the Commission that they consider the notification to be complete. The notifying bodies shall comply with a Commission decision to amend or withdraw the exemption decision within one month and shall inform the Commission accordingly. The Commission shall preserve the confidentiality of commercially sensitive information. The Commission's approval of an exemption decision shall expire two years after the date of its adoption in the event that construction of the interconnector has not yet started by that date, and five years after the date of its adoption if the interconnector has not become operational by that date, unless the Commission decides , on the basis of a reasoned request by the notifying bodies,  that any delay is due to major obstacles beyond the control of the person to whom the exemption has been granted.  new 9. Where the regulatory authorities of the Member States concerned decide to modify a decision under paragraph 1, they shall notify this decision without delay to the Commission, together with all the relevant information with respect to the decision. Paragraphs 1 to 8 shall apply to this notified decision, taking into account the particularities of the existing exemption. 10. The Commission may, upon request or on its own initiative, reopen the proceedings: (a) where, taking due consideration of legitimate expectations by the parties and of the economic balance achieved in the original exemption decision, there has been a material change in any of the facts on which the decision was based; 10681/17 BL/ns 138 ANNEX DGE 2B EN (b) where the undertakings concerned act contrary to their commitments; or (c) where the decision was based on incomplete, incorrect or misleading information provided by the parties.  714/2009 (adapted)  new 11.9 The Commission  is empowered to  may adopt Guidelines  [delegated] acts in accordance with Article 63 concerning the adoption of guidelines  for the application of the conditions laid down in paragraph 1 of this Article and to set out the procedure to be followed for the application of paragraphs 4, 7 and 8 , 9 and 10  of this Article. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(2). [Article 19 Regulatory authorities The regulatory authorities, when carrying out their responsibilities, shall ensure compliance with this Regulation and the Guidelines adopted pursuant to Article 18. Where appropriate to fulfil the aims of this Regulation the regulatory authorities shall cooperate with each other, with the Commission and the Agency in compliance with Chapter IX of Directive 2009/72/EC.] 10681/17 BL/ns 139 ANNEX DGE 2B EN Article 6020 Provision of information and confidentiality 1. Member States and the regulatory authorities shall, on request, provide to the Commission all information necessary for the purposes of  enforcing the provisions of this Regulation  Article 13(4) and Article 18. In particular, for the purposes of Article 13(4) and (6), regulatory authorities shall, on a regular basis, provide information on the actual costs incurred by national transmission system operators, as well as data and all relevant information relating to the physical flows in transmission system operators’ networks and the cost of the networks. The Commission shall fix a reasonable time limit within which the information is to be provided, taking into account the complexity of the information required and the urgency with which the information is needed. 2. If the Member State or the regulatory authority concerned does not provide the information referred to in paragraph 1 within the given time-limit pursuant to paragraph 1 of this Article, the Commission may request all information necessary for the purpose of  enforcing the provisions of this Regulation  Article 13(4) and Article 18 directly from the undertakings concerned. When sending a request for information to an undertaking, the Commission shall at the same time forward a copy of the request to the regulatory authorities of the Member State in whose territory the seat of the undertaking is situated. 10681/17 BL/ns 140 ANNEX DGE 2B EN 3. In its request for information under paragraph 1, the Commission shall state the legal basis of the request, the time-limit within which the information is to be provided, the purpose of the request, and the penalties provided for in Article 6122(2) for supplying incorrect, incomplete or misleading information. The Commission shall fix a reasonable time-limit taking into account the complexity of the information required and the urgency with which the information is needed. 4. The owners of the undertakings or their representatives and, in the case of legal persons, the persons authorised to represent them by law or by their instrument of incorporation, shall supply the information requested. Where lawyers duly authorised so to act supply the information on behalf of their clients, the client shall remain fully responsible in the event that the information supplied is incomplete, incorrect or misleading. 5. Where an undertaking does not provide the information requested within the time-limit fixed by the Commission or supplies incomplete information, the Commission may by decision require the information to be provided. That decision shall specify what information is required and fix an appropriate time-limit within which it is to be supplied. It shall indicate the penalties provided for in Article 6122(2). It shall also indicate the right to have the decision reviewed by the Court of Justice of the European  Union  Communities. The Commission shall, at the same time, send a copy of its decision to the regulatory authorities of the Member State within the territory of which the person is resident or the seat of the undertaking is situated. 6. The information referred to in paragraphs 1 and 2 shall be used only for the purposes of Article 13(4) and Article 18  enforcing the provisions of this Regulation . The Commission shall not disclose information acquired pursuant to this Regulation of the kind covered by the obligation of professional secrecy which is acquired pursuant to this Regulation. 10681/17 BL/ns 141 ANNEX DGE 2B EN Article 6122 Penalties 1. Without prejudice to paragraph 2, the Member States shall lay down rules on penalties applicable to infringements of the provisions of this Regulation  , the network codes adopted pursuant to Article 55, and the guidelines adopted pursuant to Article 57  and shall take all measures necessary to ensure that those provisions are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify the Commission by 1 July 2004 of those rules corresponding to the provisions laid down in Regulation (EC) No 1228/2003 and shall notify the Commission without delay of any subsequent amendment affecting them. They shall notify the Commission of those rules not corresponding to the provisions laid down in Regulation (EC) No 1228/2003 by 3 March 2011 and shall notify the Commission without delay of any subsequent amendment affecting them. 2. The Commission may, by decision, impose on undertakings fines not exceeding 1 % of the total turnover in the preceding business year where, intentionally or negligently, they supply incorrect, incomplete or misleading information in response to a request made pursuant to Article 6020(3) or fail to supply information within the time-limit fixed by a decision adopted pursuant to the first subparagraph of Article 6020(5). In setting the amount of a fine, the Commission shall have regard to the gravity of the failure to comply with the requirements of the first subparagraph. 3. Penalties provided for pursuant to paragraph 1 and decisions taken pursuant to paragraph 2 shall not be of a criminal law nature. 10681/17 BL/ns 142 ANNEX DGE 2B EN  714/2009 Article 6223 Committee procedure 1. The Commission shall be assisted by the committee set up by Article 6846 of Directive 2009/72/EC [recast of Directive 2009/72/EC as proposed by COM(2016) 864/2]. 2. Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.  347/2013 23. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council1 of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers shall apply. 1 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers (OJ L 55, 28.2.2011, p. 13). 10681/17 BL/ns 143 ANNEX DGE 2B EN  714/2009 Article 24 Commission report The Commission shall monitor the implementation of this Regulation. In its report under Article 47(6) of Directive 2009/72/EC, the Commission shall also report on the experience gained in the application of this Regulation. In particular the report shall examine to what extent this Regulation has been successful in ensuring non-discriminatory and cost-reflective network access conditions for cross border exchanges of electricity in order to contribute to customer choice in a well- functioning internal market in electricity and to long-term security of supply, as well as to what extent effective locational signals are in place. If necessary, the report shall be accompanied by appropriate proposals and/or recommendations.  new Article 63 Exercise of the delegation 1. The power to adopt [delegated] acts is conferred on the Commission subject to the conditions laid down in this Article. 2. The power to adopt [delegated] acts referred to in [Article 31(3), Article 46(4), Article 55(1), Article 56(1) and (4)], and Article 59(11) shall be conferred on the Commission for an undetermined period of time from the [OP: please insert the date of entry into force]. 10681/17 BL/ns 144 ANNEX DGE 2B EN 3. The delegation of power referred to in Article 31(3), Article 46(4), Article 55(1), Article 56(1) and (4), and Article 59(11) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect on the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any [delegated] act already in force. 4. Before adopting a [delegated] act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 5. As soon as it adopts a [delegated] act, the Commission shall notify it simultaneously to the European Parliament and to the Council. 6. A [delegated] act adopted pursuant to [Article 31(3), Article 46(4), Article 55(1), Article 56(1) and (4)], and Article 59(11) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council. 10681/17 BL/ns 145 ANNEX DGE 2B EN  714/2009 (adapted)  new Article 6425 Repeal Regulation (EC) No  714/2009  1228/2003 shall be  is  repealed from 3 March 2011. References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.  714/2009 (adapted) Article 6526 Entry into force This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 3 March 2011  1 January 2020 . This Regulation shall be binding in its entirety and directly applicable in all Member States. 10681/17 BL/ns 146 ANNEX DGE 2B EN Done at Brussels, For the European Parliament For the Council The President The President

**Load-Date:** November 23, 2017

**End of Document**



[***FEDERAL REGISTER: Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S Navy Marine Structure Maintenance and Pile Replacement in Washington***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5RTH-M8K1-JDG9-Y076-00000-00&context=1516831)

Impact News Service

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**Body**

Washington: Office of the Federal Register has issued the following notice:

 Department of Commerce ----------------------------------------------------------------------- National Oceanic and Atmospheric Administration ----------------------------------------------------------------------- 50 CFR Part 218 Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S Navy Marine Structure Maintenance and Pile Replacement in Washington; Proposed Rule Federal Register / Vol. 83 , No. 43 / Monday, March 5, 2018 / Proposed Rules [[Page 9366]] ----------------------------------------------------------------------- DEPARTMENT OF COMMERCE National Oceanic and Atmospheric Administration 50 CFR Part 218 [Docket No. 170919913-8186-01] RIN 0648-BH27 Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S Navy Marine Structure Maintenance and Pile Replacement in Washington AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments. ----------------------------------------------------------------------- SUMMARY: NMFS has received a request from the U.S Navy (Navy) for authorization to take marine mammals incidental to conducting construction activities related to marine structure maintenance and pile replacement at facilities in Washington, over the course of five years (2018-2023). As required by the Marine Mammal Protection Act (MMPA), NMFS is proposing regulations to govern that take, and requests comments on the proposed regulations. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision. DATES: Comments and information must be received no later than April 4, 2018. ADDRESSES: You may submit comments on this document, identified by NOAA-NMFS-2018-0032, by any of the following methods:  Electronic submission: Submit all electronic public comments via the federal e-Rulemaking Portal. Go to [*www.regulations.gov*](http://www.regulations.gov)/#!docketDetail;D=NOAA-NMFS-2018-0032, click the ``Comment Now!'' icon, complete the required fields, and enter or attach your comments.      Mail: Submit written comments to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.     Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on   [*www.regulations.gov*](http://www.regulations.gov) without change. All personal identifying information (e.g , name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ``N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Availability

    A copy of the Navy's application and any supporting documents, as well as a list of the references cited in this document, may be obtained online at: [*www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities*](http://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities). In case of problems accessing these documents, please call the contact listed above (see FOR FURTHER INFORMATION CONTACT).

Purpose and Need for Regulatory Action

    This proposed rule would establish a framework under the authority of the MMPA (16 U.S.C 1361 et seq.) to allow for the authorization of take of marine mammals incidental to the Navy's construction activities related to marine structure maintenance and pile replacement at facilities in Washington.     We received an application from the Navy requesting five-year regulations and authorization to take multiple species of marine mammals. Take would occur by Level A and Level B harassment incidental to impact and vibratory pile driving. Please see ``Background'' below for definitions of harassment.

Legal Authority for the Proposed Action

    Section 101(a)(5)(A) of the MMPA (16 U.S.C 1371(a)(5)(A)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S citizens who engage in a specified activity (other than commercial fishing) within a specified ***geographical*** region for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity and other means of effecting the ``least practicable adverse impact'' on the affected species or stocks and their habitat (see the discussion below in the ``Proposed Mitigation'' section), as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for issuing this proposed rule containing five-year regulations, and for any subsequent LOAs. As directed by this legal authority, this proposed rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Proposed Rule

    Following is a summary of the major provisions of this proposed rule regarding Navy construction activities. These measures include:      Required monitoring of the construction areas to detect the presence of marine mammals before beginning construction activities.      Shutdown of construction activities under certain circumstances to avoid injury of marine mammals.      Soft start for impact pile driving to allow marine mammals the opportunity to leave the area prior to beginning impact pile driving at full power.

Background

    Section 101(a)(5)(A) of the MMPA (16 U.S.C 1361 et seq.) directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S citizens who engage in a specified activity (other than commercial fishing) within a specified ***geographical*** region if certain findings are made, regulations are issued, and notice is provided to the public.     An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.     NMFS has defined ``negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.     The MMPA states that the term ``take'' means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal.     Except with respect to certain activities not pertinent here, the MMPA defines ``harassment'' as: Any act of

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pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

National Environmental Policy Act

    To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C 4321 et seq.) and NOAA Administrative Order (NAO) 216-6A, NMFS must evaluate our proposed action (i.e , the promulgation of regulations and subsequent issuance of incidental take authorization) and alternatives with respect to potential impacts on the human environment.     This action is consistent with categories of activities identified in Categorical Exclusion B4 of the Companion Manual for NAO 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the proposed action qualifies to be categorically excluded from further NEPA review.     Information in the Navy's application and this notice collectively provide the environmental information related to proposed issuance of these regulations and subsequent incidental take authorization for public review and comment. We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the request for incidental take authorization.

Summary of Request

    On July 24, 2017, we received an adequate and complete request from the Navy requesting authorization for take of marine mammals incidental to construction activities related to marine structure maintenance and pile replacement at six Naval installations in Washington inland waters. On August 4, 2017 (82 FR 36359), we published a notice of receipt of the Navy's application in the Federal Register, requesting comments and information related to the request for thirty days. We received comments from Whale and Dolphin Conservation (WDC). The comments received from WDC were considered in development of this proposed rule and are available online at: [*www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities*](http://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities).     The Navy proposes to conduct construction necessary for maintenance of existing in-water structures at the following facilities: Naval Base Kitsap (NBK) Bangor, NBK Bremerton, NBK Keyport, NBK Manchester, Zelatched Point, and Naval Station Everett (NS Everett). These repairs would include use of impact and vibratory pile driving, including installation and removal of steel, concrete, plastic, and timber piles. Hereafter (unless otherwise specified or detailed) we use the term ``pile driving'' to refer to both pile installation and pile removal. The use of both vibratory and impact pile driving is expected to produce underwater sound at levels that have the potential to result in harassment of marine mammals.     The Navy requests authorization to take individuals of 10 species by Level B harassment. Take by Level A harassment was requested only for the harbor seal. The proposed regulations would be valid for five years (2018-2023).

Description of the Specified Activity

Overview

    Maintaining existing wharfs and piers is vital to sustaining the Navy's mission and ensuring readiness. To ensure continuance of necessary missions at the six installations, the Navy must conduct annual maintenance and repair activities at existing marine waterfront structures, including removal and replacement of piles of various types and sizes. The Navy refers to this program as the Marine Structure Maintenance and Pile Replacement (MPR) program. Exact timing and amount of necessary in-water work is unknown, but the Navy estimates replacing up to 822 structurally unsound piles over the 5-year period, including individual actions currently planned and estimates for future marine structure repairs. Construction will include use of impact and vibratory pile driving, including removal and installation of steel, concrete, plastic, and timber piles. Aspects of construction activities other than pile driving are not anticipated to have the potential to result in incidental take of marine mammals because they are either above water or do not produce levels of underwater sound with likely potential to result in marine mammal disturbance.     The Navy's waterfront inspection program prioritizes deficiencies in marine structures and plans those maintenance and repairs for design and construction. The Navy's proposed activities include individual projects (where an existing need has been identified and funds have been requested) and estimates for emergent or emergency repairs. The latter are also referred to as contingency repairs. Estimates of activity levels for contingency repairs are based on Navy surveys of existing structures, which provide assessments of structure condition and estimates of numbers of particular pile types that may require replacement (at an assumed 1:1 ratio) over the 5-year duration of these proposed regulations. Additional allowance is made for the likelihood that future waterfront inspections will reveal unexpected damage, or that damage caused by severe weather events and/or incidents caused by vessels will result in need for additional contingency repairs. This regional programmatic approach to MMPA compliance is expected to result in significantly increased efficiency for both the Navy and NMFS, while satisfying the requirements of the MMPA. The regulations proposed here (and any issued LOAs) would replace multiple project-specific incidental take authorization requests for actions that are small in scale, similar in nature, and located within a similar geographic area. The detailed discussion of planned or anticipated projects provided here and in the Navy's application allow for more comprehensive analysis, while providing a reduction in the time and effort necessary to obtain individual incidental take authorizations. LOAs could be issued for projects conducted at any of the six facilities if they fit within the structure of the programmatic analysis provided herein and are able to meet the requirements described in the regulations.     The Navy would meet with NMFS on an annual basis prior to the start of in-water work windows to review upcoming projects, required monitoring plans, and the results of relevant projects conducted in the preceding in-water work window. The intent is to utilize lessons learned to better inform potential effects of future MPR activities and in any follow-up consultations.

Dates and Duration

    The proposed regulations would be valid for a period of five years (2018-2023). The specified activities may occur at any time during the five-year period of validity of the proposed regulations, subject to existing timing restrictions. These timing restrictions, or in-water work windows, are typically

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designed to protect fish species listed under the Endangered Species Act (ESA). For NBK Bangor and Zelatched Point (located in Hood Canal), in-water work may occur from July 16 through January 15. At the remaining four facilities (located in Puget Sound), in-water work may occur from July 16 through February 15.     For many projects the design details are not known; thus, it is not possible to state the number of pile driving days that will be required. Days of pile driving at each site were based on the estimated work days using a slow production rate, i.e , one pile removed per day and one pile installed per day for contingency pile driving and an average production rate of six piles per day for fender pile replacement. These conservative rates give the following estimates of total days at each facility over the 5-year duration: NBK Bangor, 119 days; Zelatched Point, 20 days; NBK Bremerton, 168 days; NBK Keyport, 20 days; NBK Manchester, 50 days; and NS Everett, 78 days. These totals include both extraction and installation of piles, and represent a conservative estimate of pile driving days at each facility. In a real construction situation, pile driving production rates would be maximized when possible and actual daily production rates may be higher, resulting in fewer actual pile driving days.

Specified ***Geographical*** Region

    The six installations are located within the inland waters of Washington State. Two facilities are located within Hood Canal, while the remainder are located within Puget Sound. Please see Figure 1-1 of the Navy's application for a regional map. For full details regarding the specified ***geographical*** region, please see section 2 of the Navy's application. The region is affected by high amounts of runoff from the Fraser River, which stimulates primary productivity, carrying nutrients northwards past Vancouver Island year-round. Puget Sound is one of the largest estuaries in the United States and is a place of great physical and ecological complexity and productivity. The average surface water temperature is 12.8 [deg]C in summer and 7.2 [deg]C in winter (Staubitz et al., 1997), but surface waters frequently exceed 20[deg]C in the summer and fall. With nearly six million people (doubled since the 1960s), Puget Sound is also heavily influenced by human activity.     NBK Bangor is located on the Hood Canal, a long, narrow, fjord-like basin of western Puget Sound. Please see Figure 1-2 of the Navy's application. Oriented northeast to southwest, the portion of the canal from Admiralty Inlet to a large bend, called the Great Bend, at Skokomish, Washington, is 84 kilometers (km) long. East of the Great Bend, the canal extends an additional 15 mi to Belfair. Throughout its 108-km length, the width of the canal varies from 1.6 to 3.2 km and exhibits strong depth/elevation gradients. Hood Canal is characterized by relatively steep sides and irregular seafloor topography. In northern Hood Canal, water depths in the center of the waterway near Admiralty Inlet vary between 91 and 128 meters (m). As the canal extends southwestward toward the Olympic Mountain Range and Thorndyke Bay, water depth decreases to approximately 49 m over a moraine deposit. This deposit forms a sill across the canal in the vicinity of Thorndyke Bay, which limits seawater exchange with the rest of Puget Sound. The NBK Bangor waterfront occupies approximately 8 km of the shoreline within northern Hood Canal (1.7 percent of the entire Hood Canal coastline) and lies just south of the sill feature. Zelatched Point is located on the southwestern end of the Toandos Peninsula on Dabob Bay within Hood Canal. Please see Figure 1-6 of the Navy's application. It is approximately 6.4 km west of the NBK Bangor waterfront on the western facing portion of Toandos Peninsula. Dabob Bay is a 183-m deep fjord-like basin with a 101-m sill at its entrance. It runs north 19 km from its junction with Hood Canal. The width of the Dabob Bay is approximately 4.5 km at the Zelatched Point pier.     NBK Bremerton is located on the north side of Sinclair Inlet in southern Puget Sound. Please see Figure 1-3 of the Navy's application. Sinclair Inlet is located off the main basin of Puget Sound and is about 6.9 long and 1.9 km wide. The inlet is connected to the main basin through Port Orchard Narrows and Rich Passage. Another relatively narrow waterway, Port Washington Narrows, connects Sinclair Inlet to Dyes Inlet. In-water structures, shoreline fill, and erosion protection at NBK Bremerton have resulted in a shoreline geometry and character that is quite different from undisturbed shorelines in Puget Sound. Bathymetry near existing piers and in turning basins immediately offshore has been altered by significant dredging to accommodate aircraft carriers and other Navy vessels. Water depths range from 12 to 14 m, increasing to 14 to 15 m in dredged berthing areas. West of the project sites, further into the inlet, depths gradually decrease to less than 9 m.     NBK Keyport is located on the eastern shore of the Kitsap Peninsula, approximately 24 km due west of Seattle and 16 km north of the city of Bremerton. Please see Figure 1-4 of the Navy's application. Keyport Pier is located along the shores of Liberty Bay, which flows into Port Orchard Bay and then through the narrow Agate Passage to the northeast and Port Orchard Narrows to the south. Liberty Bay and waters adjacent to Keyport are relatively shallow with water depths no greater than 30 m. Water depths increase from the northwest to south/southeast and are greatest in the southern portion of the Port Orchard Narrows.     NBK Manchester is located on Orchard Point, approximately 6.4 km due east of Bremerton. Please see Figure 1-5 of the Navy's application. The installation is bounded by Clam Bay to the northwest, Rich Passage to the northeast, and Puget Sound to the east. NBK Manchester piers are located on the north side of Orchard Point and in a small embayment open on the south side of Orchard Point. In Clam Bay, the bathymetry is gently sloping with depths in the outer portions of the bay of approximately 5.5 m below mean lower low water (MLLW). Depths off Orchard Point drop off dramatically to 18 m below MLLW approximately 150 m from shore and 90 m below MLLW 1.6 km offshore. Rich Passage is a shallow sill, less than 21 m deep.     NS Everett is located in Port Gardner Bay in Puget Sound's Whidbey Basin. Please see Figure 1-7 of the Navy's application. To the west of the installation is the channelized mouth of the Snohomish River bounded by Jetty Island, which is composed of sediment from maintenance dredging and acts as a breakwater for the northwest area along the installation's waterfront. Jetty Island separates Port Gardner Bay and Possession Sound from the Snohomish River channel. The mouth of the Snohomish River channel is a historically industrialized area of highly modified shorelines and dredged waterways that forms a protected harbor within Port Gardner Bay. East of Jetty Island lies the Snohomish River estuary, consisting of a series of interconnected sloughs that flow through the lowlands east and north of the river's main channel. Water depths in Possession Sound range from about 9 m near the industrialized shoreline in Port Gardner to 180 m in mid-channel.

Detailed Description of Activities

    As described above, the Navy has requested incidental take regulations for its MPR program, which includes maintenance and repair activities at marine waterfront structures at six installations within Washington inland

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waters. In order to address identified deficiencies in existing marine structures at the six facilities, the Navy proposes to replace up to 822 structurally unsound piles over the 5-year period using both impact and vibratory pile driving. Existing marine structures at the six facilities are identified in Table 1-2 of the Navy's application. The MPR program includes pile repair, extraction, and installation, all of which may be accomplished through a variety of methods. However, only pile extraction and installation using vibratory and impact pile drivers is expected to have the potential to result in incidental take of marine mammals. Pile repair methods include stubbing, wrapping, pile encapsulation, welding, or coating. These processes do not involve pile driving and are not expected to have the potential to result in elevated noise levels or incidental take of marine mammals. Pile removal may be accomplished via mechanical methods such as cutting/ chipping, clamshell removal, or direct pull. Water jetting may also be used to aid in pile installation. Noise levels produced through these activities are not expected to exceed baseline levels produced by other routine activities and operations at the six facilities, and any elevated noise levels produced through these activities are expected to be intermittent, of short duration, and with low peak values. Therefore, only vibratory and impact pile driving are carried forward for further analysis. To minimize underwater noise impacts on marine species, vibratory pile driving will be the primary method used to install new steel piles.     Vibratory hammers, which can be used to either install or extract a pile, contain a system of counter-rotating eccentric weights powered by hydraulic motors, and are designed in such a way that horizontal vibrations cancel out, while vertical vibrations are transmitted into the pile. The pile driving machine is lifted and positioned over the pile by means of an excavator or crane, and is fastened to the pile by a clamp and/or bolts. The vibrations produced cause liquefaction of the substrate surrounding the pile, enabling the pile to be extracted or driven into the ground using the weight of the pile plus the hammer. Impact hammers use a rising and falling piston to repeatedly strike a pile and drive it into the ground. Impact or vibratory driving could occur on any work day within in-water work windows during the period of validity of these proposed regulations.     Steel piles are typically vibratory-driven for their initial embedment depths or to refusal and finished with an impact hammer for proofing or until the pile meets structural requirements, as necessary. Proofing involves striking a driven pile with an impact hammer to verify that it provides the required load-bearing capacity, as indicated by the number of hammer blows per foot of pile advancement. Non-steel piles (concrete, timber, or plastic) are typically impact- driven for their entire embedment depth, in part because non-steel piles are often displacement piles (as opposed to pipe piles) and require some impact to allow substrate penetration. Pile installation can typically take a minute or less to 60 minutes depending on pile type, pile size, and conditions (i.e , bedrock, loose soils, etc.) to reach the required tip elevation.     The most effective and efficient method of pile installation and removal available would be implemented. The method fitting these criteria may vary based on specific project requirements and local conditions. Impact driving, while generally producing higher levels of sound, also minimizes the net amount of active driving time, thus reducing the amount of time during which marine mammals may be exposed to noise. Impact or vibratory pile driving could occur on any day, but would not occur simultaneously. Location-specific pile totals are given in Table 1 and described below. These totals assume a 1:1 replacement ratio; however, the actual number installed may result in a replacement ratio of less than 1:1. Please see Table A-1 of the Navy's application for additional detail regarding expectations for both planned work and possible contingency work.

  Table 1--Pile Types and Maximum Anticipated Number To Be Replaced at                             Each Installation ------------------------------------------------------------------------                                    Existing piles to   Anticipated piles           Installation                be replaced       to be installed ------------------------------------------------------------------------ NBK Bangor......................  44 concrete; 75     119 steel or                                    steel and/or        concrete.                                    timber. NBK Bremerton...................  75 steel and/or     100 steel (14-in                                    timber; 460         diameter and                                    timber.             sheet piles); 435                                                        concrete. NBK Keyport.....................  20 steel and/or     20 steel.                                    concrete. NBK Manchester..................  50 timber and/or    50 concrete,                                    plastic.            timber, and/or                                                        plastic. Zelatched Point.................  20 timber.........  20 steel,                                                        concrete, and/or                                                        timber. NS Everett......................  1 steel, 2          1 steel and 77                                    concrete, and 75    concrete and/or                                    timber.             timber. ------------------------------------------------------------------------

    Steel piles would be a maximum size of 36-inch (in) diameter except at NBK Bremerton where they would be 14-in diameter. Concrete piles will be a maximum of 24-in diameter and timber/plastic piles will be a maximum of 18-in diameter. For purposes of analysis, it is assumed that any unknown pile type would be steel, since this would give a worst- case scenario in terms of noise levels produced. All concrete, timber, and plastic piles are assumed to be installed entirely by impact pile driver, and all steel piles are assumed to require some use of an impact driver. This is a conservative assumption, as all steel piles would be initially driven with a vibratory driver until they reach a point of refusal (where substrate conditions make use of a vibratory hammer ineffective) or engineering specifications require impact driving to verify load-bearing capacity. Therefore, some steel piles may not in fact require use of the impact driver during installation.     At this time, of 822 piles expected to be installed as replacement piles, 121 have been identified as steel piles. These piles would be installed over the 5-year duration at NBK Bremerton, NBK Keyport, and NS Everett. In addition, another 139 piles that would be installed at NBK Bangor (119) and Zelatched Point (20) have not been identified as to pile type and could be steel, concrete, timber or plastic. For this analysis, it is assumed all 139 of these would be steel piles. Therefore, 260 piles are assumed to be steel, with 100 of these 14-in and the remainder assumed to be 36-in diameter. A total of 435 replacement piles have been identified as concrete (NBK Bremerton). The remaining 127 replacement piles (NBK Manchester and NS Everett) could ultimately be concrete, timber, or plastic, but are assumed for purposes of analysis to be concrete, which is a more conservative noise scenario.

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    NBK Bangor is the Pacific homeport for the Navy's TRIDENT submarine fleet with the mission to support and maintain a TRIDENT submarine squadron and other ships home-ported or moored at the installation and to maintain and operate administrative and personnel support facilities including security, berthing, messing, and recreational services. NBK Bangor is the only naval installation on the west coast with the specialized infrastructure able to support the TRIDENT program. The specialized infrastructure includes buildings, utilities, and systems used to support missile production shops, missile maintenance, missile component storage, and missile handling cranes, in addition to providing security and operational port facilities.     Pile-supported structures at the NBK Bangor waterfront include: Carderock Pier, Service Pier, Keyport-Bangor (K/B) Dock, Delta Pier, Marginal Wharf, Explosives Handling Wharf #1 (EHW-1), and the Magnetic Silencing Facility (see Figure 1-2 of the Navy's application). Over the 5-year duration, up to 44 piles are anticipated to be replaced at EHW-1 and up to 75 piles could be installed at any of the structures for emergent projects.     Zelatched Point supports test and evaluation operations conducted by the Naval Undersea Warfare Center Keyport within Dabob Bay, and contains a single pier historically used for mooring small craft and float planes during Navy range operations in Dabob Bay (see Figure 1-6 of the Navy's application). Two dolphins are located at the outboard end of the facility, each consisting of three timber piles. Up to 20 piles of any type are anticipated for emergent/emergency repairs during the course of the 5-year duration.     Puget Sound Naval Shipyard and Intermediate Maintenance Facility is the major tenant command of NBK Bremerton. NBK Bremerton contains multiple dry docks, piers, and wharfs and is capable of overhauling and repairing, constructing, deactivating, and dry-docking all types and sizes of ships. It also serves as the homeport for a nuclear aircraft carrier and other Navy vessels.     There are 13 pile-supported structures located at NBK Bremerton (see Figure 1-3 of the Navy's application). Two pile repair and replacement projects are planned for Piers 4 and 5. The project at Pier 4 would involve replacing missing or broken timber fender piles with 80 steel fender piles. Steel piles would be up to 14-in diameter and installed with a vibratory driver and only impact driven if they cannot be advanced to tip elevation using a vibratory driver. Prior projects at Piers 4 and 5 indicate steel piles will be able to be vibratory driven. However, some impact driving may be necessary. The project at Pier 5 would replace an existing primarily timber fendering system, with 360 concrete piles ranging in size up to 24-in diameter. All concrete piles are anticipated to be impact driven. Work on Piers 5, 6, 7, Mooring A, and Dry Dock 5 will involve replacement of up to 20 timber piles with 20 sheet steel piles. In addition, 75 concrete piles are anticipated for emergent/emergency repairs over the 5-year duration. Naval Undersea Warfare Center Keyport is the major tenant command at NBK Keyport and is the Navy's premier provider of cold-water testing and evaluation for undersea warfare systems. In this capacity, NBK Keyport provides depot maintenance and repair, in-service engineering, and fleet industrial support for torpedoes and other undersea warfare systems including mobile mines, unmanned underwater vehicles, and countermeasures.     There is one pier, Keyport Pier, in the northern portion of the NBK Keyport installation (see Figure 1-4 of the Navy's application). There are no planned pile repair and replacement projects at NBK Keyport; however, up to 20 piles are anticipated for emergent/emergency repairs or replacement at the Keyport Pier during the course of the 5-year duration.     NBK Manchester provides bulk fuel and lubricant support to area Navy afloat and shore activities. The primary pile-supported structures at NBK Manchester are the fuel pier and the finger pier with a barge mooring platform and a small boat float (see Figure 1-5 of the Navy's application). There are no planned projects at NBK Manchester. A contingency estimate of 50 concrete, timber, or plastic piles for emergent/emergency repairs at the fuel pier or finger pier is proposed for the 5-year duration.     NS Everett provides homeport ship berthing, industrial support, and a Navy administrative center. Pile-supported structures at NS Everett include Piers A, B, C, D, and E; North Wharf and South Wharf; a recreational marina; and the small boat launch (see Figure 1-7 of the Navy's application). Additionally, there are fender piles along the waterfront areas. Repairs to the North Wharf could require replacement of up to two concrete piles. Additionally, contingency planning estimated up to 75 concrete or timber piles and one steel pile could be repaired or replaced over the 5-year duration.

Description of Marine Mammals in the Area of the Specified Activity

    We have reviewed the Navy's species descriptions--which summarize available information regarding status and trends, distribution and habitat preferences, behavior and life history, and auditory capabilities of the potentially affected species--for accuracy and completeness and refer the reader to Sections 3 and 4 of the Navy's application, instead of reprinting the information here. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SAR; [*www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*](http://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments)) and more general information about these species (e.g , physical and behavioral descriptions) may be found on NMFS's website (   [*www.fisheries.noaa.gov/find-species*](http://www.fisheries.noaa.gov/find-species)).     Table 2 lists all species with expected potential for occurrence in the specified ***geographical*** region where the Navy proposes to conduct the specified activities and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2017). PBR, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population, is considered in concert with known sources of ongoing anthropogenic mortality (as described in NMFS's SARs).     Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. All managed stocks in the specified ***geographical*** regions are assessed in either NMFS's U.S Alaska SARs or U.S Pacific SARs. All values presented in Table 2 are the most recent available at the time of writing and are available in the draft 2017 SARs (available online at:   [*www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*](http://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports)).     Ten species (with 13 managed stocks) are considered to have the potential to

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co-occur with Navy activities. There are several species or stocks that occur in Washington inland waters, but which are not expected to occur in the vicinity of the six Naval installations. These species may occur in waters of the Strait of Juan de Fuca or in more northerly waters in the vicinity of the San Juan Islands and areas north to the Canadian border, and include the Pacific white-sided dolphin (Lagenorhynchus obliquidens) and the northern resident stock of killer whales. In addition, the sea otter is found in coastal waters, with the northern (or eastern) sea otter (Enhydra lutris kenyoni) found in Washington. However, sea otters are managed by the U.S Fish and Wildlife Service and are not considered further in this document.     Two populations of gray whales are recognized, eastern and western North Pacific (ENP and WNP). WNP whales are known to feed in the Okhotsk Sea and off of Kamchatka before migrating south to poorly known wintering grounds, possibly in the South China Sea. The two populations have historically been considered ***geographically*** isolated from each other; however, data from satellite-tracked whales indicate that there is some overlap between the stocks. Two WNP whales were tracked from Russian foraging areas along the Pacific rim to Baja California (Mate et al., 2011), and, in one case where the satellite tag remained attached to the whale for a longer period, a WNP whale was tracked from Russia to Mexico and back again (IWC, 2012). Between 22-24 WNP whales are known to have occurred in the eastern Pacific through comparisons of ENP and WNP photo-identification catalogs (IWC, 2012; Weller et al., 2011; Burdin et al., 2011). Urban et al. (2013) compared catalogs of photo-identified individuals from Mexico with photographs of whales off Russia and reported a total of 21 matches. Therefore, a portion of the WNP population is assumed to migrate, at least in some years, to the eastern Pacific during the winter breeding season.     However, there is no indication that WNP whales occur in waters of Hood Canal or southern Puget Sound, and it is extremely unlikely that a gray whale in close proximity to Navy construction activity would be one of the few WNP whales that have been documented in the eastern Pacific. The likelihood that a WNP whale would be present in the vicinity of Navy construction activities is insignificant and discountable, and WNP gray whales are omitted from further analysis. ---------------------------------------------------------------------------

    \1\ Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a ***strategic*** stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a ***strategic*** stock.     \2\ NMFS marine mammal stock assessment reports at: [*www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*](http://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments). CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable. For two stocks of killer whales, the abundance values represent direct counts of individually identifiable animals; therefore there is only a single abundance estimate with no associated CV. For certain stocks of pinnipeds, abundance estimates are based upon observations of animals (often pups) ashore multiplied by some correction factor derived from knowledge of the species' (or similar species') life history to arrive at a best abundance estimate; therefore, there is no associated CV. In these cases, the minimum abundance may represent actual counts of all animals ashore.     \3\ These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g , commercial fisheries, subsistence hunting, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value. All M/SI values are as presented in the draft 2017 SARs.     \4\ Transient and resident killer whales are considered unnamed subspecies (Committee on Taxonomy, 2017).     \5\ The abundance estimate for this stock includes only animals from the ``inner coast'' population occurring in inside waters of southeastern Alaska, British Columbia, and Washington--excluding animals from the ``outer coast'' subpopulation, including animals from California--and therefore should be considered a minimum count. For comparison, the previous abundance estimate for this stock, including counts of animals from California that are now considered outdated, was 354.     \6\ Abundance estimates for these stocks are not considered current. PBR is therefore considered undetermined for these stocks, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimates, as these represent the best available information for use in this document.     \7\ This stock is known to spend a portion of time outside the U.S EEZ. Therefore, the PBR presented here is the allocation for U.S waters only and is a portion of the total. The total PBR for humpback whales is 22 (one half allocation for U.S waters). Annual M/SI presented for these species is for U.S waters only.

                               Table 2--Marine Mammals Potentially Present in the Vicinity of Navy Construction Activities --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                                          ESA/MMPA status;    Stock  abundance (CV,              Common name                  Scientific name               Stock             ***Strategic*** (Y/N)     N min, most recent       PBR     Annual M/                                                                                                 \1\          abundance survey) \2\               SI \3\ --------------------------------------------------------------------------------------------------------------------------------------------------------                                           Order Cetartiodactyla--Cetacea--Superfamily Mysticeti (baleen whales) -------------------------------------------------------------------------------------------------------------------------------------------------------- Family Eschrichtiidae:     Gray whale......................  Eschrichtius robustus..  Eastern North Pacific..  -; N                20,990 (0.05; 20,125;         624        132                                                                                                              2011). Family Balaenopteridae (rorquals):     Humpback whale..................  Megaptera novaeangliae   California/Oregon/       E/D; Y              1,918 (0.03; 1,876;        \7\ 11      >=9.2                                        kuzira.                  Washington (CA/OR/WA).                       2014).     Minke whale.....................  Balaenoptera             CA/OR/WA...............  -; N                636 (0.72; 369; 2014).        3.5      >=1.3                                        acutorostrata scammoni. --------------------------------------------------------------------------------------------------------------------------------------------------------                                             Superfamily Odontoceti (toothed whales, dolphins, and porpoises) -------------------------------------------------------------------------------------------------------------------------------------------------------- Family Delphinidae:     Killer whale....................  Orcinus orca \4\.......  West Coast Transient     -; N                243 (n/a; 2009).......        2.4          0                                                                 \5\.                                                                Eastern North Pacific    E/D; Y              83 (n/a; 2016)........       0.14          0                                                                 Southern Resident. Family Phocoenidae (porpoises):     Harbor porpoise.................  Phocoena phocoena        Washington Inland        -; N                11,233 (0.37; 8,308;           66      >=7.2                                        vomerina.                Waters.                                      2015).

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      Dall's porpoise.................  Phocoenoides dalli       CA/OR/WA...............  -; N                25,750 (0.45; 17,954;         172        0.3                                        dalli.                                                                2014). --------------------------------------------------------------------------------------------------------------------------------------------------------                                                          Order Carnivora--Superfamily Pinnipedia -------------------------------------------------------------------------------------------------------------------------------------------------------- Family Otariidae (eared seals and  sea lions): California sea lion.................  Zalophus californianus.  United States..........  -; N                296,750 (n/a; 153,337;      9,200        389                                                                                                              2011). Steller sea lion....................  Eumetopias jubatus       Eastern U.S ...........  D; Y                41,638 (n/a; 2015)....      2,498        108                                        monteriensis. Family Phocidae (earless seals): Harbor seal.........................  Phoca vitulina           Washington Northern      -; N                11,036 (0.15; 7,213;       Undet.        9.8                                        richardii.               Inland Waters.\6\                            1999).                                                                Southern Puget Sound     -; N                1,568 (0.15; 1,025;        Undet.        3.4                                                                 \6\.                                         1999).                                                                Hood Canal \6\.........  -; N                1,088 (0.15; 711;          Undet.        0.2                                                                                                              1999). Northern elephant seal..............  Mirounga angustirostris  California Breeding....  -; N                179,000 (n/a; 81,368;       4,882        8.8                                                                                                              2010). --------------------------------------------------------------------------------------------------------------------------------------------------------

Gray Whale

    Gray whales are observed in Washington inland waters in all months of the year, with peak numbers from March through June (Calambokidis et al., 2010). Most whales sighted are part of a small regularly occurring group of 6 to 10 whales that use mudflats in the Whidbey Island and Camano Island area as a springtime feeding area (Calambokidis et al., 2010). Observed feeding areas are located in Saratoga Passage between Whidbey and Camano Islands including Crescent Harbor, and in Port Susan Bay located between Camano Island and the mainland north of Everett. Gray whales that are not identified with the regularly occurring feeding group are occasionally sighted in Puget Sound. These whales are not associated with feeding areas and are often emaciated (WDFW, 2012). There are typically from 2 to 10 stranded gray whales per year in Washington (Cascadia Research, 2012).     In the waterways near NBK Bremerton and Keyport (Rich Passage/ Sinclair Inlet/Dyes Inlet/Agate Passage), 11 opportunistic sightings of gray whales were reported to Orca Network (a public marine mammal sightings database) between 2003 and 2012. One stranding occurred at NBK Bremerton in 2013. Gray whales have been sighted in Hood Canal south of the Hood Canal Bridge on six occasions since 1999, including a stranded whale. The most recent report was in 2010.     Gray whales are expected to occur in the waters surrounding all of the installations considered here other than those in Hood Canal (i.e , NBK Bangor and Zelatched Point), due to rarity of occurrence. Gray whales are expected to occur primarily from March through June when in- water construction will not occur. Therefore, although some exposure to individual gray whales could occur at four facilities, project timing will help to minimize potential exposures.

Humpback Whale

    Prior to 2016, humpback whales were listed under the ESA as an endangered species worldwide. Following a 2015 global status review (Bettridge et al., 2015), NMFS established 14 distinct population segments (DPS) with different listing statuses (81 FR 62259; September 8, 2016) pursuant to the ESA. The DPSs that occur in U.S waters do not necessarily equate to the existing stocks designated under the MMPA and shown in Table 2. Because MMPA stocks cannot be portioned, i.e , parts managed as ESA-listed while other parts managed as not ESA-listed, until such time as the MMPA stock delineations are reviewed in light of the DPS designations, NMFS considers the existing humpback whale stocks under the MMPA to be endangered and depleted for MMPA management purposes (e.g , selection of a recovery factor, stock status).     Within U.S west coast waters, three current DPSs may occur: The Hawaii DPS (not listed), Mexico DPS (threatened), and Central America DPS (endangered). According to Wade et al. (2016), the probability that whales encountered in Washington waters are from a given DPS are as follows: Hawaii, 52.9% (CV = 0.15); Mexico, 41.9% (0.14); Central America, 5.2% (0.91).     Most humpback whale sightings reported since 2003 were in the main basin of Puget Sound with numerous sightings in the waters between Point No Point and Whidbey Island, Possession Sound, and southern Puget Sound in the vicinity of Point Defiance. Some of the reported sightings were in the vicinity of NS Everett and NBK Manchester. A few sightings of possible humpback whales were reported by Orca Network in the waters near NBK Bremerton and Keyport (Rich Passage to Agate Passage area including Sinclair and Dyes Inlet) between 2003 and 2015. Humpback whales were sighted in the vicinity of Manette Bridge in Bremerton in 2016 and 2017, and a carcass was found under a dock at NBK Bremerton in 2016 (Cascadia Research, 2016).     In Hood Canal, single humpback whales were observed for several weeks in 2012 and 2015. One sighting was reported in 2016. Review of the 2012 sightings information indicated they were of one individual. Prior to the 2012 sightings, there were no confirmed reports of humpback whales entering Hood Canal. The number of humpback whales potentially present near any of the six installations is expected to be very low in any month.

Minke Whale

    Sightings of minke whales in Puget Sound are infrequent, with approximately 14 opportunistic sightings recorded between 2005 and 2012, from March through October. No sightings were reported in the vicinity of NBK Bremerton and Keyport (Rich Passage through the Agate Passage including Sinclair Inlet and Dyes Inlet) or in Hood Canal. The number of minke whales potentially present near any of the six installations is expected to be very low in any month and even lower in winter months.

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Killer Whale (Transient)

    Groups of transient killer whales were observed for lengthy periods in Hood Canal in 2003 (59 days) and 2005 (172 days) (London, 2006), but were not observed again until 2016, when they were seen on a handful of days between March and May (including in Dabob Bay). Transient killer whales have been seen infrequently near NBK Bremerton, including in Dyes Inlet and Sinclair Inlet (e.g , sightings in 2010, 2013, and 2015). Sightings in the vicinity of NBK Keyport have also been infrequent, and no records were found for Rich Passage in the vicinity of NBK Manchester. Transient killer whales have been observed in Possession Sound near NS Everett.     West Coast transient killer whales most often travel in small pods averaging four individuals (Baird and Dill, 1996); however, the most commonly observed group size in Puget Sound (waters east of Admiralty Inlet, including Hood Canal, through South Puget Sound and north to Skagit Bay) from 2004 to 2010 was 6 whales (Houghton et al., 2015).

Killer Whales (Resident)

    Critical habitat for southern resident killer whales, designated pursuant to the ESA, includes three specific areas: (1) Summer core area in Haro Strait and waters around the San Juan Islands; (2) Puget Sound; and (3) Strait of Juan de Fuca (71 FR 69054; November 29, 2006). The primary constituent elements essential for conservation of the habitat are: (1) Water quality to support growth and development; (2) Prey species of sufficient quantity, quality, and availability to support individual growth, reproduction, and development, as well as overall population growth; and (3) Passage conditions to allow for migration, resting, and foraging. However, the six naval installations are specifically excluded from the critical habitat designation. A revision to the critical habitat designation is currently under consideration (80 FR 9682; February 24, 2015).     Southern resident killer whales are expected to occur occasionally in the waters surrounding all of the installations except those in Hood Canal, where they have not been reported since 1995 (NMFS, 2006). Southern resident killer whales are rare near NBK Bremerton and Keyport, with the last confirmed sighting in Dyes Inlet in 1997. Southern residents have been observed in Saratoga Passage and Possession Sound near NS Everett.     The stock contains three pods (J, K, and L pods), with pod sizes ranging from approximately 20 (in J pod) to 40 (in L pod) individuals. Group sizes encountered can be smaller or larger if pods temporarily separate or join together. Therefore, some exposure to groups of up to 20 individuals or more could occur over the 5-year duration.

Harbor Porpoise

    Sightings in Hood Canal have increased in recent years, and an average of six harbor porpoises were sighted per day in deeper waters during line transect vessel surveys conducted in 2011 near NBK Bangor and Dabob Bay (HDR, 2012). Mean group size of harbor porpoises for each survey season in the 2013-2016 aerial surveys was 1.7 (Smultea et al., 2017). Site-specific information is not available for NBK Bremerton, Keyport, or Manchester, but harbor porpoises have been seen infrequently at NS Everett.

Dall's Porpoise

    Dall's porpoise are known to occur in Puget Sound, and have been sighted as far south as Carr Inlet in southern Puget Sound and as far north as Saratoga Passage, north of NS Everett (Nysewander et al., 2005; WDFW, 2008). Dall's porpoise could also occasionally occur in Hood Canal. with the last observation in deeper water near NBK Bangor in 2008 (Tannenbaum et al., 2009). However, Dall's porpoise were not observed during vessel line-transect surveys and other monitoring efforts completed in Hood Canal (including Dabob Bay) in 2011 (HDR, 2012). Dall's porpoises have not been documented in the Rich Passage to Agate Passage area in the vicinity of NBK Bremerton or Keyport, but have been observed in Possession Sound near NS Everett (primarily during winter) (Nysewander et al., 2005; WDFW, 2008). Dall's porpoises could be present in waters in the vicinity of any of the installations considered here, and are considered more likely to occur during winter months than summer months in groups of up to 25 individuals.     The Navy conducts surveys at installations with known pinniped haul-outs, which are located at NBK Bangor, NBK Bremerton, NBK Manchester, and NS Everett (see Figures 4-2, 4-3, 4-4, and 4-5 of the Navy's application). More detail regarding these surveys may be found in Appendix C of the Navy's application.

Steller Sea Lion

    Steller sea lions have been seasonally documented during shore- based surveys at NBK Bangor in Hood Canal since 2008, with up to 13 individuals observed hauled out on submarines at Delta Pier. Steller sea lions begin arriving at NBK Bangor in September and depart by the end of May.     Shore-based surveys at NBK Bremerton have not detected Steller sea lions since the surveys were initiated in 2010. A Steller sea lion was sighted on the floating security barrier in 2012 and others were detected during aerial surveys conducted by the Washington Department of Fish and Wildlife (WDFW) in 2013 (Jeffries, 2013).     Steller sea lions haul out on floating platforms in Clam Bay approximately 800 m offshore from the Manchester Fuel Depot's finger pier, approximately 13 km from NBK Bremerton. The Navy conducted surveys of sea lions on the floats from 2012 through 2016; Steller sea lions were seen in all surveyed months except for June, July, and August with as many as 42 individuals present in November 2014. Aerial surveys were conducted by WDFW from March-April 2013, July-August 2013, November 2013, and February 2014. These surveys detected Steller sea lions on the floating platforms during all survey months except July and August, with up to 37 individuals present on one survey in November 2013.     No haul-outs are known in the vicinity of NBK Keyport or Zelatched Point; therefore, no shore-based surveys have been conducted at these installations. No opportunistic sightings have been reported at these installations. The nearest Steller sea lion haul-outs to NBK Keyport are navigation buoys that can support at most two individuals, located over 15 km away in Puget Sound. Therefore, Steller sea lions are not expected to frequent waters off this installation. The only Steller sea lion haul-out in Hood Canal is at NBK Bangor, as described above, which is over 14 km from Zelatched Point.     Shore-based surveys conducted from July 2012 through June 2014 at NS Everett did not detect Steller sea lions. However, occasional observations have been reported from the port security barrier (PSB). Other than these detections on the installation's PSBs, the nearest known Steller sea lion haul-out is 22.5 km away; therefore, Steller sea lions are not expected to occur in waters off this installation.

California Sea Lion

    California sea lion haul-outs occur at NBK Bangor, NBK Bremerton, and NS Everett. California sea lions are typically present most of the year except for mid-June through July in Washington inland waters, with peak abundance numbers between October and May (NMFS, 1997; Jeffries et al., 2000). During summer months and associated breeding

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periods, the inland waters would not be considered a high-use area by California sea lions, as they would be returning to rookeries in California waters. However, as described below, surveys at Bangor indicate that a few individuals are present through mid-June and have arrived as early as August with at least one individual remaining in July 2014. Surveys at NS Everett from 2012 to 2016 indicate a few individuals may remain year-round.     California sea lions have been documented during shore-based surveys at NBK Bangor in Hood Canal since 2008 in all survey months, with as many as 122 individuals observed at one time (November 2013) hauled out on submarines at Delta Pier and on PSB floats.     California sea lions have been documented during shore- and boat- based surveys at NBK Bremerton since 2010, with as many as 315 individuals hauled out at one time (November 2015) on PSB floats.     California sea lions haul out on floating platforms in Clam Bay approximately 800 m offshore from the Manchester Fuel Depot's finger pier, approximately 13 km from NBK Bremerton. The Navy conducted surveys of sea lions on the floats incidental to other surveys from 2012 through 2016. California sea lions were seen in every survey month except July and August, with as many as 130 individuals present in one survey in October 2014. Aerial surveys were conducted by WDFW from March-April 2013, July-August 2013, November 2013, and February 2014. These surveys detected California sea lions on the floating platforms during all survey months except July, with up to 54 individuals present on one survey in November 2013.     California sea lions have been documented during shore-based surveys at NS Everett from 2012 to 2016 in all survey months, with as many as 215 individuals hauled out at one time (April 2016) on PSB floats.     No shore-based surveys have been conducted at NBK Keyport or Zelatched Point and no opportunistic sightings have been reported at these installations. No haul-outs are known in the vicinity of these installations. The nearest California sea lion haul-outs to NBK Keyport are navigation buoys that can support at most two individuals, located over 15 km away in Puget Sound. Therefore, California sea lions are not expected to frequent waters off this installation. The only California sea lion haul-out in Hood Canal is at NBK Bangor, as described above, which is over 14 km from Zelatched Point.     California sea lions are expected to be exposed to noise from project activities at NBK Bangor, Bremerton, Manchester, and NS Everett because haul-outs are at these installations or nearby. Exposure is estimated to occur primarily from August through the end of the in- water work window in mid-January or early March.

Harbor Seal

    Harbor seals in Washington inland waters have been divided into three stocks: Hood Canal, Northern Inland Waters, and Southern Puget Sound. The range of the northern inland waters stock includes Puget Sound north of the Tacoma Narrows Bridge, the San Juan Islands, and the Strait of Juan de Fuca, while the southern Puget Sound stock range includes waters south of the Tacoma Narrows Bridge. Therefore, animals present at NBK Bremerton, NBK Keyport, NBK Manchester, and NS Everett are most likely to be from the northern inland waters stock, while those present at NBK Bangor and Zelatched Point are expected to be from the Hood Canal stock.     Harbor seals are expected to occur year-round at all installations, with the greatest numbers expected at installations with nearby haul- out sites. In Hood Canal, known haul-outs occur on the west side of Hood Canal at the mouth of the Dosewallips River and on the western and northern shorelines in Dabob Bay located approximately 13 and 3.7 km away from NBK Bangor and Zelatched Point, respectively. Site-specific surveys have not been conducted at Zelatched Point because no haul-outs are documented in this part of Dabob Bay. Vessel-based surveys conducted from 2007 to 2010 at NBK Bangor observed harbor seals in every month of surveys (Agness and Tannenbaum, 2009; Tannenbaum et al., 2009, 2011). Harbor seals were routinely seen during marine mammal monitoring for two construction projects (HDR, 2012; Hart Crowser, 2013, 2014, 2015). Small numbers of harbor seals have been documented hauling out opportunistically at NBK Bangor (e.g , on the PSB floats, wave screen at Carderock Pier, buoys, barges, marine vessels, and logs) and on man-made floating structures near K/B Dock and Delta Pier. Surveys conducted in August and September 2016 recorded as many as 28 harbor seals hauled out under Marginal Wharf or swimming in adjacent waters. On two occasions, four to six individuals were observed hauled out near Delta Pier. Known harbor seal births include one on the Carderock wave screen in August 2011 and at least one on a small floating dock in fall 2013, and afterbirth reported on a float at Magnetic Silencing Facility. In addition, harbor seal pupping has occurred on a section of the Service Pier since approximately 2001. Harbor seal mother and pup sets were observed in 2014 hauled out on the Carderock wave screen and swimming in nearby waters, and swimming in the vicinity of Delta Pier.     At NS Everett, Navy surveys conducted regularly from 2012 to 2016 have documented up to 491 harbor seals hauling out adjacent to the installation on log rafts in Notch Basin in the East Waterway. Harbor seals occupy the waters and haul-out sites near NS Everett year-round. Based on the survey data, the number of individuals peaks from August to October, with an average maximum number of 343 seals in October. The log rafts are privately owned and their location can vary within the East Waterway, which ranges from approximately 200-300 m wide. Only harbor seals on logs rafts that are within sight distance from NS Everett are counted, and if visible, numbers on floats outside the Notch Basin are noted, but not counted. Therefore, Navy counts of harbor seals hauled out do not necessarily represent the number of hauled out seals in the East Waterway. Pupping is documented on the log rafts; however, no pup counts have been conducted.     No haul-outs have been identified at NBK Bremerton, Keyport, or Manchester. The nearest documented haul-outs to NBK Bremerton are across Sinclair Inlet, approximately 1.1 km away. The nearest documented haul-out to NBK Keyport is in Liberty Bay at the Poulsbo Marina approximately 3.2 km from the Keyport Pier. The nearest documented haul-out to NBK Manchester is Blakely Rocks approximately 5.6 km away on the east side of Bainbridge Island. All haul-outs listed here near the three installations are estimated to have less than 100 individuals.

Northern Elephant Seal

    No haul-outs occur in Puget Sound with the exception of individual elephant seals occasionally hauling out for two to four weeks to molt, usually during the spring and summer and typically on sandy beaches (Calambokidis and Baird, 1994). These animals are usually yearlings or subadults and their haul-out locations are unpredictable. One male subadult elephant seal was observed hauled out to molt at Manchester Fuel Depot in 2004. Although regular haul-outs occur in the Strait of Juan de Fuca, the

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occurrence of elephant seals in Puget Sound is unpredictable and rare.

Unusual Mortality Events (UME)

    A UME is defined under the MMPA as ``a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response.'' The only currently ongoing UME investigation involves California sea lions along the west coast. Beginning in January 2013, elevated strandings of California sea lion pups were observed in southern California, with live sea lion strandings nearly three times higher than the historical average. Findings to date indicate that a likely contributor to the large number of stranded, malnourished pups was a change in the availability of sea lion prey for nursing mothers, especially sardines. The causes and mechanisms of this remain under investigation ([*www.nmfs.noaa.gov/pr/health/mmume/californiasealions2013.htm;*](http://www.nmfs.noaa.gov/pr/health/mmume/californiasealions2013.htm;) accessed November 24, 2017).

Marine Mammal Hearing

    Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (e.g , Richardson et al., 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall et al. (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (i.e , low-frequency cetaceans). Subsequently, NMFS (2016) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 dB threshold from the normalized composite audiograms, with an exception for lower limits for low-frequency cetaceans where the result was deemed to be biologically implausible and the lower bound from Southall et al. (2007) retained. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):      Low-frequency cetaceans (mysticetes): Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz;      Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz;      High-frequency cetaceans (porpoises, river dolphins, and members of the genera Kogia and Cephalorhynchus; including two members of the genus Lagenorhynchus, on the basis of recent echolocation data and genetic data): Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz;      Pinnipeds in water; Phocidae (true seals): Functional hearing is estimated to occur between approximately 50 Hz to 86 kHz;      Pinnipeds in water; Otariidae (eared seals): Functional hearing is estimated to occur between 60 Hz and 39 kHz for Otariidae.     For more detail concerning these groups and associated frequency ranges, please see NMFS (2016) for a review of available information. Ten marine mammal species (six cetacean and four pinniped (two otariid and two phocid) species) have the potential to co-occur with Navy construction activities. Please refer to Table 2. Of the six cetacean species that may be present, three are classified as low-frequency cetaceans (i.e , all mysticete species), one is classified as a mid- frequency cetacean (i.e , killer whales), and two are classified as high-frequency cetaceans (i.e , porpoises).

Potential Effects of the Specified Activity on Marine Mammals and Their Habitat

    This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The ``Estimated Take'' section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ``Negligible Impact Analysis and Determination'' section considers the content of this section and the material it references, the ``Estimated Take'' section, and the ``Proposed Mitigation'' section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks. In the following discussion, we provide general background information on sound before considering potential effects to marine mammals from sound produced by pile driving.

Description of Sound Sources

    This section contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. For general information on sound and its interaction with the marine environment, please see, e.g , Au and Hastings (2008); Richardson et al. (1995); Urick (1983).     Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the ``loudness'' of a sound and is typically described using the relative unit of the decibel (dB). A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal ([mu]Pa)), and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a distance of 1 m from the source (referenced to 1 [mu]Pa), while the received level is the SPL at the listener's position (referenced to 1 [mu]Pa).     Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral

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effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.     Sound exposure level (SEL; represented as dB re 1 [mu]Pa\2\-s) represents the total energy in a stated frequency band over a stated time interval or event, and considers both intensity and duration of exposure. The per-pulse SEL is calculated over the time window containing the entire pulse (i.e , 100 percent of the acoustic energy). SEL is a cumulative metric; it can be accumulated over a single pulse, or calculated over periods containing multiple pulses. Cumulative SEL represents the total energy accumulated by a receiver over a defined time window or during an event. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure.     When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam or beams or may radiate in all directions (omnidirectional sources), as is the case for sound produced by the pile driving activity considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.     Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound, which is defined as environmental background sound levels lacking a single source or point (Richardson et al., 1995). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (e.g , wind and waves, earthquakes, ice, atmospheric sound), biological (e.g , sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (e.g , vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 hertz (Hz) and 50 kilohertz (kHz) (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, sonar, and explosions. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly.     The sum of the various natural and anthropogenic sound sources that comprise ambient sound at any given location and time depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10-20 decibels (dB) from day to day (Richardson et al., 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.     Underwater ambient sound in Puget Sound is comprised of sounds produced by a number of natural and anthropogenic sources and varies both ***geographically*** and temporally. Human-generated sound is a significant contributor to the ambient acoustic environment at the installations considered here. The underwater acoustic environment at each installation will vary depending on the amount of anthropogenic activity, weather conditions, and tidal currents. In high-use installations, such as NBK Bremerton, anthropogenic noise may dominate the ambient soundscape. In areas with less anthropogenic activity (e.g , Zelatched Point), ambient sound is likely to be dominated by sound from natural sources. Under normal weather and traffic conditions, average ambient sound at all installations is assumed to be below 120 dB rms. More detail regarding specific installations is available in section 2.3.1.5 of the Navy's application. Details of source types are described in the following text.     Sounds are often considered to fall into one of two general types: Pulsed and non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (e.g , Ward, 1997 in Southall et al., 2007). Please see Southall et al. (2007) for an in-depth discussion of these concepts. The distinction between these two sound types is not always obvious, as certain signals share properties of both pulsed and non-pulsed sounds. A signal near a source could be categorized as a pulse, but due to propagation effects as it moves farther from the source, the signal duration becomes longer (e.g , Greene and Richardson, 1988).     Pulsed sound sources (e.g , airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.     Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or intermittent (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (e.g , rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems. The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.     The impulsive sound generated by impact hammers is characterized by rapid rise times and high peak levels. Vibratory hammers produce non- impulsive, continuous noise at levels significantly lower than those produced by impact hammers. Rise time is slower,

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reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (e.g , Nedwell and Edwards, 2002; Carlson et al., 2005).

Acoustic Effects

    We previously provided general background information on marine mammal hearing (see ``Description of Marine Mammals in the Area of the Specified Activity''). Here, we discuss the potential effects of sound on marine mammals.     Potential Effects of Underwater Sound--Note that, in the following discussion, we refer in many cases to a review article concerning studies of noise-induced hearing loss conducted from 1996-2015 (i.e , Finneran, 2015). For study-specific citations, please see that work. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can potentially result in one or more of the following: Temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson et al., 1995; Gordon et al., 2004; Nowacek et al., 2007; Southall et al., 2007; G[ouml]tz et al., 2009). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We first describe specific manifestations of acoustic effects before providing discussion specific to pile driving.     Richardson et al. (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area within which the acoustic signal would be audible (potentially perceived) to the animal but not strong enough to elicit any overt behavioral or physiological response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (i.e , when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.     We describe the more severe effects (i.e , certain non-auditory physical or physiological effects) only briefly as we do not expect that there is a reasonable likelihood that pile driving may result in such effects (see below for further discussion). Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton et al., 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (e.g , change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox et al., 2006; Southall et al., 2007; Zimmer and Tyack, 2007; Tal et al., 2015). The construction activities considered here do not involve the use of devices such as explosives or mid- frequency tactical sonar that are associated with these types of effects.     Threshold Shift--Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall et al., 2007). Repeated sound exposure that leads to TTS could cause PTS. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).     When PTS occurs, there is physical damage to the sound receptors in the ear (i.e , tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall et al., 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (e.g , Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.     Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several decibels above (a 40-dB threshold shift approximates PTS onset; e.g , Kryter et al., 1966; Miller, 1974) that inducing mild TTS (a 6-dB threshold shift approximates TTS onset; e.g , Southall et al. 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulse sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall et al., 2007). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.     TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals.     Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (i.e , recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for

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successful mother/calf interactions could have more serious impacts.     Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin (Tursiops truncatus), beluga whale (Delphinapterus leucas), harbor porpoise, and Yangtze finless porpoise (Neophocoena asiaeorientalis)) and three species of pinnipeds (northern elephant seal, harbor seal, and California sea lion) exposed to a limited number of sound sources (i.e , mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). TTS was not observed in trained spotted (Phoca largha) and ringed (Pusa hispida) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth et al., 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. There are no data available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall et al. (2007), Finneran and Jenkins (2012), Finneran (2015), and NMFS (2016).     Behavioral Effects--Behavioral disturbance may include a variety of effects, including subtle changes in behavior (e.g , minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (e.g , species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (e.g , Richardson et al., 1995; Wartzok et al., 2003; Southall et al., 2007; Weilgart, 2007; Archer et al., 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison et al., 2012), and can vary depending on characteristics associated with the sound source (e.g , whether it is moving or stationary, number of sources, distance from the source). Please see Appendices B-C of Southall et al. (2007) for a review of studies involving marine mammal behavioral responses to sound.     Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok et al., 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ``progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder et al., 2009). The ***opposite*** process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson et al., 1995; NRC, 2003; Wartzok et al., 2003). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway et al., 1997; Finneran et al., 2003). Observed responses of wild marine mammals to loud pulsed sound sources (typically airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; see also Richardson et al., 1995; Nowacek et al., 2007). However, many delphinids approach low-frequency airgun source vessels with no apparent discomfort or obvious behavioral change (e.g , Barkaszi et al., 2012), indicating the importance of frequency output in relation to the species' hearing sensitivity.     Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (e.g , Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.     Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (e.g , Frankel and Clark, 2000; Costa et al., 2003; Ng and Leung, 2003; Nowacek et al.; 2004; Goldbogen et al., 2013a, 2013b). Variations in dive behavior may reflect interruptions in biologically significant activities (e.g , foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.     Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (e.g , bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (e.g , Croll et al., 2001; Nowacek et al.; 2004; Madsen et al., 2006; Yazvenko et al., 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.     Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (e.g , Kastelein et al., 2001,

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2005, 2006; Gailey et al., 2007; Gailey et al., 2016).     Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller et al., 2000; Fristrup et al., 2003; Foote et al., 2004), while right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks et al., 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles et al., 1994).     Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson et al., 1995). For example, gray whales are known to change direction--deflecting from customary migratory paths--in order to avoid noise from airgun surveys (Malme et al., 1984). Avoidance may be short-term, with animals returning to the area once the noise has ceased (e.g , Bowles et al., 1994; Goold, 1996; Stone et al., 2000; Morton and Symonds, 2002; Gailey et al., 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (e.g , Blackwell et al., 2004; Bejder et al., 2006; Teilmann et al., 2006).     A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (e.g , directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (Evans and England, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.     Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (i.e , when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (e.g , Beauchamp and Livoreil, 1997; Fritz et al., 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (e.g , decline in body condition) and subsequent reduction in reproductive success, survival, or both (e.g , Harrington and Veitch, 1992; Daan et al., 1996; Bradshaw et al., 1998). However, Ridgway et al. (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a five-day period did not cause any sleep deprivation or stress effects.     Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall et al., 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall et al., 2007). Note that there is a difference between multi-day substantive behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.     Stress Responses--An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (e.g , Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.     Neuroendocrine stress responses often involve the hypothalamus- pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress--including immune competence, reproduction, metabolism, and behavior--are regulated by pituitary hormones. Stress- induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (e.g , Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano et al., 2004).     The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ``distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.     Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (e.g , Holberton et al., 1996; Hood et al., 1998; Jessop et al., 2003; Krausman et al., 2004; Lankford et al., 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano et al., 2002b) and, more rarely, studied in wild populations (e.g , Romano et al., 2002a). For example, Rolland et al. (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that

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some of these would be classified as ``distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).     Auditory Masking--Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (e.g , those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson et al., 1995; Erbe et al., 2016). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (e.g , snapping shrimp, wind, waves, precipitation) or anthropogenic (e.g , shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (e.g , signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (e.g , sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions.     Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.     The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low- frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (e.g , Clark et al., 2009) and may result in energetic or other costs as animals change their vocalization behavior (e.g , Miller et al., 2000; Foote et al., 2004; Parks et al., 2007; Di Iorio and Clark, 2009; Holt et al., 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson et al., 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (e.g , Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (e.g , Branstetter et al., 2013).     Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (e.g , from vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.     Potential Effects of Navy Activity--As described previously (see ``Description of Active Acoustic Sound Sources''), the Navy proposes to conduct pile driving, including impact and vibratory driving. The effects of pile driving on marine mammals are dependent on several factors, including the size, type, and depth of the animal; the depth, intensity, and duration of the pile driving sound; the depth of the water column; the substrate of the habitat; the standoff distance between the pile and the animal; and the sound propagation properties of the environment. With both types of pile driving, it is likely that the onset of pile driving could result in temporary, short term changes in an animal's typical behavioral patterns and/or avoidance of the affected area. These behavioral changes may include (Richardson et al., 1995): changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located; and/or flight responses.     The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, or reproduction. Significant behavioral modifications that could lead to effects on growth, survival, or reproduction, such as drastic changes in diving/surfacing patterns or significant habitat abandonment are extremely unlikely in this area (i.e , shallow waters in modified industrial areas).     The onset of behavioral disturbance from anthropogenic sound depends on both external factors (characteristics of sound sources and their paths) and the specific characteristics of the receiving animals (hearing, motivation, experience, demography) and is difficult to predict (Southall et al., 2007).     Whether impact or vibratory driving, sound sources would be active for relatively short durations, with relation to potential for masking. The frequencies output by pile driving activity are lower than those used by most species expected to be regularly present for communication or foraging. We expect insignificant impacts from masking, and any masking event that could possibly rise to Level B harassment under the MMPA would occur concurrently within the zones of behavioral harassment already estimated for vibratory and impact pile driving, and which have already been taken into account in the exposure analysis.

Anticipated Effects on Marine Mammal Habitat

    The proposed activities would not result in permanent impacts to habitats used directly by marine mammals, but may have potential short- term impacts to food sources such as forage fish. The proposed activities could also affect acoustic habitat (see masking discussion above), but meaningful impacts are unlikely. There are no known foraging hotspots, or other ocean bottom structures of significant biological importance to marine mammals present in the marine waters in the vicinity of the project areas. Therefore, the main impact issue associated with the proposed activity would be temporarily elevated sound levels and the associated direct effects on marine mammals, as discussed previously in this preamble. The most likely impact to marine mammal habitat occurs from pile driving effects on likely marine mammal

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prey (i.e , fish) near the six installations. Impacts to the immediate substrate during installation and removal of piles are anticipated, but these would be limited to minor, temporary suspension of sediments, which could impact water quality and visibility for a short amount of time, but which would not be expected to have any effects on individual marine mammals. Impacts to substrate are therefore not discussed further.     Effects to Prey--Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (e.g , crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.     Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (e.g , Zelick et al., 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay et al., 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.     Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (e.g , feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (e.g , Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (e.g , Fewtrell and McCauley, 2012; Pearson et al., 1992; Skalski et al., 1992; Santulli et al., 1999; Paxton et al., 2017). However, some studies have shown no or slight reaction to impulse sounds (e.g , Pena et al., 2013; Wardle et al., 2001; Jorgenson and Gyselman, 2009; Cott et al., 2012). More commonly, though, the impacts of noise on fish are temporary.     SPLs of sufficient strength have been known to cause injury to fish and fish mortality. However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen et al. (2012a) showed that a TTS of 4-6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen et al., 2012b; Casper et al., 2013).     The most likely impact to fish from pile driving activities at the project areas would be temporary behavioral avoidance of the area. The duration of fish avoidance of an area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the expected short daily duration of individual pile driving events and the relatively small areas being affected. It is also not expected that the industrial environment of the Naval installations provides important fish habitat or harbors significant amounts of forage fish.     The area likely impacted by the activities is relatively small compared to the available habitat in inland waters in the region. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. As described in the preceding, the potential for Navy construction to affect the availability of prey to marine mammals or to meaningfully impact the quality of physical or acoustic habitat is considered to be insignificant. Effects to habitat will not be discussed further in this document.

Estimated Take

    This section provides an estimate of the number of incidental takes proposed for authorization, which will inform both NMFS's consideration of whether the number of takes is ``small'' and the negligible impact determination.     Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ``harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).     Take of marine mammals incidental to Navy construction activities could occur as a result of Level A or Level B harassment. Below we describe how the potential take is estimated.

Acoustic Thresholds

    NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to exhibit behavioral disruptions (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).     Level B Harassment--Although available data are consistent with the basic concept that louder sounds evoke more significant behavioral responses than softer sounds, defining sound levels that disrupt behavioral patterns is difficult because responses depend on the context in which the animal receives the sound, including an animal's behavioral mode when it hears sounds (e.g , feeding, resting, or migrating), prior experience, and biological factors (e.g , age and sex). Some species, such as beaked whales, are known to be more highly sensitive to certain anthropogenic sounds than other species. Other contextual factors, such as signal characteristics, distance from the source, and signal to noise ratio, may also help determine response to a given received level of sound. Therefore, levels at which responses occur are not necessarily consistent and can be difficult to predict (Southall et al., 2007; Ellison et al., 2012; Bain and Williams, 2006).     However, based on the practical need to use a relatively simple threshold based on available information that is both predictable and measurable for most activities, NMFS has historically used a generalized acoustic threshold

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based on received level to estimate the onset of Level B harassment. These thresholds are 160 dB rms (impulsive sources) and 120 dB rms (continuous sources).     Level A Harassment--NMFS's Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (NMFS, 2016) identifies dual criteria to assess the potential for auditory injury (Level A harassment) to occur for different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise. The technical guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity for all underwater anthropogenic sound sources, and reflects the best available science on the potential for noise to affect auditory sensitivity by:      Dividing sound sources into two groups (i.e , impulsive and non-impulsive) based on their potential to affect hearing sensitivity;      Choosing metrics that best address the impacts of noise on hearing sensitivity, i.e , peak sound pressure level (peak SPL) (reflects the physical properties of impulsive sound sources to affect hearing sensitivity) and cumulative sound exposure level (cSEL) (accounts for not only level of exposure but also duration of exposure); and      Dividing marine mammals into hearing groups and developing auditory weighting functions based on the science supporting that not all marine mammals hear and use sound in the same manner.     The premise of the dual criteria approach is that, while there is no definitive answer to the question of which acoustic metric is most appropriate for assessing the potential for injury, both the received level and duration of received signals are important to an understanding of the potential for auditory injury. Therefore, peak SPL is used to define a pressure criterion above which auditory injury is predicted to occur, regardless of exposure duration (i.e , any single exposure at or above this level is considered to cause auditory injury), and cSEL is used to account for the total energy received over the duration of sound exposure (i.e , both received level and duration of exposure) (Southall et al., 2007; NMFS, 2016). As a general principle, whichever criterion is exceeded first (i.e , results in the largest isopleth) would be used as the effective injury criterion (i.e , the more precautionary of the criteria). Note that cSEL acoustic threshold levels incorporate marine mammal auditory weighting functions, while peak pressure thresholds do not (i.e , flat or unweighted). Weighting functions for each hearing group (e.g , low-, mid-, and high-frequency cetaceans) are described in NMFS (2016).     NMFS (2016) recommends 24 hours as a maximum accumulation period relative to cSEL thresholds. These thresholds were developed by compiling and synthesizing the best available science, and are provided in Table 3 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS (2016), which is available online at: [*www.nmfs.noaa.gov/pr/acoustics/guidelines.htm*](http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm)

                                 Table 3--Exposure Criteria for Auditory Injury ----------------------------------------------------------------------------------------------------------------                                                                                      Cumulative sound exposure                                                                                              level \2\                           Hearing group                           Peak  pressure -------------------------------                                                                      \1\ (dB)        Impulsive     Non-impulsive                                                                                        (dB)            (dB) ---------------------------------------------------------------------------------------------------------------- Low-frequency cetaceans.........................................             219             183             199 Mid-frequency cetaceans.........................................             230             185             198 High-frequency cetaceans........................................             202             155             173 Phocid pinnipeds................................................             218             185             201 Otariid pinnipeds...............................................             232             203             219 ---------------------------------------------------------------------------------------------------------------- \1\ Referenced to 1 [mu]Pa; unweighted within generalized hearing range. \2\ Referenced to 1 [mu]Pa\2\-s; weighted according to appropriate auditory weighting function.

Zones of Ensonification

    Sound Propagation--Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

    TL = B \* log10(R1/R2)

Where:

B = transmission loss coefficient (assumed to be 15) R1 = the distance of the modeled SPL from the driven pile, and R2 = the distance from the driven pile of the initial measurement.

    This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6 dB reduction in sound level for each doubling of distance from the source (20 \* log(range)). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source (10 \* log(range)). As is common practice in coastal waters, here we assume practical spreading loss (4.5 dB reduction in sound level for each doubling of distance). Practical spreading is a compromise that is often used under conditions where water depth increases as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions.     Sound Source Levels--The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. There are source level measurements available for certain pile types and sizes from the specific environment of several of the installations considered here (i.e , NBK Bangor and NBK Bremerton), but not from all. Numerous studies have examined sound pressure levels (SPLs)

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recorded from underwater pile driving projects in California (e.g , Caltrans, 2015) and elsewhere in Washington. In order to determine reasonable SPLs and their associated effects on marine mammals that are likely to result from pile driving at the six installations, studies with similar properties to the specified activity were evaluated. Full details are available in Appendix B of the Navy's application, which evaluates available data sources for each pile size and type in order to develop reasonable proxy values.

                                         Table 4--Assumed Source Levels ----------------------------------------------------------------------------------------------------------------                                                                                  SPL (peak) 1 2            Method                   Type         Size  (in)     SPL (rms) \1\                        SEL 1 3 ---------------------------------------------------------------------------------------------------------------- Impact......................  Plastic........              13  156............  Not available..  Not available.                               Timber.........           12/14  170............  Not available..  Not available.                               Concrete.......              18  170............  184............  159.                                                            24  178............  189............  166.                               Steel pipe.....           12/13  177............  192............  167.                                                            14  184............  200............  174.                                                            24  193............  210............  181.                                                            30  195............  216............  186.                                                            36  194 (Bangor)...  211............  181 (Bangor).                                                                192 (others)...                   184 (others). Vibratory...................  Timber.........              12  153............  n/a............  n/a.                                                         13/14  155............  n/a............  n/a.                               Steel pipe.....           13/14  155............  n/a............  n/a.                                                         16/24  161............  n/a............  n/a.                                                         30/36  166 (Bangor)...  n/a............  n/a.                                                                167 (others)...                               Steel sheet....             n/a  163............  n/a............  n/a. ---------------------------------------------------------------------------------------------------------------- \1\ Source levels presented at standard distance of 10 m from the driven pile. Peak source levels are not   typically evaluated for vibratory pile driving, as they are lower than the relevant thresholds for auditory   injury. SEL source levels for vibratory driving are equivalent to SPL (rms) source levels.

    Acoustic measurements were conducted during impact driving of 24- and 36-in steel piles in 2011 at NBK Bangor (Navy, 2012). However, for the 24-in piles only seven strikes from a single pile were measured, and the reported values are lower than those from other projects reviewed. Therefore, these data were not considered in the selection of the most appropriate proxy value. For 36-in piles, the reported values from this study are directly used in evaluating similar pile driving at NBK Bangor. For 24-in piles, data from projects conducted by the Washington State Department of Transportation (WSDOT) at Bainbridge Island and Friday Harbor, as well as data from several projects conducted in California and Oregon were considered. The two Washington projects were used in developing the proxy value, as these locations were considered to be representative of substrate conditions likely encountered in other locations in Puget Sound (WSDOT, 2005a, 2005b). For 30-in piles, data from projects conducted by WSDOT at three locations--Bainbridge Island, Friday Harbor, and Vashon Island (WSDOT, 2005b, 2008, 2010b; Jasco, 2005)--as well as from one project in California were considered. The three Washington projects were again used in developing the proxy value, for the same reasons. For impact driving of 36-in piles, data from the Navy project at NBK Bangor (Navy, 2012), from two WSDOT projects (at Mukilteo and Anacortes) (WSDOT, 2007a, 2007b), and from one project in California were considered. The three projects conducted in Washington inland waters were used in developing the proxy value. Values for impact driving of small diameter steel pipe piles were taken from the summary value tables provided by Caltrans (2015) (see Table I.2-1 in that publication). No values are provided for 13-in steel piles; therefore, we assume that source levels for 12-in piles would apply to 13-in piles. While values for both 12-in and 14-in piles are provided, we believe that the 12-in values are more appropriate as the water depth for these measurements is closer to what would be encountered at the Navy project sites. No SEL source level is provided; therefore, we assume that the SEL source level is 10 dB less than the SPL (rms) source level. This is a conservative assumption, as the average difference between SPL (rms) and SEL source levels given in the Caltrans (2015) summary table is 11.5 dB.     The 2011 Navy study described above provided data from measurements of vibratory driving of 36-in steel piles (Navy, 2012), while a separate 2011 project at NBK Bangor provided measurements from vibratory driving of 30-in piles (Miner, 2012). These projects together provide directly applicable data for use in evaluating vibratory driving of 30- and 36-in steel piles at NBK Bangor. For vibratory driving of 30- and 36-in steel piles at other locations, data from a variety of additional studies from other locations in Washington (Coupeville, Edmonds, Vashon Island, Port Townsend, and Anacortes) (WSDOT 2010c, 2010d, 2010e, 2011b, 2012) were considered and, with the two Navy studies, used in developing a proxy value for 30- and 36-in piles. The same 2011 NBK Bangor study provided limited data for vibratory driving of 24-in piles, while the separate 2012 NBK Bangor provided data from vibratory driving of 16-in piles. These were considered together with a WSDOT study from Friday Harbor (WSDOT, 2010a) and with data from a project at the Trinidad Bay in Humboldt County, CA (Caltrans, 2015) to develop a generally applicable proxy value for 16- and 24-in piles. The proxy source level for vibratory driving of 13-in steel piles is taken from a study at the Mad River Slough in Arcata, CA, and is assumed to be applicable to 14-in piles as well (Caltrans, 2015). Caltrans (2015) also provides a summary value of 155 dB rms for vibratory driving of 12-in steel piles. For vibratory driving of sheet piles, data from multiple projects conducted in Oakland, CA (Berth 23, Berth 30, and Berth 35/37 at Port of Oakland; Caltrans, 2015) were considered in developing an appropriate proxy value. Values for vibratory installation are conservatively assumed to apply to vibratory extraction of same-sized piles.

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    Acoustic measurements were conducted during impact driving of 24-in concrete piles in 2015 at NBK Bremerton (Navy, 2016). These measurements provide a proxy value for use during impact driving of 24- in concrete piles at all facilities. For impact driving of smaller concrete piles, data from three projects conducted at Concord, CA and Berkeley, CA and involving impact driving of 16- and 18-in piles (Caltrans, 2015) were evaluated and used in developing a proxy value.     Relatively few data are available for timber and plastic piles. The proxy value for impact driving of plastic piles is from a project conducted in Solano County, CA (Illingworth and Rodkin, 2008). For impact driving of timber piles, data from one study in Alameda, CA, provides the proxy source level (Caltrans, 2015). However, we assume that the assumed source level for impact driving of 14-in steel piles is a suitable proxy for impact driving of larger diameter timber piles (18-in). For vibratory extraction of timber piles, the Navy considered measured values from NBK Bremerton (Navy, 2016) as well as data from a WSDOT project at Port Townsend involving removal of 12-in timber piles (WSDOT, 2011a). Source levels for vibratory driving of 13/14-in timber piles is assumed as a reasonable proxy for vibratory removal of timber and plastic piles up to 18-in diameter.     The Navy proposes to use bubble curtains when impact driving steel piles of 24-in diameter and greater, except at NBK Bremerton and NBK Keyport (see Proposed Mitigation for further discussion). For the reasons described in the next paragraph, we assume here that use of the bubble curtain would result in a reduction of 8 dB from the assumed SPL (rms) and SPL (peak) source levels for these pile sizes, and reduce the applied source levels accordingly. For determining distances to the cumulative SEL injury thresholds, auditory weighting functions were applied to the attenuated one-second SEL spectra for steel pipe piles (see Appendix E of the Navy's application).     During the 2011 study at NBK Bangor, the Navy conducted comparative measurements of source levels when impact driving steel piles with and without a bubble curtain. Across all piles (36- and 48-in) and all metrics (rms, peak, SEL), the weighted average effective attenuation was 9 dB. The Navy also reviewed unconfined bubble curtain attenuation rates from available reports from projects in Washington, California, and Oregon that impact drove steel pipe piles of up to 48-in diameter. These results are summarized in Table 3-2 of Appendix A in the Navy's application. Of the studies reviewed, significant variability in attenuation occurred; however, an average of at least 8 dB of peak SPL attenuation was achieved on ten of the twelve projects. Some of the lower attenuation levels reported were attributed to failures in setting up or operating the bubble curtain system (e.g , bottom ring not seated on the substrate, poor airflow). While proper set-up and operation of the system is critical, and variability in performance should be expected, we believe that in the circumstances evaluated here an effective attenuation performance of 8 dB is a reasonable assumption.     Level A Harassment--In order to assess the potential for injury on the basis of the cumulative SEL metric, one must estimate the total strikes per day (impact driving) or the total driving duration per day (vibratory driving). To provide a general estimate of pile driving daily durations/strikes, the Navy reviewed information from past projects (Table 5). Navy geotechnical and engineering staff used data from a large wharf construction project at NBK Bangor to estimate pile driving time and strikes needed to install steel piles using impact hammers. Vibratory installation was estimated to take a median time of 10 minutes per pile with 45 minutes estimated as a maximum.     For steel piles that are ``proofed,'' a median of approximately 600 strikes per pile was estimated. However, not all projects will require proofing every pile. Some projects will require only a subset of piles be proofed and some projects, such as those installing fender piles, may not require any proofing because the structure is not load-bearing. Other piles may encounter difficult substrate and need to be advanced further with an impact driver. For piles that cannot be advanced with a vibratory driver, less than approximately 1,300 strikes was conservatively estimated to complete installation. Based on these estimates, no more than 4,000 strikes are estimated to occur on any one day. This estimate would account for approximately six steel piles installed with a median time of 14 minutes per pile (~1.5 hours of drive time) or three steel piles needing extended driving. Estimates of concrete pile impact driving durations are based on data for the installation of fender piles at NBK Bremerton. For purposes of analysis, impact pile driving of concrete piles is estimated to take a maximum of 4 hours or an average of 1.5 hours in a day.     Actual driving duration at any of the project sites will vary due to substrate conditions and the type and energy of impact hammers. For example, during a past project at NBK Bangor (where most of the steel pile work will occur), four piles were installed with a vibratory driver and impact proofed in 61 minutes total (vibratory and impact driving) with an average of 172 strikes/pile. Additionally, some of the anticipated pile driving is contingent on emergent needs or emergencies that could potentially never occur. Therefore, estimates of marine mammal exposure based on the maximum strike numbers would be too conservative for this programmatic analysis of all potential project sites. Table 5 presents an estimate of average strikes per day; average strikes per day and average daily duration values are used in the exposure analyses. For vibratory driving of piles less than 16-in, a daily duration of 0.5 hours was assumed; for vibratory driving of larger piles a daily duration of 2.25 hours was assumed.

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                              Table 5--Estimated Daily Strikes and Driving Duration ----------------------------------------------------------------------------------------------------------------                                                                            Estimated duration                                         Installation  ----------------------------------------------------------          Pile type and method           rate per day       Average                                                          strikes/day             Average daily duration ---------------------------------------------------------------------------------------------------------------- 14-in steel; impact..................         No data     \1\ <<1,000  No data. 24- to 30-in steel; impact...........             1-6           1,000  4.5 minutes to 1.5 hours. 18- to 24-in concrete; impact........            1-11       \2\ 4,000  3 minutes to 4 hours. 13-in steel; vibratory...............            2-17             n/a  0-31 minutes. \3\ 24- to 30-in steel; vibratory........             1-6             n/a  10 minutes to 4.5 hours. \4\ ---------------------------------------------------------------------------------------------------------------- \1\ All 14-in piles are expected to be vibratory driven for full embedment depth. In the event that conditions   requiring impact driving are encountered, very few strikes are expected to be necessary. \2\ Estimate based on data from 272 piles installed at NBK Bremerton. \3\ Estimate based on data from 70 piles installed at NBK Bremerton. \4\ Estimate based on data from 809 piles installed at NBK Bangor. Maximum assumes six piles advanced at a rate   of 45 minutes per pile.

    Delineation of potential injury zones on the basis of the peak pressure metric was performed using the SPL(peak) values provided in Table 4 above. As described previously, source levels for peak pressure are unweighted within the generalized hearing range, while SEL source levels are weighted according to the appropriate auditory weighting function. Delineation of potential injury zones on the basis of the cumulative SEL metric for vibratory driving was performed using a single-frequency weighting factor adjustment (WFA) of 2.5 kHz, as recommended by the NMFS User Spreadsheet, described in Appendix D of NMFS's Technical Guidance (NMFS, 2016). In order to assist in simple application of the auditory weighting functions, NMFS recommends WFAs for use with specific types of activities that produce broadband or narrowband noise. WFAs consider marine mammal auditory weighting functions by focusing on a single frequency. This will typically result in higher predicted exposures for broadband sounds, since only one frequency is being considered, compared to exposures associated with the ability to fully incorporate the Technical Guidance's weighting functions.     Because use of the WFA typically results in an overestimate of zone size, the Navy took an alternative approach to delineating potential injury zones for impact driving of 24- and 36-in steel piles and 24-in concrete piles. Note that, because data is not available for all pile sizes and types, we conservatively assume the following in using the available data for 24- and 36-in steel piles and 24-in concrete piles: (1) Injury zones for impact driving 14-in piles are equivalent to the zones for 24-in piles with no bubble curtain; (2) injury zones for impact driving plastic and timber piles and for 18-in concrete piles are equivalent to the zones for 24-in concrete piles; and (3) injury zones for impact driving 30-in steel piles are equivalent to the zones calculated for 36-in piles (both with and without bubble curtain).     This approach, described in detail in Appendix E of the Navy's application, incorporated frequency weighting adjustments by applying the auditory weighting function over the entire one-second SEL spectral data sets from impact pile driving. If this information for a particular pile size was not available, the next highest source level was used to produce a conservative estimate of areas above threshold values. Sound level measurements from construction activities during the 2011 Test Pile Program at NBK Bangor were used for evaluation of impact-driven steel piles, and sound level measurements from construction activities during the 2015 Intermediate Maintenance Facility Pier 6 Fender Pile Replacement Project at NBK Bremerton were used for evaluation of impact-driven concrete piles.     In consideration of the assumptions relating to propagation, sound source levels, and the methodology applied by the Navy towards incorporating frequency weighting adjustments for delineation of cumulative SEL injury zones for impact driving of steel and concrete piles, notional radial distances to relevant thresholds were calculated (Table 6). However, these distances are sometimes constrained by topography. Actual notional ensonified zones at each facility are shown in Tables 6-1 to 6-6b of the Navy's application. These zones are modeled on the basis of a notional pile located at the seaward end of a given structure in order to provide a conservative estimate of ensonified area.

                                                Table 6--Calculated Distances to Level A Harassment Zones --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                        PW                OW                LF                MF                HF                  Pile                           Driver         -----------------------------------------------------------------------------------------                                                                    pk      cSEL      pk      cSEL      pk      cSEL      pk      cSEL      pk      cSEL -------------------------------------------------------------------------------------------------------------------------------------------------------- 24-in concrete \1\...................  Impact.................        0       34        0        2        0      216        0        3        1      136 24-in steel \2\......................  Impact; BC.............        1       25        0      1.4        1      136        0        3       10      185 24-in steel \2\......................  Impact; no BC..........        3       86        0        5        3      159        0        6       34      342 36-in steel \2\......................  Impact; BC.............        1      158        0        9        1      736        0       10       12      541 36-in steel \2\......................  Impact; no BC..........        3      736        0       46        3    2,512        1       63       40    2,512 12- to 14-in timber \3\..............  Vibratory..............      n/a        1      n/a       <1      n/a        2      n/a       <1      n/a        3 16- and 24-in steel \4\..............  Vibratory..............      n/a        7      n/a        1      n/a       12      n/a        1      n/a       17 30- and 36-in steel (Bangor) \4\.....  Vibratory..............      n/a       15      n/a       11      n/a       25      n/a        2      n/a       37 30- and 36-in steel (others) \4\.....  Vibratory..............      n/a       18      n/a        1      n/a       30      n/a        3      n/a       43 Sheet steel \4\......................  Vibratory..............      n/a       10      n/a        1      n/a       16      n/a        1      n/a       24 -------------------------------------------------------------------------------------------------------------------------------------------------------- PW=Phocid; OW=Otariid; LF=low frequency; MF=mid frequency; HF=high frequency; pk=peak pressure; cSEL=cumulative SEL; BC=bubble curtain. \1\ Assumes 4,000 strikes per day. \2\ Assumes 1,000 strikes per day. Bubble curtain will be used for 24-, 30-, and 36-in steel piles except at NBK Bremerton and NBK Keyport. Steel piles   will not be installed at NBK Manchester. \3\ Assumes 30 minute daily driving duration. \4\ Assumes 2.25 hour daily driving duration.

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    Airborne Noise--Although pinnipeds are known to haul-out regularly on man-made objects in the vicinity of some of the potential project sites, we believe that incidents of take resulting solely from airborne sound are unlikely. There is a possibility that an animal could surface in-water, but with head out, within the area in which airborne sound exceeds relevant thresholds and thereby be exposed to levels of airborne sound that we associate with harassment, but any such occurrence would likely be accounted for in our estimation of incidental take from underwater sound.     Certain locations where pinnipeds may haul-out may be within an airborne noise harassment zone. We generally recognize that pinnipeds occurring within an estimated airborne harassment zone, whether in the water or hauled out, could be exposed to airborne sound that may result in behavioral harassment. However, any animal exposed to airborne sound above the behavioral harassment threshold is likely to also be exposed to underwater sound above relevant thresholds (which are typically in all cases larger zones than those associated with airborne sound). Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Multiple incidents of exposure to sound above NMFS's thresholds for behavioral harassment are not believed to result in increased behavioral disturbance, in either nature or intensity of disturbance reaction. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here. Further information regarding anticipated airborne noise from pile driving may be found in section 6.8 of the Navy's application.     Summary--Here, we summarize facility-specific information about piles to be removed and installed. In general, it is likely that pile removals may be accomplished via a combination of methods (e.g , vibratory driver, cut at mudline, direct pull). However, for purposes of analysis we assume that all removals would be via vibratory driver. In addition, we assume that installation of all steel piles larger than 14-in would require use of both impact and vibratory drivers, although it is likely that some of these piles would be installed solely via use of the vibratory driver. All concrete, timber, and plastic piles would be installed solely via impact driver. Steel sheet piles and steel pipe piles of 14-in diameter and smaller would be installed solely via vibratory driver. All piles removed are assumed to be replaced at a 1:1 ratio, although it is likely that a lesser number of replacement piles would be required. For full details, please see Appendix A of the Navy's application.      NBK Bangor: The Navy anticipates ongoing maintenance work at the older Explosives Handling Wharf (EHW-1), including removal and replacement of up to 44 piles. Replacement of up to 75 piles is anticipated for contingency repairs at any existing structure. Piles to be removed would be steel, timber, and/or concrete, and replacement piles would be steel and/or concrete. As a conservative scenario, all piles are assumed to be 36-in steel for purposes of analysis.      Zelatched Point: Replacement of up to 20 piles is anticipated for contingency repairs. Piles to be removed would be 12-in timber piles, while replacement piles could be steel, timber, and/or concrete. As a conservative scenario, all replacement piles are assumed to be 36-in steel for purposes of analysis.      NBK Bremerton: The Navy anticipates ongoing maintenance work at multiple existing structures. At Pier 5, 360 timber fender piles would be removed and replaced with concrete piles. Timber piles are assumed to be 14-in diameter, and concrete piles are assumed to be 24-in. At Pier 4, 80 timber fender piles would be replaced with steel piles--timber and steel piles are assumed to be 14-in diameter. Anticipated repairs to other piers would require removal of up to 20 timber piles, followed by installation of steel sheet piles. Replacement of up to 75 piles is anticipated for contingency repairs at any existing structure. Piles to be removed would be steel and/or timber, and replacement piles would be 24-in concrete. The largest estimated Level B ZOI results from vibratory driving of sheet piles, which is expected to occur for only twenty of the estimated total of 168 activity days. The Navy has elected to assume this largest estimated ZOI for all 168 activity days as a conservative scenario.      NBK Keyport: Replacement of up to 20 piles is anticipated for contingency repairs. Piles to be removed would be steel and/or concrete (up to 18-in), while replacement piles would be steel. As a conservative scenario, all replacement piles are assumed to be 36-in steel for purposes of analysis.      NBK Manchester: Replacement of up to 50 piles is anticipated for contingency repairs. Piles to be removed would be timber and/or plastic (up to 18-in), while replacement piles could be timber, plastic, and/or concrete. As a conservative scenario, all replacement piles are assumed to be 24-in concrete for purposes of analysis.      NS Everett: The Navy anticipates minor repairs at the North Wharf, requiring replacement of two concrete piles (assumed to be 24-in). Replacement of up to 76 piles is anticipated for contingency repairs. Piles to be removed would include one steel pile and 75 timber piles. The one steel pile would be replaced by a 36-in steel pile, while the timber piles could be replaced by concrete and/or timber piles. As a conservative scenario, these replacement piles are assumed to be 24-in concrete for purposes of analysis.     Behavioral harassment zones and associated areas of ensonification are identified in Table 7 below. Although not all zones are applied to the exposure analysis, these may be effected as part of the required monitoring. Ensonified areas vary based on topography in the vicinity of the facility and are provided for each relevant facility.

           Table 7--Radial Distances to Relevant Behavioral Isopleths and Associated Ensonified Areas ----------------------------------------------------------------------------------------------------------------                                     Impact (160-dB                         Vibratory (120-         Pile size and type             rms) \1\      Ensonified area \2\       dB) \3\      Ensonified area \2\ ---------------------------------------------------------------------------------------------------------------- Plastic (13-in)...................               5  0.001 ...............             n/a  n/a. Timber (12-in)....................              46  0.01 ................             1.6  3.8 (Manchester                                                                                             Finger Pier); 4.6                                                                                             (Manchester Fuel                                                                                             Pier). Timber (13/14-in) \4\.............              46  0.01 ................             2.2  6.8 (Bremerton); 5.9                                                                                             (Manchester Finger                                                                                             Pier); 7.8                                                                                             (Manchester Fuel                                                                                             Pier); \6\ 9.4                                                                                             (Everett) Concrete (24-in) \4\..............             159  0.08 ................             n/a  n/a. Steel (14-in).....................             398  0.5 (Bremerton)......             2.2  6.8 (Bremerton).

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  Steel (24-in; BC).................             464  0.54 (Bangor)........             n/a  n/a.                                                     0.48 (Zelatched                                                      Point). Steel (24-in; no BC) \5\..........           1,585  2.09 (Keyport).......             5.4  26.8 (Bangor); 4.9                                                                                             (Keyport); 37.9                                                                                             (Zelatched Point). Steel (30-in; BC).................             631  0.91 (Bangor); 0.85               n/a  n/a.                                                      (Zelatched Point);                                                      1.2 (Everett). Steel (30-in; no BC)..............           2,154  1.94 (Keyport).......   Same as 36-in  Same as 36-in. Steel (36-in; BC).................   541 (Bangor);  0.7 (Bangor); 0.36                n/a  n/a.                                       398 (others)   (Zelatched Point);                                                      0.5 (Everett). Steel (36-in; no BC)..............           1,359  0.42 (Keyport).......  11.7 (Bangor);  4.9 (Keyport); 75.24                                                                             13.6 (others)   (Zelatched Point);                                                                                             117.8 (Everett);                                                                                             40.9 (Bangor). Sheet steel.......................             n/a  n/a..................             7.4  15.0 (Bremerton). ---------------------------------------------------------------------------------------------------------------- BC=bubble curtain. \1\ Radial distance to threshold in meters. \2\ Ensonified area in square kilometers. \3\ Radial distance to threshold in kilometers. \4\ Zones for impact driving of 18-in concrete piles are equivalent to those for impact driving of timber piles.   Zones for vibratory removal of up to 18-in diameter plastic/timber piles are assumed to be equivalent to those   for 13/14-in timber piles. \5\ Zones for vibratory driving of 16-in steel piles assumed equivalent to those for 24-in steel piles. \6\ Worst-case values for vibratory extraction of timber/plastic piles at NBK Manchester, where piles to be   removed are a maximum 18-in diameter.

Marine Mammal Occurrence

    Available information regarding marine mammal occurrence in the vicinity of the six installations includes density information aggregated in the Navy's Marine Mammal Species Density Database (NMSDD; Navy, 2015) or site-specific survey information from particular installations (e.g , local pinniped counts). More recent density estimates for harbor porpoise are available in Smultea et al. (2017). The latter of these is described in Appendix C of the Navy's application. First, for each installation we describe anticipated frequency of occurrence and the information deemed most appropriate for the exposure estimates. For all facilities, large whales (humpback whale, minke whale, and gray whale), killer whales (transient and resident), and the elephant seal are considered as occurring only rarely and unpredictably, on the basis of past sighting records. For these species, average group size is considered in concert with expected frequency of occurrence to develop the most realistic exposure estimate. Although certain species are not expected to occur at all at some facilities--for example, resident killer whales are not expected to occur in Hood Canal--the Navy has developed an overall take estimate and request for these species that would apply to activities occurring over the 5-year duration at all six installations.      NBK Bangor: In addition to the species described above, the Dall's porpoise is considered as a rare, unpredictably occurring species. A density-based analysis is used for the harbor porpoise, while data from site-specific abundance surveys is used for the California sea lion, Steller sea lion, and harbor seal.      Zelatched Point: In addition to the species described above, the Dall's porpoise is considered as a rare, unpredictably occurring species. A density-based analysis is used for the harbor porpoise, California sea lion, Steller sea lion, and harbor seal.      NBK Bremerton: A density-based analysis is used for the harbor porpoise, Dall's porpoise, and Steller sea lion, while data from site-specific abundance surveys is used for the California sea lion and harbor seal.      NBK Keyport: A density-based analysis is used for the harbor porpoise, Dall's porpoise, California sea lion, Steller sea lion, and harbor seal.      NBK Manchester: A density-based analysis is used for the harbor porpoise, Dall's porpoise, and harbor seal, while data from site-specific abundance surveys is used for the California sea lion and Steller sea lion.      NS Everett: A density-based analysis is used for the harbor porpoise, Dall's porpoise, and Steller sea lion, while data from site-specific abundance surveys is used for the California sea lion and harbor seal.

                    Table 8--Marine Mammal Densities ------------------------------------------------------------------------                                                          Density (June-              Species                     Region            February) ------------------------------------------------------------------------ Harbor porpoise.................  Hood Canal (Bangor,               0.44                                    Zelatched Point).                                   East Whidbey                      0.75                                    (Everett).                                   Bainbridge                        0.53                                    (Bremerton,                                    Keyport).                                   Vashon (Manchester)               0.25 Dall's porpoise.................  Puget Sound........              0.039 Steller sea lion................  Puget Sound........             0.0368                                   Dabob Bay..........             0.0251 California sea lion.............  Puget Sound........             0.1266                                   Dabob Bay..........              0.279 Harbor seal.....................  Everett............             2.2062                                   Keyport/Manchester.              1.219

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                                    Dabob Bay..........              9.918 ------------------------------------------------------------------------ Sources: Navy, 2015; Smultea et al., 2017 (harbor porpoise).

Exposure Estimates

    To quantitatively assess exposure of marine mammals to noise from pile driving activities, the Navy proposed three methods, to be used depending on the species' spatial and temporal occurrence. For species with rare or infrequent occurrence at a given installation during the in-water work window, the likelihood of interaction was reviewed on the basis of past records of occurrence (described in Description of Marine Mammals in the Area of the Specified Activity) and the potential maximum duration of work days at each installation, as well as total work days for all installations. Occurrence of the species in this category (i.e , large whales, killer whales, elephant seal (all installations), and Dall's porpoise (Hood Canal)) would not be anticipated to extend for multiple days. For the large whales and killer whales, the duration of occurrence was set to two days, expected to be roughly equivalent to one transit in the vicinity of a project site. The calculation for species with rare or infrequent occurrence is:

Exposure estimate = expected group size x probable duration

    For species that occur regularly but for which site-specific abundance information is not available, density estimates (Table 8) were used to determine the number of animals potentially exposed on any one day of pile driving or extraction. The calculation for density- based analysis of species with regular occurrence is:

Exposure estimate = N (density) x ZOI (area) x maximum days of pile driving

    For remaining species, site-specific abundance information (i.e , average monthly maximum over the time period when pile driving will occur) was used:

Exposure estimate = Abundance x maximum days of pile driving

    Large Whales--For each species of large whale (i.e , humpback whale, minke whale, and gray whale), we assume rare and infrequent occurrence at all installations. For all three species, if observed, they typically occur singly or in pairs. Therefore, for all three species, we assume that a pair of whales may occur in the vicinity of an installation for a total of two days. We do not expect that this would happen multiple times, and cannot predict where such an occurrence may happen, so propose to authorize a total of four takes of each species in total for the 5-year duration (across all installations).     It is important to note that the Navy proposes to implement a shutdown of pile driving activity if any large whale is observed within any defined harassment zone (see Proposed Mitigation). Therefore, the proposed take authorization is intended to provide insurance against the event that whales occur within Level B harassment zones that cannot be fully observed by monitors. As a result of this proposed mitigation, we do not believe that Level A harassment is a likely outcome upon occurrence of any large whale. While the calculated Level A harassment zone is as large as 2.5 km for impact driving of 36-in steel piles without a bubble curtain (ranging from 136-736 m for other impact driving scenarios), this requires that a whale be present at that range for the full assumed duration of 1,000 pile strikes (expected to require 1.5 hours). Given the Navy's commitment to shut down upon observation of a large whale, and the likelihood that the presence of a large whale in the vicinity of any Navy installation would be known due to reporting via Orca Network, we do not expect that any whale would be present within a Level A harassment zone for sufficient duration to actually experience PTS.     Killer Whales--For killer whales, the proposed take authorization is derived via the same thought process described above for large whales. For transient killer whales, we assume an average group size of six whales occurring for a period of two days. The resulting total proposed take authorization of 12 would also account for the low probability that a larger group occurred once. For resident killer whales, we assume an average group size of 20 whales occurring for two days. This is equivalent to the expected pod size for J pod, which is most likely to occur in the vicinity of Navy installations, but would also account for the unlikely occurrence of L pod (with a size of approximately 40 whales) once in the vicinity of any Navy installation.     Similar to large whales, the Navy proposes to implement shutdown of pile driving activity at any time that any killer whale is observed within any calculated harassment zone. We expect this to minimize the extent and duration of any behavioral harassment. Given the small size of calculated Level A harassment zones--maximum of 63 m for the worst- case scenario of impact-driven 36-in steel piles with no bubble curtain, other scenarios range from 1-10 m--we do not anticipate any potential for Level A harassment of killer whales.     Dall's Porpoise--Using the density given in Table 8, the largest appropriate ZOI for each of the four installations in Puget Sound, and the number of days associated with each of these installations (as indicated in harbor porpoise section below), the total estimated exposure of Dall's porpoises above Level B harassment thresholds is 146. Dall's porpoises are not expected to occur in Hood Canal. Dall's porpoises are not expected to occur frequently in the vicinity of Navy installations and have not been reported in recent years. This total proposed take authorization (146) is applied to all installations over the 5-year duration.     The Navy proposes to implement shutdown of pile driving activity at any time if a Dall's porpoise is observed in any harassment zone. Therefore, the take estimate is precautionary in accounting for potential occurrence in areas that cannot be visually observed or in the event that porpoises appear within behavioral harassment zones before shutdown can be implemented. As was described for large whales, as a result of this proposed mitigation, we do not believe that Level A harassment is a likely outcome. While the calculated Level A harassment zone is as large as 2.5 km for impact driving of 36-in steel piles without a bubble curtain (ranging from 136-541 m for other impact driving scenarios), this requires that a porpoise be present at that range for the full assumed duration of 1,000 pile strikes (expected to require 1.5 hours). Given the Navy's commitment to shut down upon observation of a porpoise, and the likelihood that a porpoise would engage in aversive behavior prior to experiencing PTS, we do not expect that any porpoise would be present within a Level A harassment zone for

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sufficient duration to actually experience PTS.     Harbor Porpoise--Level B exposure estimates for harbor porpoise were calculated for each installation using the appropriate density given in Table 8, the largest appropriate ZOI for each installation, and the appropriate number of days.      NBK Bangor: Using the Hood Canal sub-region density, 119 days of pile driving, and the largest ZOI calculated for pile driving at this location (40.9 km\2\ for vibratory installation of 30- or 36-in steel piles) produces an estimate of 2,142 incidents of Level B exposure for harbor porpoise.      Zelatched Point: Using the Hood Canal sub-region density, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (75.24 km\2\ for vibratory installation of 30- or 36-in steel piles) produces an estimate of 662 incidents of Level B exposure for harbor porpoise.      NBK Bremerton: Using the Bainbridge sub-region density, 168 days of pile driving, and the largest ZOI calculated for pile driving at this location (15 km\2\ for vibratory installation of sheet steel piles) produces an estimate of 1,336 incidents of Level B exposure for harbor porpoise.      NBK Keyport: Using the Bainbridge sub-region density, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (4.9 km\2\ for vibratory installation of 30- or 36-in steel piles) produces an estimate of 52 incidents of Level B exposure for harbor porpoise.      NBK Manchester: Using the Vashon sub-region density, 50 days of pile driving, and the largest ZOI calculated for vibratory removal of timber piles (7.8 km\2\ for vibratory extraction of timber piles) produces an estimate of 98 incidents of Level B exposure for harbor porpoise.      NS Everett: Using the East Whidbey sub-region density, 78 days of pile driving, and the largest ZOI calculated for vibratory extraction of timber piles (9.4 km\2\) produces an estimate of 552 incidents of Level B exposure for harbor porpoise. Although some vibratory installation is anticipated for a single steel pile, we anticipate this would occur for only a brief period. Therefore, use of the assumed zone for vibratory extraction of timber piles is appropriate in accounting for reasonably expected marine mammal exposure at this location.     The Navy proposes to implement shutdown of pile driving activity at any time if a harbor porpoise is observed in any harassment zone. Therefore, the take estimate is precautionary in accounting for potential occurrence in areas that cannot be visually observed or in the event that porpoises appear within behavioral harassment zones before shutdown can be implemented. As was described for large whales, as a result of this proposed mitigation, we do not believe that Level A harassment is a likely outcome. While the calculated Level A harassment zone is as large as 2.5 km for impact driving of 36-in steel piles without a bubble curtain (ranging from 136-541 m for other impact driving scenarios), this requires that a porpoise be present at that range for the full assumed duration of 1,000 pile strikes (expected to require 1.5 hours). Given the Navy's commitment to shut down upon observation of a porpoise, and the likelihood that a porpoise would engage in aversive behavior prior to experiencing PTS, we do not expect that any porpoise would be present within a Level A harassment zone for sufficient duration to actually experience PTS.     Steller Sea Lion--Level B exposure estimates for Steller sea lions were calculated for each installation using the appropriate density given in Table 8 or site-specific abundance, the largest appropriate ZOI for each installation, and the appropriate number of days. Please see Appendix C of the Navy's application for details of site-specific abundance information.      NBK Bangor: Steller sea lions are routinely seen hauled out from mid-September through May, with a maximum daily haul-out count of 13 individuals in November 2014. Because the daily average number of Steller sea lions hauled out at Bangor has increased since 2013 compared to prior years, the Navy relied on 2013-2016 monitoring data to determine the average of the maximum count of hauled out Steller sea lions for each month in the in-water work window. The average of the monthly maximum counts during the in-water work window provides an estimate of three sea lions present per day. Using this value for 119 days results in an estimate of 357 incidents of Level B exposure.      Zelatched Point: Using the Dabob Bay density value, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (75.24 km\2\ for vibratory installation of 30- or 36- in steel piles) produces an estimate of 38 incidents of Level B exposure for Steller sea lions.      NBK Bremerton: Using the Puget Sound density value, 168 days of pile driving, and the largest ZOI calculated for pile driving at this location (15 km\2\ for vibratory installation of sheet steel piles) produces an estimate of 93 incidents of Level B exposure for Steller sea lions.      NBK Keyport: Using the Puget Sound density value, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (4.9 km\2\ for vibratory installation of 30- or 36-in steel piles) produces an estimate of four incidents of Level B exposure for Steller sea lions.      NBK Manchester: Sea lions haul out on floats approximately 800 m offshore. Based on shore-based observations conducted intermittently in 2012-2013 and more frequently in 2014-2016, in addition to aerial surveys conducted by WDFW in selected months in 2013-2014, the Navy estimates that 10 Steller sea lions may be present on any given day. Using this average value for 50 days results in an estimate of 500 incidents of Level B exposure.      NS Everett: Using the Puget Sound density value, 78 days of pile driving, and the largest ZOI calculated for this location (9.4 km\2\) produces an estimate of 27 incidents of Level B exposure for harbor porpoise.     Given the small size of calculated Level A harassment zones-- maximum of 43 m for the worst-case scenario of impact-driven 36-in steel piles with no bubble curtain, other scenarios range from 1-11 m-- we do not anticipate any potential for Level A harassment of Steller sea lions.     California Sea Lions--Level B exposure estimates for California sea lions were calculated for each installation using the appropriate density given in Table 8 or site-specific abundance, the largest appropriate ZOI for each installation, and the appropriate number of days. Please see Appendix C of the Navy's application for details of site-specific abundance information.      NBK Bangor: California sea lions are routinely seen hauled out in all months other than July. Because the daily average number of California sea lions hauled out at Bangor has increased since 2013 compared to prior years, the Navy relied on 2013-2016 monitoring data to determine the average of the maximum count of hauled out California sea lions for each month in the in-water work window. The average of the monthly maximum counts during the in-water work window provides an estimate of 49 sea lions per day. Using this value for 119 days results in an estimate of 5,831 incidents of Level B exposure.      Zelatched Point: Using the Dabob Bay density value, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (75.24 km\2\ for vibratory installation of 30- or

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36-in steel piles) produces an estimate of 420 incidents of Level B exposure for California sea lions.      NBK Bremerton: California sea lions are routinely seen hauled out on floats at NBK Bremerton. Survey data from 2012-2016 indicate as many as 144 animals hauled out each day during this time period, with the majority of animals observed August through May and the greatest numbers observed in November. The average of the monthly maximum counts during the in-water work window provides an estimate of 69 sea lions per day. Using this value for 168 days results in an estimate of 11,592 incidents of Level B exposure.      NBK Keyport: Using the Puget Sound density value, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (4.9 km\2\ for vibratory installation of 30- or 36-in steel piles) produces an estimate of 12 incidents of Level B exposure for California sea lions.      NBK Manchester: Sea lions haul out on floats approximately 800 m offshore. Based on shore-based observations conducted intermittently in 2012-2013 and more frequently in 2014-2016, in addition to aerial surveys conducted by WDFW in selected months in 2013-2014, the Navy estimates that 43 California sea lions may be present on any given day. Using this average value for 50 days results in a Level B exposure estimate of 2,150 incidents of Level B exposure.      NS Everett: California sea lions are routinely seen hauled out on floats at NS Everett. Survey data from 2012-2016 indicate as many as 130 animals hauled out each day during this time period, with the majority of animals observed July through February and the greatest numbers observed in November. The average of the monthly maximum counts during the in-water work window provides an estimate of 67 sea lions per day. Using this value for 78 days results in an estimate of 5,148 incidents of Level B exposure.     Given the small size of calculated Level A harassment zones-- maximum of 43 m for the worst-case scenario of impact-driven 36-in steel piles with no bubble curtain, other scenarios range from 1-11 m-- we do not anticipate any potential for Level A harassment of California sea lions.     Harbor Seal--Harbor seals are expected to occur year-round at all installations, with the greatest numbers expected at installations with nearby haul-out sites. Level B exposure estimates for harbor seals were calculated for each installation using the appropriate density given in Table 8 or site-specific abundance, the largest appropriate ZOI for each installation, and the appropriate number of days. Please see Appendix C of the Navy's application for details of site-specific abundance information.     Harbor seals are expected to be the most abundant marine mammal at all installations, often occurring in and around existing in-water structures in a way that may restrict observers' ability to adequately observe seals and subsequently implement shutdowns. In addition, the calculated Level A harassment zones are significantly larger than those for sea lions, which may also be abundant at various installations at certain times of year. For harbor seals, the largest calculated Level A harassment zone is 736 m (compared with a maximum zone of 43 m for sea lions), calculated for the worst-case scenario of impact-driven 36-in steel piles without use of the bubble curtain. Other scenarios range from 25-158 m. Therefore, we assume that some Level A harassment is likely to occur for harbor seals and provide installation-specific estimates below.      NBK Bangor: The closest major haul-outs to NBK Bangor that are regularly used by harbor seals are located approximately 13.2 km away. However, a small haul-out occurs under Marginal Wharf and small numbers of harbor seals are known to routinely haul out around the Carderock pier. Boat-based surveys and monitoring indicate that harbor seals regularly swim in the waters at NBK Bangor. Surveys conducted in August and September 2016 recorded as many as 28 harbor seals hauled out per day under Marginal Wharf or swimming in adjacent waters. Assuming a few other individuals may be present elsewhere on the Bangor waterfront, the Navy estimates that 35 harbor seals may be present per day near the installation during summer and early fall, which are expected to be months with greatest abundance of seals. Using this value for 119 days results in an estimate of 4,165 incidents of Level B exposure.     Considering the largest Level A harassment zone expected to typically occur at NBK Bangor (158 m), and assuming as a precaution that one seal per day could remain within the calculated zone for a sufficient period to accumulate enough energy to result in PTS, we propose to authorize 119 incidents of take by Level A harassment. It is important to note that the estimate of potential Level A harassment for NBK Bangor is expected to be an overestimate, as planned projects are not expected to occur near Marginal Wharf--the location where most harbor seal activity occurs.      Zelatched Point: Using the Dabob Bay density value, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (75.24 km\2\ for vibratory installation of 30- or 36- in steel piles) produces an estimate of 14,925 incidents of Level B exposure for harbor seals. The largest calculated Level A harassment zone at Zelatched Point would be 158 m. However, because harbor seals are not known to haul-out or congregate in the vicinity of in-water structures, as is the case at NBK Bangor, we do not anticipate that Level A harassment will occur at Zelatched Point and do not propose to authorize such take.      NBK Bremerton: Harbor seals do not typically haul out at NBK Bremerton, but are commonly present in the nearby vicinity within Sinclair Inlet. Marine mammal surveys conducted nearby during the construction of the Manette Bridge (WSDOT, 2011, 2012) indicate that approximately 11 animals may be present per day. Using this value for 168 days results in an estimate of 1,848 incidents of Level B exposure. The largest Level A harassment zone at NBK Bremerton would be 86 m and, given the lack of regular presence of harbor seals in close proximity to existing in-water structures, we do not anticipate that Level A harassment will occur at NBK Bremerton and do not propose to authorize such take.      NBK Keyport: No harbor seal haul-outs have been identified at this installation. Using the Puget Sound density value, 20 days of pile driving, and the largest ZOI calculated for pile driving at this location (4.9 km\2\ for vibratory installation of 30- or 36-in steel piles) produces an estimate of 119 incidents of Level B exposure for harbor seals. Given the lack of haul-outs and of regular harbor seal presence at this installation, we do not anticipate that Level A harassment will occur at NBK Keyport and do not propose to authorize such take.      NBK Manchester: No harbor seal haul-outs have been identified at this installation. Using the appropriate density value, 50 days of pile driving, and the largest ZOI calculated for vibratory extraction of timber piles (7.8 km\2\) produces an estimate of 477 incidents of Level B exposure for harbor seals. Given the lack of haul- outs and of regular harbor seal presence at this installation, we do not anticipate that Level A harassment will occur at NBK Manchester and do not propose to authorize such take.      NS Everett: Harbor seals haul out year-round on log rafts adjacent to NS Everett. Surveys from 2012-2016 indicate as many as 491 animals hauled

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out each day during the in-water work period from July through January with the maximum number observed in September and October. The average of the monthly maximum counts during the in-water work window provides an estimate of 212 seals per day. Using this value for 78 days results in an estimate of 16,536 incidents of Level B exposure.     The largest Level A harassment zone calculated for NS Everett (158 m) would occur for only one day during impact driving of the single 36- in steel pile. During the remainder of pile driving at this installation, the largest Level A zone would be 34 m (impact driving of 24-in concrete piles). Given the abundant seal population at this site, we assume that some portion of the seal population may be present and unobserved within these zones for a sufficient period to accumulate enough energy to result in PTS. For the larger zone, the Navy assumes that five percent of animals present (11) may occur within the Level A zone for such a duration, while for the smaller zone associated with concrete piles, the Navy assumes that one percent (2) of the population may occur within the zone for such a duration. Therefore, we propose to authorize 165 incidents of take by Level A harassment (i.e , two seals on each of the 77 concrete pile driving days in addition to 11 seals on the one day on which a steel pile would be installed).     Northern Elephant Seal--Northern elephant seals are considered rare visitors to Puget Sound. However, solitary juvenile elephant seals have been known to sporadically haul out to molt in Puget Sound during spring and summer months. Because there are occasional sightings in Puget Sound, the Navy reasons that exposure of up to one seal to noise above Level B harassment thresholds could occur for a two-day duration. This event could occur at any installation over the 5-year duration.     The total proposed take authorization for all species and installations is summarized in Table 9 below. No authorization of take by Level A harassment is proposed for authorization, except a total of 286 such incidents for harbor seals (anticipated to occur at NBK Bangor and NS Everett only).

                                               Table 9--Proposed Take Authorization by Level B Harassment --------------------------------------------------------------------------------------------------------------------------------------------------------                                                                             Zelatched                                                           Percent                             Species                                Bangor     Point    Bremerton   Keyport   Manchester   Everett     Total       \1\ -------------------------------------------------------------------------------------------------------------------------------------------------------- Humpback whale.................................................                   Applies across all installations                          4        0.2                                                                 ------------------------------------------------------------------- Minke whale....................................................                   Applies across all installations                          4       0.02                                                                 ------------------------------------------------------------------- Gray whale.....................................................                   Applies across all installations                          4        0.6                                                                 ------------------------------------------------------------------- Killer whale (transient).......................................                   Applies across all installations                         12        4.9                                                                 ------------------------------------------------------------------- Killer whale (resident)........................................                   Applies across all installations                         40       48.2                                                                 ------------------------------------------------------------------- Dall's porpoise................................................                   Applies across all installations                        146        0.6                                                                 ------------------------------------------------------------------- Harbor porpoise................................................      2,142        662      1,336         52          98        552      4,842       43.1 Steller sea lion...............................................        357         38         93          4         500         27      1,019        2.4 California sea lion............................................      5,831        420     11,592         12       2,150      5,148     25,153        8.5 Harbor seal....................................................      4,680     14,925      1,848        119         477     16,536     38,585        n/a                                                                 ------------------------------------------------------------------- Elephant seal..................................................                   Applies across all installations                          2      0.001 -------------------------------------------------------------------------------------------------------------------------------------------------------- \1\ Please see Small Numbers Analysis for more details about these percentages.

Proposed Mitigation

    Under Section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (``least practicable adverse impact''). NMFS does not have a regulatory definition for ``least practicable adverse impact.'' However, NMFS's implementing regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).     In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, we carefully consider two primary factors:     (1) The manner in which, and the degree to which, implementation of the measure(s) is expected to reduce impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses. This analysis will consider such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation.     (2) The practicability of the measure for applicant implementation. Practicability of implementation may consider such things as cost, impact on operations, personnel safety, and practicality of implementation.     The mitigation strategies described below largely follow those required and successfully implemented under previous incidental take authorizations issued in association with similar construction activities. Measurements from similar pile driving events were coupled with practical spreading loss and other relevant information to estimate zones of influence (ZOI; see ``Estimated Take''); these ZOI values were used to develop mitigation measures for pile driving activities at the six installations. Background discussion related to underwater sound concepts and terminology is provided in the section on ``Description of Sound Sources,'' earlier in this preamble. The ZOIs were used to inform the mitigation zones that would be established to prevent Level A harassment and to minimize Level B harassment for all cetacean species, while providing estimates of the areas within which Level B harassment might occur.

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    During installation of steel piles, the Navy would use vibratory driving to the maximum extent practicable. In addition to the specific measures described later in this section, the Navy would conduct briefings for construction supervisors and crews, the marine mammal monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, the marine mammal monitoring protocol, and operational procedures. Other mitigation requirements committed to by the Navy but not relating to marine mammals (e.g , construction best management practices) are described in section 11 of the Navy's application.

Timing

    As described previously, the Navy would adhere to in-water work windows designed for the protection of fish. These timing windows would also benefit marine mammals by limiting the annual duration of construction activities. At NBK Bangor and Zelatched Point, the Navy would adhere to a July 16 through January 15 window, while at the remaining facilities this window is extended to February 15.     On a daily basis, in-water construction activities will occur only during daylight hours (sunrise to sunset) except from July 16 to September 15 when impact pile driving will only occur starting two hours after sunrise and ending two hours before sunset in order to protect marbled murrelets (Brachyramphus marmoratus) during the nesting season.

Monitoring and Shutdown for Pile Driving

    The following measures would apply to the Navy's mitigation through shutdown and disturbance zones:     Shutdown Zone--The purpose of a shutdown zone is to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area), thus preventing some undesirable outcome, such as auditory injury or behavioral disturbance of sensitive species (serious injury or death are unlikely outcomes even in the absence of mitigation measures). For all pile driving activities, the Navy would establish a minimum shutdown zone with a radial distance of 10 m. This minimum zone is intended to prevent the already unlikely possibility of physical interaction with construction equipment and to establish a precautionary minimum zone with regard to acoustic effects.     Using NMFS's user spreadsheet, an optional companion spreadsheet associated with the alternative implementation methodology provided in Appendix D of NMFS's acoustic guidance (NMFS, 2016), pile type, size, and pile driving methodology-specific zones within which auditory injury (i.e , Level A harassment) could occur were calculated. For larger steel piles and concrete piles, an alternative methodology (described in greater detail in ``Estimated Take'' and in Appendix E of the Navy's application) was used. The user spreadsheet is publicly available online at [*www.nmfs.noaa.gov/pr/acoustics/guidelines.htm*](http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm) In using the spreadsheet, practical spreading loss was used in addition to information regarding assumed number of pile strikes per day (for impact pile driving) and daily duration of pile driving (for vibratory pile driving). Relevant information was provided in Tables 3-5 and calculated zones were provided in Table 6.     In many cases, especially for vibratory driving, the minimum shutdown zone of 10 m is expected to contain the area in which auditory injury could occur. In all circumstances where the predicted Level A harassment zone exceeds the minimum zone, the Navy proposes to implement a shutdown zone equal to the predicted Level A harassment zone (see Table 6). In all cases, predicted injury zones are calculated on the basis of cumulative sound exposure, as peak pressure source levels produce smaller predicted zones. In addition, the Navy proposes to implement shutdown upon observation of any cetacean within a calculated Level B harassment zone (see Table 7).     Injury zone predictions generated using the optional user spreadsheet are precautionary due to a number of simplifying assumptions. For example, the spreadsheet tool assumes that marine mammals remain stationary during the activity and does not account for potential recovery between intermittent sounds. In addition, the tool incorporates the acoustic guidance's weighting functions through use of a single-frequency weighting factor adjustment intended to represent the signal's 95 percent frequency contour percentile (i.e , upper frequency below which 95 percent of total cumulative energy is contained; Charif et al., 2010). This will typically result in higher predicted exposures for broadband sounds, since only one frequency is being considered, compared to exposures associated with the ability to fully incorporate the guidance's weighting functions. Note that the caveats related to WFA do not apply to the alternative method used by the Navy and applied to impact driving of 24- and 36-in steel piles and 24-in concrete piles.     Disturbance Zone--Disturbance zones are the areas in which sound pressure levels equal or exceed 160 and 120 dB rms (for impact and vibratory pile driving, respectively). Disturbance zones provide utility for monitoring conducted for mitigation purposes (i.e , shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones and, as noted above, the disturbance zones act as de facto shutdown zones for cetaceans. Monitoring of disturbance zones enables observers to be aware of and communicate the presence of marine mammals in the project area but outside the shutdown zone, and thus prepare for potential shutdowns of activity. For cetaceans, the Navy would implement shutdowns upon observation of any cetacean within a disturbance zone (while acknowledging that some disturbance zones are too large to practicably monitor)--these would also be recorded as incidents of harassment. For pinnipeds, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see ``Proposed Monitoring and Reporting''). Nominal radial distances for disturbance zones are shown in Table 7.     In order to document observed incidents of harassment, monitors record all marine mammal observations, regardless of location. The observer's location and the location of the pile being driven are known, and the location of the animal may be estimated as a distance from the observer and then compared to the location from the pile. It may then be estimated whether the animal was exposed to sound levels constituting incidental harassment on the basis of predicted distances to relevant thresholds in post-processing of observational data, and a precise accounting of observed incidents of harassment created. This information may then be used to extrapolate observed takes to reach an approximate understanding of actual total takes, in cases where the entire zone was not monitored.     Monitoring Protocols--Monitoring would be conducted before, during, and after pile driving activities. In addition, observers will record all incidents of marine mammal occurrence, regardless of distance from activity, and monitors will document any behavioral reactions in concert with distance from piles being driven. Observations made

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outside the shutdown zone will not result in shutdown; that pile segment will be completed without cessation, unless the animal approaches or enters the shutdown zone, at which point all pile driving activities would be halted. Monitoring will take place from 15 minutes prior to initiation through 30 minutes post-completion of pile driving activities. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.     The following additional measures apply to visual monitoring:     (1) Monitoring will be conducted by qualified, trained protected species observers, who will be placed at the best vantage point(s) practicable (i.e , from a small boat, construction barges, on shore, or any other suitable location) to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Observers would have no other construction-related tasks while conducting monitoring. Observers should have the following minimum qualifications:      Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;      Ability to conduct field observations and collect data according to assigned protocols;      Experience or training in the field identification of marine mammals, including the identification of behaviors;      Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;      Writing skills sufficient to document observations including, but not limited to: The number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury of marine mammals from construction noise within a defined shutdown zone; and marine mammal behavior; and      Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.     Observer teams employed by the Navy in satisfaction of the mitigation and monitoring requirements described herein must meet the following additional requirements:      Independent observers (i.e , not construction personnel) are required.      At least one observer must have prior experience working as an observer.      Other observers may substitute education (degree in biological science or related field) or training for experience.      Where a team of three or more observers are required, one observer should be designated as lead observer or monitoring coordinator. The lead observer must have prior experience working as an observer.      We will require submission and approval of observer CVs.     (2) Prior to the start of pile driving activity, the shutdown zone will be monitored for 15 minutes to ensure that it is clear of marine mammals. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals; animals will be allowed to remain in the shutdown zone (i.e , must leave of their own volition), and their behavior will be monitored and documented. The shutdown zone may only be declared clear, and pile driving started, when the entire shutdown zone is visible (i.e , when not obscured by dark, rain, fog, etc.). In addition, if such conditions should arise during impact pile driving that is already underway, the activity would be halted.     (3) If a marine mammal approaches or enters the shutdown zone during the course of pile driving operations, activity will be halted and delayed until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of the animal. Monitoring will be conducted throughout the time required to drive a pile and for thirty minutes following the conclusion of pile driving.

Soft Start

    The use of a soft start procedure is believed to provide additional protection to marine mammals by warning marine mammals or providing them with a chance to leave the area prior to the hammer operating at full capacity, and typically involves a requirement to initiate sound from the hammer at reduced energy followed by a waiting period. This procedure is repeated two additional times. It is difficult to specify the reduction in energy for any given hammer because of variation across drivers and, for impact hammers, the actual number of strikes at reduced energy will vary because operating the hammer at less than full power results in ``bouncing'' of the hammer as it strikes the pile, resulting in multiple ``strikes.'' The Navy will utilize soft start techniques for impact pile driving. We require an initial set of three strikes from the impact hammer at reduced energy, followed by a 30- second waiting period, then 2 subsequent 3-strike sets. Soft start will be required at the beginning of each day's impact pile driving work and at any time following a cessation of impact pile driving of thirty minutes or longer; the requirement to implement soft start for impact driving is independent of whether vibratory driving has occurred within the prior 30 minutes.

Bubble Curtain

    Sound levels can be greatly reduced during impact pile driving using sound attenuation devices, including bubble curtains, which create a column of air bubbles rising around a pile from the substrate to the water surface. The air bubbles absorb and scatter sound waves emanating from the pile, thereby reducing the sound energy. Bubble curtains may be confined or unconfined. Cushion blocks are also commonly used by construction contractors in order to protect equipment and the driven pile; use of cushion blocks typically reduces emitted sound pressure levels to some extent.     The literature presents a wide array of observed attenuation results for bubble curtains (see Appendix B of the Navy's application). The variability in attenuation levels is due to variation in design, as well as differences in site conditions and difficulty in properly installing and operating in-water attenuation devices. As a general rule, reductions of greater than 10 dB cannot be reliably predicted. Prior monitoring by the Navy during a project at NBK Bangor reported a range of measured values for realized attenuation mostly within 6 to 12 dB, but with an overall average of 9 dB in effective attenuation (Illingworth and Rodkin, 2012).     The Navy would use a bubble curtain during impact driving of all steel piles greater than 14-in diameter in water depths greater than 2 ft (0.67 m), except at NBK Bremerton and Keyport. Bubble curtains are not proposed for use during impact driving of smaller steel piles or other pile types due to the relatively low source levels, as the requirement to deploy the curtain system at each driven pile results in a significantly lower production rate. Where a bubble curtain is used, the contractor would be required to turn it on prior to the soft start in order to flush fish from the area closest to the driven pile.     Bubble curtains cannot be used at NBK Bremerton and Keyport due to the

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risk of disturbing contaminated sediments at these sites. Sediment contamination within Sinclair Inlet, including the project areas at NBK Bremerton, includes a variety of metals and organic chemicals originating from human sources. The marine sediments have been affected by past shipyard operations, leaching from creosote-treated piles, and other activities in Sinclair Inlet. Sediments at the project sites and adjacent to the piers at Bremerton have a pollution control plan for various metals, polycyclic aromatic hydrocarbons, polychlorinated biphenyls, and other semivolatile organic compounds (SVOC), and active cleanup is occurring pursuant to the terms of an agreement developed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) in cooperation with the U.S Environmental Protection Agency and the Washington Department of Ecology. The sediment at and near Keyport in Liberty Bay also has a pollution control plan, for multiple heavy metals, polychlorinated aromatic hydrocarbons, phthalates, and various other SVOCs.     To avoid loss of attenuation from design and implementation errors, the Navy will require specific bubble curtain design specifications, including testing requirements for air pressure and flow at each manifold ring prior to initial impact hammer use, and a requirement for placement on the substrate. The bubble curtain must distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column. The lowest bubble ring shall be in contact with the mudline for the full circumference of the ring, and the weights attached to the bottom ring shall ensure 100 percent mudline contact. No parts of the ring or other objects shall prevent full mudline contact. The contractor shall also train personnel in the proper balancing of air flow to the bubblers, and must submit an inspection/ performance report to the Navy for approval within 72 hours following the performance test. Corrections to the noise attenuation device to meet the performance standards shall occur prior to use for impact driving.     We have carefully evaluated the Navy's proposed mitigation measures and considered a range of other measures in the context of ensuring that we prescribed the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of these measures, we have preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses.

Proposed Monitoring and Reporting

    In order to issue an LOA for an activity, Section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of the authorized taking. NMFS's MMPA implementing regulations further describe the information that an applicant should provide when requesting an authorization (50 CFR 216.104(a)(13)), including the means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and the level of taking or impacts on populations of marine mammals.     Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:      Occurrence of significant interactions with marine mammal species in action area (e.g , animals that came close to the vessel, contacted the gear, or are otherwise rare or displaying unusual behavior).      Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (e.g , source characterization, propagation, ambient noise); (2) affected species (e.g , life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (e.g , age, calving or feeding areas).      Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors.      How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks.      Effects on marine mammal habitat (e.g , marine mammal prey species, acoustic habitat, or important physical components of marine mammal habitat).      Mitigation and monitoring effectiveness.

Coordination and Plan Development

    An installation-specific marine mammal monitoring plan for each year's anticipated work will be developed by the Navy and presented in March of each year for approval by NMFS prior to the start of construction. Final monitoring plans will be prepared and submitted to NMFS within 30 days following receipt of comments on the draft plans from NMFS. Please see Appendix D of the Navy's application for a marine mammal monitoring plan template. During each in-water work period covered by an LOA, the Navy would update NMFS every two months on the progress of ongoing projects (September 15, November 15, and January 15).

Visual Marine Mammal Observations

    The Navy will collect sighting data and behavioral responses to pile driving activity for marine mammal species observed in the region of activity during the period of activity. The number and location of required observers would be determined specific to each installation on an annual basis, depending on the nature of work anticipated (including the size of zones to be monitored). All observers will be trained in marine mammal identification and behaviors and are required to have no other construction-related tasks while conducting monitoring. The Navy would monitor all shutdown zones at all times, and would monitor disturbance zones to the extent practicable (some zones are too large to fully observe (Table 7)). The Navy would conduct monitoring before, during, and after pile driving, with observers located at the best practicable vantage points.     As described in ``Proposed Mitigation'' and based on our requirements, the Navy would implement the following procedures for pile driving:      Marine mammal observers would be located at the best vantage point(s) in order to properly see the entire shutdown zone and as much of the disturbance zone as possible.      During all observation periods, observers will use binoculars and the naked eye to search continuously for marine mammals.      If the shutdown zones are obscured by fog or poor lighting conditions, pile driving at that location will not be initiated until that zone is visible. Should such conditions arise while impact driving is underway, the activity would be halted.      The shutdown zone around the pile would be monitored for the presence of marine mammals before, during, and

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after all pile driving activity, while disturbance zone monitoring would be implemented according to the schedule proposed here.     Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Any modifications to the protocol will be coordinated between NMFS and the Navy.

Data Collection

    We require that observers use standardized data forms. Among other pieces of information, the Navy will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and a description of specific actions that ensued and resulting behavior of the animal, if any. We require that, at a minimum, the following information be collected on the sighting forms:      Date and time that monitored activity begins or ends;      Construction activities occurring during each observation period;      Weather parameters (e.g , wind speed, percent cloud cover, visibility);      Water conditions (e.g , sea state, tide state);      Species, numbers, and, if possible, sex and age class of marine mammals;      Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;      Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;      Description of implementation of mitigation measures (e.g , shutdown or delay).      Locations of all marine mammal observations; and      Other human activity in the area.     The Navy will note in behavioral observations, to the extent practicable, if an animal has remained in the area during construction activities. Therefore, it may be possible to identify if the same animal or different individuals are being exposed.

Acoustic Monitoring

    The Navy will conduct hydroacoustic monitoring for a subset of impact-driven steel piles for projects including more than three piles where a bubble curtain is used. The USFWS has imposed requirements relating to impact driving of steel piles, including restrictions on unattenuated driving of such piles, as a result of concern regarding impacts to the ESA-listed marbled murrelet. If USFWS allows the Navy to conduct minimal driving of steel piles without the use of the bubble curtain, baseline sound measurements of steel pile driving will occur prior to the implementation of noise attenuation to evaluate the performance of the device. Impact pile driving without noise attenuation would be limited to the number of piles necessary to obtain an adequate sample size for each project.

Marine Mammal Surveys

    Subject to funding availability, the Navy would continue pinniped haul-out survey counts at specific installations. Biologists conduct counts of seals and sea lions at NBK Bremerton, Bangor, Manchester, and NS Everett. Counts are conducted several times per month, depending on the installation. All animals are identified to species where possible. This information aids in determination of seasonal use of each site and trends in the number of animals.

Reporting

    A draft report would be submitted to NMFS within 90 days of the completion of monitoring for each installation's in-water work window. The report will include marine mammal observations pre-activity, during-activity, and post-activity during pile driving days, and will also provide descriptions of any behavioral responses to construction activities by marine mammals and a complete description of all mitigation shutdowns and the results of those actions and an extrapolated total take estimate based on the number of marine mammals observed during the course of construction. A final report must be submitted within 30 days following resolution of comments on the draft report. The Navy would also submit a comprehensive annual summary report covering all activities conducted under the incidental take regulations.

Negligible Impact Analysis and Determination

    NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (i.e , population- level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ``taken'' by mortality, serious injury, and Level A or Level B harassment, we consider other factors, such as the likely nature of any behavioral responses (e.g , intensity, duration), the context of any such responses (e.g , critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (e.g , as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, and specific consideration of take by M/SI previously authorized for other NMFS research activities).     Pile driving activities associated with the maintenance projects, as described previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment (behavioral disturbance) only (for all species other than the harbor seal) from underwater sounds generated from pile driving. Potential takes could occur if individual marine mammals are present in the ensonified zone when pile driving is happening.     No serious injury or mortality would be expected even in the absence of the proposed mitigation measures. For all species other than the harbor seal, no Level A harassment is anticipated given the nature of the activities, i.e , much of the anticipated activity would involve vibratory driving and/or installation of small-diameter, non-steel piles, and measures designed to minimize the possibility of injury. The potential for injury is small for cetaceans and sea lions, and is expected to be essentially eliminated through implementation of the planned mitigation measures--use of the bubble curtain for larger steel piles at most installations, soft start (for impact driving), and shutdown zones. Impact driving, as compared with vibratory driving, has source characteristics (short, sharp pulses with higher peak levels and much sharper rise time to reach those peaks) that are potentially injurious or more likely to produce severe behavioral reactions. Given sufficient notice through use of soft start, marine mammals are expected

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to move away from a sound source that is annoying prior to its becoming potentially injurious or resulting in more severe behavioral reactions. Environmental conditions in inland waters are expected to generally be good, with calm sea states, and we expect conditions would allow a high marine mammal detection capability, enabling a high rate of success in implementation of shutdowns to avoid injury.     As described previously, there are multiple species that should be considered rare in the proposed project areas and for which we propose to authorize only nominal and precautionary take of a single group for a minimal period of time (two days). Therefore, we do not expect meaningful impacts to these species (i.e , humpback whale, gray whale, minke whale, transient and resident killer whales, and northern elephant seal) and preliminarily find that the total marine mammal take from each of the specified activities will have a negligible impact on these marine mammal species.     For remaining species, we discuss the likely effects of the specified activities in greater detail. Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (e.g , Thorson and Reyff, 2006; HDR, Inc., 2012; Lerma, 2014). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities conducted in San Francisco Bay and in the Puget Sound region, which have taken place with no known long-term adverse consequences from behavioral harassment.     The Navy has conducted multi-year activities potentially affecting marine mammals, and typically involving greater levels of activity than is contemplated here in various locations such as San Diego Bay and some of the installations considered herein (NBK Bangor and NBK Bremerton). Reporting from these activities has similarly reported no apparently consequential behavioral reactions or long-term effects on marine mammal populations (Lerma, 2014; Navy, 2016). Repeated exposures of individuals to relatively low levels of sound outside of preferred habitat areas are unlikely to significantly disrupt critical behaviors. Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in viability for the affected individuals, and thus would not result in any adverse impact to the stock as a whole. Level B harassment will be reduced to the level of least practicable adverse impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring. While vibratory driving associated with some project components may produce sound at distances of many kilometers from the pile driving site, thus intruding on higher-quality habitat, the project sites themselves and the majority of sound fields produced by the specified activities are within industrialized areas. Therefore, we expect that animals annoyed by project sound would simply avoid the area and use more-preferred habitats.     In addition to the expected effects resulting from authorized Level B harassment, we anticipate that harbor seals may sustain some limited Level A harassment in the form of auditory injury at two locations (NBK Bangor and NS Everett), assuming they remain within a given distance of the pile driving activity for the full number of pile strikes. However, seals in these locations that experience PTS would likely only receive slight PTS, i.e minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by pile driving, i.e the low-frequency region below 2 kHz, not severe hearing impairment or impairment in the regions of greatest hearing sensitivity. If hearing impairment occurs, it is most likely that the affected animal would lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics. As described above, we expect that marine mammals would be likely to move away from a sound source that represents an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice through use of soft start.     In summary, this negligible impact analysis is founded on the following factors: (1) The possibility of serious injury or mortality may reasonably be considered discountable; (2) as a result of the nature of the activity in concert with the planned mitigation requirements, injury is not anticipated for any species other than the harbor seal; (3) the anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior; (4) the additional impact of PTS of a slight degree to few individual harbor seals at two locations is not anticipated to increase individual impacts to a point where any population-level impacts might be expected; (5) the absence of any significant habitat within the industrialized project areas, including known areas or features of special significance for foraging or reproduction; and (6) the presumed efficacy of the proposed mitigation measures in reducing the effects of the specified activity to the level of least practicable adverse impact.     In addition, although affected humpback whales may be from DPSs that are listed under the ESA, and southern resident killer whales are depleted under the MMPA as well as listed as endangered under the ESA, it is unlikely that minor noise effects in a small, localized area of sub-optimal habitat would have any effect on the stocks' ability to recover. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.     Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, we preliminarily find that the total marine mammal take from the Navy's maintenance construction activities will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

    As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(A) of the MMPA for specified activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such

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as the temporal or spatial scale of the activities.     Please see Table 9 for information relating to this small numbers analysis. We propose to authorize incidental take of 12 marine mammal stocks. The total amount of taking proposed for authorization is less than one percent for five of these, less than five percent for an additional two stocks, and less than ten percent for another stock, all of which we consider relatively small percentages and we preliminarily find are small numbers of marine mammals relative to the estimated overall population abundances for those stocks.     For the southern resident killer whale (in addition to the humpback whale, gray whale, minke whale, transient killer whale, and northern elephant seal), we propose to authorize take resulting from a brief exposure of one group of the stock. We believe that a single incident of take of one group of any of these species represents take of small numbers for that species.     For the two affected stocks of harbor seal (Hood Canal and Northern Inland Waters), no valid abundance estimate is available. The most recent abundance estimates for harbor seals in Washington inland waters are from 1999, and it is generally believed that harbor seal populations have increased significantly during the intervening years (e.g , Mapes, 2013). However, we anticipate that takes estimated to occur for harbor seals are likely to occur only within some portion of the relevant populations, rather than to animals from the stock as a whole. For example, takes anticipated to occur at NBK Bangor or at NS Everett would be expected to accrue to the same individual seals that routinely occur on haul-outs at these locations, rather than occurring to new seals on each construction day. Similarly, at Zelatched Point in Hood Canal many known haul-outs are at locations elsewhere in Hood Canal and, although a density estimate rather than haul-out count is used to inform the exposure estimate for Zelatched Point, we expect that exposed individuals would comprise some limited portion of the overall stock abundance. In summary, harbor seals taken as a result of the specified activities at each of the six installations are expected to comprise only a limited portion of individuals comprising the overall relevant stock abundance. Therefore, we preliminarily find that small numbers of marine mammals will be taken relative to the population size of both the Hood Canal and Northern Inland Waters stocks of harbor seal.     The estimated taking for harbor porpoise comprises greater than one-third of the best available stock abundance. However, due to the nature of the specified activity--construction activities occurring at six specific locations, rather than a mobile activity occurring throughout the stock range--the available information shows that only a portion of the stock would likely be impacted. Recent aerial surveys (2013-2016) that inform the current abundance estimate for harbor porpoise involved effort broken down by region and subregion. According to the data available as a result of these surveys, the vast majority of harbor porpoise abundance occurs in the ``northern waters'' region, including the San Juan Islands and Strait of Juan de Fuca, where no Navy construction activity is proposed to occur. The six installations considered here occur within the Hood Canal, North Puget Sound, and South Puget Sound regions, which contain approximately 24 percent of stock-wide harbor porpoise abundance (Jefferson et al., 2016). Therefore, we assume that affected individuals would most likely be from the 24 percent of the stock expected to occur in these regions. This figure itself may be an overestimate, as Navy facilities are located within only three of seven subregions within the North and South Puget Sound regions (i.e , East Whidbey, Bainbridge, and Vashon). However, at this finer scale, it is possible that harbor porpoise individuals transit across subregions. In consideration of this conservative scenario, i.e , that 24 percent of the stock abundance is taken, we preliminarily find that small numbers of marine mammals will be taken relative to the population size of the Washington inland waters stock of harbor porpoise.     Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population sizes of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

    There are no relevant subsistence uses of marine mammals implicated by these actions. Therefore, we have determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Adaptive Management

    The regulations governing the take of marine mammals incidental to Navy maintenance construction activities would contain an adaptive management component.     The reporting requirements associated with this proposed rule are designed to provide NMFS with monitoring data from the previous year to allow consideration of whether any changes are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or ***deletions***). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.     The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring reports, as required by MMPA authorizations; (2) results from general marine mammal and sound research; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs.

Endangered Species Act (ESA)

    The southern resident killer whale, as well as multiple DPSs of humpback whale, are listed under the ESA (see Table 3). The proposed authorization of incidental take pursuant to the Navy's specified activity would not affect any designated critical habitat. OPR has initiated consultation with NMFS's West Coast Regional Office under section 7 of the ESA on the promulgation of five-year regulations and the subsequent issuance of LOAs to the Navy under section 101(a)(5)(A) of the MMPA. This consultation will be concluded prior to issuing any final rule.

Request for Information

    NMFS requests interested persons to submit comments, information, and suggestions concerning the Navy request and the proposed regulations (see ADDRESSES). All comments will be reviewed and evaluated as we prepare a final rule and make final determinations on whether to issue the requested authorization. This notice and referenced documents provide all environmental information relating to our proposed action for public review.

Classification

    Pursuant to the procedures established to implement Executive

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Order 12866, the Office of Management and Budget has determined that this proposed rule is not significant. Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The U.S Navy is the sole entity that would be subject to the requirements in these proposed regulations, and the Navy is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. Because of this certification, a regulatory flexibility analysis is not required and none has been prepared.     This proposed rule does not contain a collection-of-information requirement subject to the provisions of the Paperwork Reduction Act (PRA) because the applicant is a federal agency. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number. These requirements have been approved by OMB under control number 0648-0151 and include applications for regulations, subsequent LOAs, and reports.

List of Subjects in 50 CFR Part 218

    Exports, Fish, Imports, Indians, Labeling, Marine mammals, Penalties, Reporting and recordkeeping requirements, Seafood, Transportation.

    Dated: February 23, 2018. Samuel D. Rauch III, Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.     For reasons set forth in the preamble, 50 CFR part 218 is proposed to be amended as follows:

PART 218--REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

0 1. The authority citation for part 218 continues to read as follows:

    Authority:  16 U.S.C 1361 et seq.

0 2. Add subpart C to part 218 to read as follows:

Subpart C--Taking Marine Mammals Incidental to U.S Navy Marine Structure Maintenance and Pile Replacement in Washington

Sec. 218.20 Specified activity and specified ***geographical*** region. 218.21 Effective dates. 218.22 Permissible methods of taking. 218.23 Prohibitions. 218.24 Mitigation requirements. 218.25 Requirements for monitoring and reporting. 218.26 Letters of Authorization. 218.27 Renewals and modifications of Letters of Authorization. 218.28 [Reserved] 218.29 [Reserved]

Sec.  218.20   Specified activity and specified ***geographical*** region.

    (a) Regulations in this subpart apply only to the U.S Navy (Navy) and those persons it authorizes or funds to conduct activities on its behalf for the taking of marine mammals that occurs in the areas outlined in paragraph (b) of this section and that occurs incidental to maintenance construction activities.     (b) The taking of marine mammals by the Navy may be authorized in a Letter of Authorization (LOA) only if it occurs within Washington inland waters in the vicinity of one of the following six naval installations: Naval Base Kitsap Bangor, Zelatched Point, Naval Base Kitsap Bremerton, Naval Base Kitsap Keyport, Naval Base Kitsap Manchester, and Naval Station Everett.

Sec.  218.21   Effective dates.

    Regulations in this subpart are effective from [EFFECTIVE DATE OF FINAL RULE] through [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

Sec.  218.22   Permissible methods of taking.

    Under LOAs issued pursuant to Sec.  216.106 of this chapter and Sec.  218.26, the Holder of the LOA (hereinafter ``Navy'') may incidentally, but not intentionally, take marine mammals within the area described in Sec.  218.20(b) by Level A or Level B harassment associated with maintenance construction activities, provided the activity is in compliance with all terms, conditions, and requirements of the regulations in this subpart and the appropriate LOA.

Sec.  218.23   Prohibitions.

    Notwithstanding takings contemplated in Sec.  218.22 and authorized by a LOA issued under Sec.  216.106 of this chapter and Sec.  218.26, no person in connection with the activities described in Sec.  218.20 may:     (a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or a LOA issued under Sec.  216.106 of this chapter and Sec.  218.26;     (b) Take any marine mammal not specified in such LOAs;     (c) Take any marine mammal specified in such LOAs in any manner other than as specified;     (d) Take a marine mammal specified in such LOAs if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal; or     (e) Take a marine mammal specified in such LOAs if NMFS determines such taking results in an unmitigable adverse impact on the species or stock of such marine mammal for taking for subsistence uses.

Sec.  218.24   Mitigation requirements.

    When conducting the activities identified in Sec.  218.20(a), the mitigation measures contained in any LOA issued under Sec.  216.106 of this chapter and Sec.  218.26 must be implemented. These mitigation measures shall include but are not limited to:     (a) General conditions:     (1) A copy of any issued LOA must be in the possession of the Navy, its designees, and work crew personnel operating under the authority of the issued LOA.     (2) The Navy shall conduct briefings for construction supervisors and crews, the monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, the marine mammal monitoring protocol, and operational procedures.     (b) Shutdown zones:     (1) For all pile driving activity, the Navy shall implement a minimum shutdown zone of a 10 m radius around the pile. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.     (2) For all pile driving activity, the Navy shall implement shutdown zones with radial distances as identified in any LOA issued under Sec.  216.106 of this chapter and Sec.  218.26 If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.     (3) For all pile driving activity, the Navy shall designate monitoring zones with radial distances as identified in any LOA issued under Sec.  216.106 of this chapter and Sec.  218.26 Anticipated observable zones within the designated monitoring zones shall be identified in annual Marine Mammal Monitoring Plans, subject to approval by NMFS. If

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any cetacean is observed outside the shutdown zone identified pursuant to Sec.  218.24(b)(1)-(2) of this subpart, but within the designated monitoring zone, such operations shall cease.     (c) Shutdown protocols:     (1) The Navy shall deploy marine mammal observers as indicated in annual Marine Mammal Monitoring Plans, which shall be subject to approval by NMFS, and as described in Sec.  218.25     (2) For all pile driving activities, a minimum of one observer shall be stationed at the active pile driving rig or in reasonable proximity in order to monitor the shutdown zone.     (3) Monitoring shall take place from 15 minutes prior to initiation of pile driving activity through 30 minutes post-completion of pile driving activity. Pre-activity monitoring shall be conducted for 15 minutes to ensure that the shutdown zone is clear of marine mammals, and pile driving may commence when observers have declared the shutdown zone clear of marine mammals. In the event of a delay or shutdown of activity resulting from marine mammals in the shutdown zone, animals shall be allowed to remain in the shutdown zone (i.e , must leave of their own volition) and their behavior shall be monitored and documented. Monitoring shall occur throughout the time required to drive a pile. A determination that the shutdown zone is clear must be made during a period of good visibility (i.e , the entire shutdown zone and surrounding waters must be visible to the naked eye).     (4) If a marine mammal approaches or enters the shutdown zone, all pile driving activities at that location shall be halted. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of the animal.     (5) Monitoring shall be conducted by trained observers, who shall have no other assigned tasks during monitoring periods. Trained observers shall be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator. The Navy shall adhere to the following additional observer qualifications:     (i) Independent observers (i.e , not construction personnel) are required.     (ii) At least one observer must have prior experience working as an observer.     (iii) Other observers may substitute education (degree in biological science or related field) or training for experience.     (iv) Where a team of three or more observers are required, one observer shall be designated as lead observer or monitoring coordinator. The lead observer must have prior experience working as an observer.     (v) The Navy shall submit observer CVs for approval by NMFS.     (d) The Navy shall use soft start techniques for impact pile driving. Soft start for impact drivers requires contractors to provide an initial set of three strikes at reduced energy, followed by a thirty-second waiting period, then two subsequent reduced energy three- strike sets. Soft start shall be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of thirty minutes or longer.     (e) The Navy shall employ a bubble curtain (or other sound attenuation device with proven typical performance of at least 8 decibels effective attenuation) during impact pile driving of steel piles greater than 14 inches diameter in water depths greater than 2 feet, except at Naval Base Kitsap Bremerton and Naval Base Kitsap Keyport. In addition, the Navy shall implement the following performance standards:     (1) The bubble curtain must distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column.     (2) The lowest bubble ring shall be in contact with the mudline for the full circumference of the ring, and the weights attached to the bottom ring shall ensure 100 percent mudline contact. No parts of the ring or other objects shall prevent full mudline contact.     (3) The Navy shall require that construction contractors train personnel in the proper balancing of air flow to the bubblers, and shall require that construction contractors submit an inspection/ performance report for approval by the Navy within 72 hours following the performance test. Corrections to the attenuation device to meet the performance standards shall occur prior to impact driving.

Sec.  218.25   Requirements for monitoring and reporting.

    (a) Not later than March 1 of each year, the Navy shall develop and submit for NMFS's approval an installation-specific Marine Mammal Monitoring Plan for each year's anticipated work. Final monitoring plans shall be prepared and submitted to NMFS within 30 days following receipt of comments on the draft plans from NMFS.     (b) During each in-water work period, the Navy shall update NMFS every two months on the progress of ongoing projects.     (c) Trained observers shall receive a general environmental awareness briefing conducted by Navy staff. At minimum, training shall include identification of marine mammals that may occur in the project vicinity and relevant mitigation and monitoring requirements. All observers shall have no other construction-related tasks while conducting monitoring.     (d) For shutdown zone monitoring, the Navy shall report on implementation of shutdown or delay procedures, including whether the procedures were not implemented and why (when relevant).     (e) The Navy shall deploy additional observers to monitor disturbance zones according to the minimum requirements defined in annual Marine Mammal Monitoring Plans, subject to approval by NMFS. These observers shall collect sighting data and behavioral responses to pile driving for marine mammal species observed in the region of activity during the period of activity, and shall communicate with the shutdown zone observer as appropriate with regard to the presence of marine mammals. All observers shall be trained in identification and reporting of marine mammal behaviors.     (f) Reporting:     (1) Annual reporting:     (i) Navy shall submit an annual summary report to NMFS not later than 90 days following the end of construction during each in-water work period. Navy shall provide a final report within 30 days following resolution of comments on the draft report.     (ii) These reports shall contain, at minimum, the following:     (A) Date and time that monitored activity begins or ends;     (B) Construction activities occurring during each observation period;     (C) Weather parameters (e.g , wind speed, percent cloud cover, visibility);     (D) Water conditions (e.g , sea state, tide state);     (E) Species, numbers, and, if possible, sex and age class of marine mammals;     (F) Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;     (G) Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;

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    (H) Description of implementation of mitigation measures (e.g , shutdown or delay);     (I) Locations of all marine mammal observations; and     (J) Other human activity in the area.     (2) Navy shall submit a comprehensive summary report to NMFS not later than ninety days following the conclusion of marine mammal monitoring efforts described in this subpart.     (g) Reporting of injured or dead marine mammals:     (1) In the unanticipated event that the activity defined in Sec.   218.20 clearly causes the take of a marine mammal in a prohibited manner, Navy shall immediately cease such activity and report the incident to the Office of Protected Resources (OPR), NMFS, and to the West Coast Regional Stranding Coordinator, NMFS. Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with Navy to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Navy may not resume their activities until notified by NMFS. The report must include the following information:     (i) Time, date, and location (latitude/longitude) of the incident;     (ii) Description of the incident;     (iii) Environmental conditions (e.g , wind speed and direction, Beaufort sea state, cloud cover, visibility);     (iv) Description of all marine mammal observations in the 24 hours preceding the incident;     (v) Species identification or description of the animal(s) involved;     (vi) Fate of the animal(s); and     (vii) Photographs or video footage of the animal(s). Photographs may be taken once the animal has been moved from the waterfront area.     (2) In the event that Navy discovers an injured or dead marine mammal and determines that the cause of the injury or death is unknown and the death is relatively recent (e.g , in less than a moderate state of decomposition), Navy shall immediately report the incident to OPR and the West Coast Regional Stranding Coordinator, NMFS. The report must include the information identified in paragraph (g)(1) of this section. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Navy to determine whether additional mitigation measures or modifications to the activities are appropriate.     (3) In the event that Navy discovers an injured or dead marine mammal and determines that the injury or death is not associated with or related to the activities defined in Sec.  218.20 (e.g , previously wounded animal, carcass with moderate to advanced decomposition, scavenger damage), Navy shall report the incident to OPR and the West Coast Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. Navy shall provide photographs or video footage or other documentation of the stranded animal sighting to NMFS. Photographs may be taken once the animal has been moved from the waterfront area.

Sec.  218.26   Letters of Authorization.

    (a) To incidentally take marine mammals pursuant to these regulations, the Navy must apply for and obtain an LOA.     (b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of these regulations.     (c) If an LOA expires prior to the expiration date of these regulations, the Navy may apply for and obtain a renewal of the LOA.     (d) In the event of projected changes to the activity or to mitigation and monitoring measures required by an LOA, the Navy must apply for and obtain a modification of the LOA as described in Sec.   218.27     (e) The LOA shall set forth:     (1) Permissible methods of incidental taking;     (2) Means of effecting the least practicable adverse impact (i.e , mitigation) on the species, its habitat, and on the availability of the species for subsistence uses; and     (3) Requirements for monitoring and reporting.     (f) Issuance of the LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations.     (g) Notice of issuance or denial of an LOA shall be published in the Federal Register within thirty days of a determination.

Sec.  218.27   Renewals and modifications of Letters of Authorization.

    (a) An LOA issued under Sec.  216.106 of this chapter and Sec.   218.26 for the activity identified in Sec.  218.20(a) shall be renewed or modified upon request by the applicant, provided that:     (1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section), and     (2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA under these regulations were implemented.     (b) For LOA modification or renewal requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the Federal Register, including the associated analysis of the change, and solicit public comment before issuing the LOA.     (c) An LOA issued under Sec.  216.106 of this chapter and Sec.   218.26 for the activity identified in Sec.  218.20(a) may be modified by NMFS under the following circumstances:     (1) Adaptive Management--NMFS may modify (including augment) the existing mitigation, monitoring, or reporting measures (after consulting with the Navy regarding the practicability of the modifications) if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations.     (i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA:     (A) Results from the Navy's monitoring from the previous year(s).     (B) Results from other marine mammal and/or sound research or studies.     (C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by these regulations or subsequent LOAs.     (ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of proposed LOA in the Federal Register and solicit public comment.

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    (2) Emergencies--If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to Sec.  216.106 of this chapter and Sec.  218.26, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the Federal Register within thirty days of the action.

Sec.  218.28   [Reserved]

Sec.  218.29   [Reserved]

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[***The Human Conditioning: International Law and Science-Fiction***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:6BNK-CF41-DY41-72F3-00000-00&context=1516831)

Law, Culture and the Humanities

February 2018

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**ABSTRACT**

This article introduces the subject-matter of a symposium on international law and science-fiction. The impact of new technologies on human rights, humanitarian issues and indeed on what it means to be human in a technological age, suffers from a paucity of international legal attention. The latter has been attributed to various factors ranging from technophobia and technological illiteracy, inclusive of an instrumentalist view of technology, to the sense that such attention is the domain of science-fiction, not of international law. The article extends an invitation to pay attention to the attention science-fiction has given to the man-machine interaction and its impact on the human condition. Placing this invitation in the context of the ‘‘law and literature’’ movement, the article exemplifies its value with respect to two technologies, one directed at creating life or saving it (cloning and organ donation) and the other at ending life (lethal autonomous robots).

**FULL TEXT**

**I. Introduction**

“Law”, as Clifford Geertz famously observed, is “a distinctive way of imagining the real.’’1 This article extends an invitation to engage the international legal imagination relative to scientific developments. It presents a three-fold proposition: first, there are significant discrepancies in certain key areas between the observed world and international rules purporting to regulate it. These discrepancies reflect a failure of international law to consider both the nature of technological innovations and their impact on its basic presuppositions. Such consideration is a prelude for a search for new regulative frameworks, and may suggest that the time is ripe for a paradigmatic shift. Second, resistance to change, while expected and understandable, may be too costly: interpretative maneuvers designed to impose traditional rules – and their underlying presuppositions and narratives – on a reality which ultimately defies them, may render our normative, ethical and political discourses subservient to technology and to the latter’s modes of thinking.2 Respect for scientific ‘‘know how’’ is no substitute for critical sensibilities directed at the ‘‘why’’ and the ‘‘what for.’’ This is so because, as Hannah Arendt observed already in the late 1950s, if it should turn out to be true that knowledge (in the modern sense of know-how) and thought have parted company for good, then we would indeed become the helpless slaves, not so much of our machines as of our know-how, thoughtless creatures at the mercy of every gadget which is technically possible, no matter how murderous it is.3

Arendt chose to describe, in the opening paragraphs of the prologue to *The Human Condition*, the popular reaction to the 1957 Soviet launching of the first satellite as a sense of relief at having achieved the first ‘‘step toward escape from men’s imprisonment to the earth.’’ Such feelings, says Arendt, have been commonplace for some time. They show that men … are by no means slow to catch up and adjust to scientific discoveries and technological developments, but that on the contrary, they have out-sped them by decades. Here as in other respects, science has realized and affirmed what men anticipated in dreams that were neither wild nor idle. What is new is that one of the country’s most respectable newspapers finally brought to its front page what up to then has been *buried in the highly non-respectable literature of science fiction (to which, unfortunately, nobody yet has paid the attention it deserves …*).4

The third proposition advanced in this article is that the time has come to pay such attention; that the international legal imagination may well benefit from dipping its stately toes in this ostensibly less reputable pond. This is so not because science-fiction provides answers, but because the best of this genre does not settle for describing a fictional world different in time and space from our own; it invites us to consider what difference such differences make.5 Such consideration challenges the instrumentalist perception of technological innovations as mere means to progressive ends.6

Inviting international law to the world of imaginative literature in general and to science-fiction in particular appears neither self-evident nor self-explanatory. Part II discusses the merits of this invitation, placing it in the context of the ‘‘law and literature’’ movement. Part III seeks to ignite the international legal imagination regarding the implications of technological innovations on our understanding of what it means to be human, focusing on two issues: organ donation and the use of cloning technology for therapeutic and reproductive purposes, and the military development of lethal autonomous robots (LARs). International law is yet to address adequately the nature and implications of these technologies. Science-fiction texts, however, have not merely anticipated these developments but have also insightfully contemplated their ontology and effects on a myriad of issues. They may well provide an inspirational source for the regeneration of legal scholarship. Such regeneration, as Part IV posits by way of conclusion, is required lest we succumb to the banality of technological neutrality conditioning the human condition.

**II. International Law and Science-Fiction**

**1 Law and literature**

Literature has been fascinated by, and occasionally symbiotic with law, since time immemorial.7 Given that literature is, and perceives itself to be not merely an aesthetic, but also an ethical endeavor, this is not surprising. Law, however, was otherwise preoccupied. It began to notice that it, too, speaks prose only pursuant to its failure to affiliate itself with science. From the perspective of legal scholarship, literature becomes a subject of interest as a late, somewhat unexpected offspring of American legal realism in the early 1970s, with James Boyd White’s *The Legal Imagination*.8

Bearing in mind that Cleo is not very amenable to linear containment, it is nevertheless useful to note that the marriage of law and literature produced an interdisciplinary project consisting of three successive movements: ‘‘law in literature’’; ‘‘law as literature’’ and legal story-telling, or what could be termed ‘‘narrato*law*gy.’’9 ‘‘Law in literature’’ is engaged with the representation of law and lawyers in imaginative literature. ‘‘Law as literature’’ is an essentially hermeneutic movement, interested is subjecting legal texts to interpretive methods developed in literary theory.10 The power of law to tell a particular story (and the exposition of stories it is silent about) is the focus of the ‘‘narrato*law*gy’’ movement.11 The latter, in effect, proposes that law is literature, a particular literary genre.

Taxonomic elegance notwithstanding, these movements often intersect. Nevertheless, reflecting as they surely do, liberal as well as critical and post-modern approaches to the study of law, they have generated feuds within this interdisciplinary project.12 The differences between these approaches, indeed political *Weltanschauungen*, are often significant, but they should not obfuscate the common grounds of the project: understanding that literature as well as law are cultural constructs, and seeking to tease out the boundaries between them to ‘‘speak truth’’ (even when it is merely exposing a lie) to both law and power is a humanizing engagement par excellence to which all are committed. It is probably this commitment which explains why these scholarly battles, far from signaling the demise of the enterprise,13 are contributing to its continued vitality and to its expansion to other cultural discourses, both highbrow14 and popular.15

**2 International law and literature**

International legal scholarship has not been oblivious to the law and literature project. The three movements sketched in Part II.1 have permeated it as well.

Theodor Meron’s *Henry’s Wars and Shakespeare’s Law*s and *Bloody Constraint* provide a classic example of an engagement with international law in literature.16 The first book focuses on what has been gained by the substitution of a legal code of warfare for the customary code of chivalry found in Shakespeare’s plays17; the second, on what has been thus lost. In this manner, Meron does more than tracing the genealogy of military ethics and exposing the thick narratives underlying international humanitarian law (IHL): he suggests that to the extent we still consider that courage, shame and guilt are sensibilities worth nurturing, the ethos of chivalry remains relevant, perhaps more than a myriad of technical rules.18

In *The Aesthetic of International Law*, Ed Morgan offers a reading of international law as literature.19 Reading international law itself as well as specific international problems (ranging from terrorism to cross-border environmentalism) in the light of literary texts, Morgan proposes that the narrative determines the normative; that form determines function not only in literature, but also in international law. Literary authors have long recognized that, and Morgan invites international legal scholarship to become equally self-aware that ‘‘the container that holds the law is more important than the law itself.’’20

Narrato*law*gy is at the heart of Joseph Slaughter’s *Human Rights, Inc.: The World Novel, Narrative Form, and International Law*.21 Slaughter posits that the successful incorporation of the human rights discourse into the global imagination, despite its enforcement deficit, is to be explained not merely by global capitalism, national constitutions and international conventions – but by literature: the worldwide dissemination of the *Bildungsroman*22 – a literary genre that celebrates liberal ideology and values – accounts for this phenomenon.

Whereas most readings of human rights and humanitarian law in the light of literary texts (normally classified within the ‘‘law in literature’’ paradigm) expose the distance between the normative promise and its fulfillment,23 Slaughter reverses the argument: legal stories and imaginative fiction reinforce each other and the gap ‘‘between what everyone knows and what everyone should know’’ is bridged ‘‘not by the coercive force of law but by the ‘consensual’ work of culture.’’24

These and similar works25 attest to the enrichment of international legal scholarship by the ‘‘law and literature’’ project. It is nevertheless true that such contributions have been few and far between. Two factors may plausibly explain the reluctance of international legal scholarship to be thus engaged. First, the enforcement deficit of the international legal system, and the gap thereby evidenced between word and deed, renders it more vulnerable than other legal systems to Hamlet’s charge that it is just ‘‘words, words, words’’;26 that international law *is* fiction. The observation that fiction, not less than law, has a very real impact on the way we perceive the world and ergo on our normative behavior notwithstanding, much scholarly sweat has been poured over the years in an effort to dispel this charge. Affiliation with imaginative literature thus seems not merely counter-productive but indeed counter-intuitive to international legal scholars.

The second factor relates to a perceived discrepancy in the gravitation force between international law and literature: the former is drawn primarily to the relations between its main subjects: states and other corporate entities. It is from this perspective that it is also concerned with their impact on individuals. It is the story of the individual that most entices literature, even as it deals with universal issues of war and peace. The dialectical tension that stretches between the abstract and the concrete, the universal and the particular, may thus explain the relative estrangement between international law and literature. It is this very tension that suggests an affinity between international law and science-fiction.

**3 International law and science-fiction**

Let us begin with a story. A flying saucer lands on the President’s Park in Washington DC. In it are Klaatu, a humanoid, and Gort, a robot. Klaatu is on a goodwill mission: to tell us that the galactic civilization he represents is indifferent to humans fighting among themselves, but that it will not tolerate the threat presented to it by human nuclear technology.

Klaatu, whose human face is concealed by a helmet, emerges from the spaceship carrying a package (which, we later learn, was a gift for the President) and says ‘‘take me to your President.’’ A nervous soldier, mistaking the gift for a weapon, shoots Klaatu, harming him superficially and destroying the gift. In response, Gort, with a ray emanating from his head, disintegrates all weapons present. He would have continued melting away the soldiers and the crowd, had Klaatu not used a safe-word to stop him.

When Klaatu learns more about Earth, he decides that it would be better to address the scientific community than wait for world leaders to resolve their political impasses. Informing an international gathering that his civilization has enough power to destroy earth, he explains:27… We have an organization for the mutual protection of all planets and for the complete elimination of aggression … For our policemen, we created a race of robots. Their function is to patrol the planet in spaceships … and preserve the peace. In matters of aggression, we have given them absolute power over us. This power cannot be revoked. At the first sight of violence, they act automatically against the aggressor … The result is, we live in peace …

Gort represents this race of robots. The safe-word Klaatu had earlier used for stopping Gort from eliminating the soldier – and presumably everybody else – is operational only during diplomatic missions. Otherwise, the robot is programmed to use retaliatory force irrevocably. These are the facts. The choice, Klaatu came to forewarn us, is ours.

The story, based on the 1951 film *The Day the Earth Stood Still*,28 invites reflection on the ethical principles (both deontological and utilitarian) underlying the jus ad bellum paradigm, its adequacy in general, and the merits of anticipatory and preventive self-defense (as opposed to the robot’s retaliatory power), in particular;29 the armed-conflict vs. the law-enforcement paradigms; the nature of the agency (international as opposed to individual sovereign states) empowered to make the decision to use lethal force and the assignment of decision-making power within states in an age of technology (elected politicians or scientific experts); the balance of power between a sovereign agency endowed with an irrevocable power (and the very notion of irrevocability) to use force and its subjects;30 the programming of robots with an autonomous capacity to act upon a perceived threat,31 and correlated questions regarding discretion and the locus of accountability.32

Science-fiction stories have probed a myriad of questions of direct relevance to international law. A highly incomplete inventory includes issues related to our political choices, legal institutions and the technological logic which informs our decision-making processes (e.g., Aldous Huxley’s *Brave New World*;33 Anthony Burgess’ *A Clockwork Orange*34); International (interstellar) dispute resolution mechanisms (*Star-Trek: The Next Generation; Dr. Who* presented all that and more35); alternatives to the nation-state which include not only a world government (*Dr. Who; Star-Trek*) but a few giant multinational corporations defending their economic interests (e.g., William Gibson, *Neuromancer*;36 Jack Womack, *Terraplane*37), and our attitudes towards aliens (the English word, interestingly enough, is not limited to extra-terrestrials) in ways that challenge our very basic distinctions, including the difference between humans and non-humans, and ergo our understanding of the scope of applicability *ratione personae* of ‘‘inalienable human rights’’ and consequential tensions between our loyalty to our reference-group and our conceptions of justice.38

International law thus shares with science-fiction thematic interests and structural concerns, which are peripheral to both mainstream literature and to domestic legal systems: in both international law and science-fiction, the ‘‘hero’’ is an idea, not a person; both are less concerned with interpersonal relationships than with our rapport with the world; less excited by the minutiae of human experience and more by the expandability and limitations of human potential.39

This may explain why science-fiction rarely attracted scholars engaged with the law and literature project,40 but begs the question of the virtual lack of interest on the part of international legal scholarship.41 Indeed, the mere suggestion of an affinity between international law and science-fiction is likely to raise a skeptical highbrow: after all, drawing moral inspirations from Shakespeare is one thing; approaching seriously science-fiction – a literary genre the golden age of which is assumed to be twelve, as even its own proponents happily admit42 – is quite another.

Such dismissal of science-fiction as a genre of lower artistic value (reminiscent of the traditional distinction between ‘‘literary fiction’’ and ‘‘genre fiction,’’ the latter indicating that some guilt is to be attached to the pleasure of reading) is unfortunate given the inspiration it could evoke for rethinking some of the most fundamental international legal paradigms.43 Science-fiction, probably the most speculative literary genre, is a thought experiment built around the ‘‘what if’’ method, and thus highly akin to and inviting the engagement of both philosophical and jurisprudential discourses.44 It focuses on our present ideological, moral and legal disputes and in playing them out in imagined futures, proposes both criticism and alternatives. We could, and often should dismiss the alternatives, but without thereby refusing the invitation to interrogate our presuppositions and our role in the construction of our knowledge. After all, this is the very same invitation for critical reflection most of us have enthusiastically accepted from Kant and Kafka.45

This thematic and structural intersection between international law and science-fiction is but an effect of a deeper affinity. This proposition requires a closer look at the basic characteristics of this genre. In his groundbreaking study, *Metamorphoses of Science Fiction*, Darko Suvin defines science-fiction as follows:46… a literary genre whose necessary and sufficient conditions are the presence and interaction of estrangement and cognition, and whose main formal device is an imaginative framework alternative to the author’s empirical environment.

This widely accepted definition implies that the genre is characterized by two tenets. The first is *cognitive estrangement*; the second is, in Suvin’s terminology, *the novum*.

*Cognitive estrangement* means that the text presents aspects of the reader’s empirical reality ‘‘made strange’’ through a ‘‘new perspective implying a new set of norms.’’47 The recasting of the familiar has a cognitive purpose and uses cognitive means: the purpose is to better understand the socio-political conditions of human existence; the means is the imitation of the logical process of scientific cognition. Put differently, the creation of a fictional world, which in not taking our mundane environment for granted, but presents an alternative one, produces a sense of estrangement.48 Since the text gives a rational account of the imagined world and its relations to the lived world, a critique of the latter is generated: the relation between estrangement and cognition is, thus, dialectical.49 The *novum* is an invention or a discovery (often technologically driven) around which the characters and the plot are organized in a plausible way.

Taken together, these two characteristics of the genre do not settle merely for a critique of the existing world; they also provide a sense that change is possible and that, in a world that is neither merely deterministic nor only random – a world that is both – human intervention can make a difference.

We suggest that the impulse of international law, at least when it tilts towards its utopian rather than apologetic edge,50 is quite similar to that of science-fiction: its very existence in a world of sovereign states which it purports to regulate is a feat of human imagination, consisting of both a *novum* and *cognitive estrangement*. Together, they have the potential of producing both a critique of current conditions and faith that thoughtful human intervention can change it for the better.51 Much like science-fiction, international law is a thought experiment speaking an international language which transcends national boundaries. International legal scholarship, at its best, shares with science-fiction a sense of awe at our scientific and technologically-driven achievements, and, like it, does not stop there but proceeds to think about the consequences relative to the way we experience and experiment with the world. ‘‘The former allows one to admire the aesthetics of the mushroom cloud; the latter to consider the ethics of its fall-out.’’52

Science-fiction invites us to think imaginatively about our unthinking assumptions; presuppositions that obfuscate our vision of the paths we take and of roads not taken. We may well engage with such questions without resort to science-fiction, but there is little evidence, as the following part suggests, that we do. To the extent that international law and institutions do not wish to be satisfied with having prevented successfully the wars and other miseries which preceded their current formation, but to actively regulate the course of the future, they could do worse than accepting this invitation.

**III. Re-imagining International Legal Issues**

**1 Technology, the human conditioning, and the law**

What does it mean to be human? How does technology affect this question? What is the impact of the human-technology interface on legal subjectivity, agency and accountability?

Isaac Asimov foresaw the potential impact of new technologies on our understanding of who is a ‘‘human’’ and invited us to think about them before technology transformed science-fiction into science. His 1976 novella *The Bicentennial Man*53 tells the story of Andrew Martin, a robot who seeks to become human. Andrew is creative, inventive and capable of having feelings. His two-hundred-year quest to become human involves questions of freedom (can a robot be enslaved? Free? Autonomous?); robot/human rights (can robots have human rights?), and of shifting legal paradigms and definitions (determined by judicial and socio-economic processes).

Purchased as a butler robot, NDR (later named ‘‘Andrew’’ by the owner’s daughter) reveals surprising emotional capabilities and intelligence. Eventually, he is emancipated by his owner, and, being a robot, and therefore immortal, survives him. Wishing to become human, he dresses up as a man; contributes to knowledge; acquires economic wealth by virtue of his work and talents; seeks to have an android’s body replace his steel one, and invents a digestive system for robots, so, like humans he too could eat and digest food.

Yet his efforts to be legally recognized as a man fail. ‘‘My dear Andrew,’’ he is told by the head of the firm for which he works, ‘‘… you are treated as a human being by both robots *and* human beings. You are, therefore, a human being *de facto*.’’ Andrew’s reply is that he wants ‘‘not only to be treated as one, but to be legally identified as one … to be a human being *de jure*.’’54

Recalling historical fights of various human groups for their own recognition as human and ergo as bearers of human rights, a sympathetic member of the World Legislature explains to Andrew that the chances for this recognition are as high as congress passing a law ‘‘declaring that a stone statue be defined as a man’’ because ‘‘[c]ongress people are as human as the rest of the population and there is always that element of suspicion against robots.’’55

Understanding that one of the main concerns of humans is robots’ immortality, Andrew decides to undergo an experimental surgery that would render his brain mortal. Having thus chosen to sacrifice his life, he is then recognized a *de jure* human.

What is ‘‘human,’’ then? Asimov suggests that there is nothing necessarily natural in being ‘‘human.’’ It is a matter for human determination. And yet, there is a mysterious component embedded in the being, whether human or, as the novella implies, one who aspires to be considered human: after all, other robots from the same assembly line had neither the need nor the will to become human. Or perhaps they were not given an opportunity by their owners to become one?

It seems that mortality coupled with the potential for creativity, capability for emotions and responsibility are preconditions for being declared by humans as a human. But are they? Being born (rather than manufactured) is not a necessary criterion in Asimov’s (and others’) world, and the ‘‘real world’’ is characterized by a myriad of de-humanizing technologies of control rendering questionable the ‘‘humanity’’ we ascribe to both those in and those under said control on the one hand, and by the development of ever more intelligent robots, on the other hand. In this world, Asimov’s suggestion that being human is not only a question of having certain traits but also a question of legal definition invites us to ponder the connection between technology and international law in new ways. That connection has both ontological and moral/legal dimensions.

Ontological issues are most evident in thinking about technologies designed to assist in the creation and safeguarding of life. Thus, for instance, humans with metals or digital equipment in their bodies (pacemakers, artificial joints, etc.) are undoubtedly considered humans, but how much steel (or flesh, for that matter) does it take for a creature to be deemed non-human? Does it matter whether we ‘‘enhance’’ a human with steel or the other way around? Are these relevant criteria for distinction? How should law relate to the eventual development of robo-sapiens (or clono-sapiens, for that matter)? Should it reconsider concepts such as human dignity, identity, autonomy and indeed human rights?

Military technologies raise, inter-alia, complex questions of liability and accountability. If robots replace soldiers, they are arguably, functionally human. What would be the impact of this functional definition on the robot-subject as the bearer of duties and obligations (and perhaps also of rights and privileges)? If they are not thus recognized, should accountability remain attached to their programmer, manufacturer, owner and/or operator? Would such assignment of accountability be but a fiction? Should a new legal fiction be proposed? In an age where ‘‘[T]he science fiction of yesterday is steadily becoming the reality of today,’’56 what is the relationship between science, science-fiction and legal fiction?

In the following sections we explore two technologies that demonstrate the complexity and surprising fluidity of the ‘‘human’’: organ donation and cloning, and the military development of LARs.

**2 Written on the body: organ transplantation and cloning**

**a Am I ‘‘My Sister’s Keeper’’? The fiction of *res extra commercium***

The use of people as organ donors is not a new idea. It has already become common practice, both legal and illegal. Concerns stemming from such use (or abuse) are not new either. Recently, for example, the British Medical Association has offered a reform in the treatment of terminally ill patients that would allow doctors to keep neurologically dead (colloquially known as ‘‘brain-dead’’) patients hooked up to machines in order to use them as sources for organ donations.57 This proposal, designed to alleviate the chronic shortage of organs, raises questions of the commodification of the human body and its parts, consent and duress. As some have argued, while permitting sale of organs by the poor entails the risk of compromising their personhood, a ban on ‘‘desperate exchanges’’ might leave them bereft of livelihood, thus equally compromising said personhood.58

The rule in liberal democracies concerning the human body and its parts is that they are *res extra commercium*, i.e., ‘‘things outside commerce’’:59 they cannot be the object of private law. They are not subject to property or personal rights, and cannot be given, sold, rented or otherwise traded.

European regulations stipulating that ‘‘[n]o substance may be offered for profit,’’60 lack global application and fail to address the shortage in organs for transplantation. Indeed, they exacerbated the problem, generating a boom in ‘‘transplant tourism,’’ the organizing principle of which is the ‘‘race to the bottom,’’61 whereby the poorest and most vulnerable parts of the world’s population are increasingly becoming organ banks for the rich.62

This phenomenon has prompted the World Health Organization to adopt a resolution urging countries to protect their poor citizens from such abuse.63 Domestic legal regulation varies: while India has adopted in 1994 a law prohibiting trading in human organs,64 China has become a major and most controversial exporter of organs: it allows foreigners to buy organs that have been procured from the bodies of executed prisoners,65 some of them allegedly executed just in order to harvest their organs.66

Urged to better regulate the matter,67 the EU adopted two instruments: the EU Directive on Standards of Quality and Safety of Organs Intended for Transplantation68 and the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin.69 The Directive aims to resolve both ethical and legal issues arising from organ donation technologies.70 The Convention and its Protocol strive to flesh out unified criteria for organ donation processes, covering the gamut from the types of consent needed from living donors through the protection of incompetent donors to the articulation of criteria for determining one’s death. For example, the treaty suggests that doctors certifying a person’s death shall not be the same doctors who participate directly in removal of organs or tissues from the deceased person.71 These instruments contain no unified international norm and are given varying effect through domestic legislation.72

Developments in the area of organ transplants, and their life-saving potential coupled with the hope it has brought to many otherwise terminally ill patients and their families, are thus forcing lawmakers, both domestic and international, to rethink old concepts such as freedom, consent, autonomy, dignity and personhood. This process is yet to culminate in a satisfying solution.

Imaginative literature, both fiction and science-fiction, has been intrigued by the impact of these technologies on the concept of human dignity and the dangers of human objectification and commodification. One of the most famous representations of the use of a human being as a source for organ donation is Jodi Picoult’s 2004 novel *My Sister’s Keeper.* It tells the story of Anna Fitzgerald, a girl who was conceived in order to harvest umbilical cord blood during her birth, to be used in treating her older sister for cancer. Over the course of the first 13 years of her life, she donates other body parts to her sick sister. Finally, when asked to donate a kidney, she rebels.73

Picoult’s novel exemplifies the power of fiction to crystalize and illuminate the moral and legal dilemmas of the technology in a thought-provoking way. It also provides an important link between the dilemmas that organ transplants raise and what appears to be the linear progression to the next step, namely, the manufacturing of humans for the sole purpose of harvesting their organs for transplants. Such dilemmas are discussed in the following section.

**b The double face of cloning: science and legal fictions of therapeutic and reproductive cloning**

Material (shortage in available organs for transplant) and mental (concerns about the instrumental view of the human being attached to organ transplantation) inhibitions have triggered scientific efforts to manufacture certain organs in the laboratory.74 Cloning technology may ostensibly offer a comprehensive solution. But should it be thus used? In what sense, if any, is the clone different from the sexually reproduced creature we currently refer to a ‘‘human’’?

Kazuo Ishiguro’s 2005 dystopian science-fiction novel *Never Let Me Go*75 challenges us to reassess our ideas, perhaps prejudices, regarding who is ‘‘human,’’ and what is humane behavior. The main characters are clones, as is the narrator. They are as diverse as humans in terms of the range of their emotions and capabilities: they fall in love, experience sexual attraction, create art (good and bad, just like non-clones) and have a sense of morality and responsibility, self-awareness, curiosity and a need to learn. They too bleed when they are injured; they too die. They were all raised in Hailsham, a fictional boarding school in East Essex, England. They know that they are clones created to provide vital organs for non-clones, referred to as ‘‘originals.’’ Once they reach maturity, they are expected to ‘‘donate’’ organs in about three to four cycles, until they ‘‘complete’’ (a euphemism for death). Later in the novel, the protagonists discover that Hailsham, the boarding school in which they were raised in chillingly idyllic conditions, had been an experiment in giving clones humane treatment; elsewhere, clones were treated like livestock.

It is not only science-fiction literature but also scientific and legal literature that maintains that human clones are fully human rather than carbon copies of other, ‘‘original’’ humans:76 cloning is a technology which can create embryos, not full persons. The embryos still need to be implanted in a uterus, and their development depends on pregnancy, birth, and nurture.77 Why is it then that much of the ***opposition*** to the legalization of the technology imagines clones as less than human; the bastard children of technology?78 Conversely, could this imagination reflect but suppressed existential Angst stemming from the clones’ humanity?

The ethical questions raised in the book should be contemplated by any legal system which purports to regulate the technology. At present, such contemplation leaves much to be desired: international law distinguishes between reproductive and therapeutic cloning. Therapeutic cloning currently uses stem cells in order to develop remedies for degenerative diseases,79 and thus does not disturb our perception of what human reproduction should be like. This may well account for the fact that the objection to this technology is less fierce than the objection to reproductive cloning.80 The latter is a form of asexual reproduction that will allow, when it becomes technologically and legally available, infertile men and women to conceive children to whom they will be genetically related;81 assist fertile men and women who carry genetic diseases;82 and benefit lesbians who wish to become parents to genetically-related children without seeking sperm donations.83

Despite these benefits, legislative efforts are geared towards banning reproductive cloning: it has already been outlawed in several states, and the American Congress is currently considering a national ban on it.84 In Europe, the Council of Europe promulgated the 1998 Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings.85 The protocol’s preamble states that ‘‘deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine.’’ In the international arena, the UN General Assembly adopted in 2005 the Declaration on Human Cloning, which urges ‘‘[m]ember States … to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life.’’86 The Declaration reflects a sentiment; not law. In the absence of a binding international instrument, doctors and patients are able to travel to states in which such procedures are not banned.87

Why does our current legal imagination consider human cloning for procreation purposes to be necessarily incompatible with human dignity? After all, human culture has been saturated with stories of asexual human reproduction, in ways far more radical than reproductive cloning technology: Eve was created from Adam’s rib;88 Athena was born out of Zeus’s head, and Jesus was God’s son. Furthermore, given that new reproductive technologies have not only advanced the notion that there is a human right to procreate, but have also enhanced and broadened the scope of such a right,89 could it not be argued that the prohibition on reproductive cloning infringes the human right to become a biological parent?

It is not inconceivable that the ban on reproductive cloning is based on the image of clones as carbon copies of others in science-fiction literature. Such images (and fears) of non-sexual human reproduction have been in existence in science-fiction literature since its dawn. Aldous Huxley’s *Brave New World* (1932), is a most famous example. Set in London in the year 2540, the novel explores the nature, operation and values of the ‘‘World State,’’ a futuristic global society in which sexual reproduction does not exist. Children are created in Hatcheries and Conditioning Centers. The children are divided into castes: the upper caste is allowed to develop naturally; children of other castes are chemically manipulated so that their physical and mental growth is obstructed.90 The manufacturing – and conditioning – of human types that take place in the world depicted in the book upsets many liberal and humanistic sensibilities. Just like in *My Sister’s Keeper*, although more brutally, humans are being objectified and their personhood denied.

Such blatant intervention in human development and instrumental treatment of human life was actually contemplated and attempted in real life as well. Long before 2540, unimagined reality appeared to have mimicked this imagined dystopia: World War II and the rise (and fall) of the eugenic movement,91 brought on an unprecedented scale processes of dehumanization through abuse of technology, industrialization of life and death, and the elimination of human subjectivity. To the extent that experience does determine consciousness, this may explain why reproductive cloning since has often been equated in fiction with terrifying monstrosity: popular representations of non-sexual human reproduction such as *The Boys from Brazil*, a novel on cloning Hitler (later adapted to a movie);92 and *Star Wars: The Attack of the Clones*, a movie in which a horrific army comprising identical creatures is created, underscore the point.

It has been suggested that legal consciousness, much like popular perception, has been shaped by such artistic metaphors in a manner that accounts, at least in part, for the ban on cloning. It is, after all, not only experience that determines consciousness but also consciousness that determines experience. Literal reading of artistic texts is, however, poor reading: science-fiction literature is a form of art. Like all such forms, it may be good or bad; good art purports neither to offer solutions nor to numb our senses with worse-case scenarios, but to represent complexities in ways that other texts, including legal texts, cannot. Good science-fiction is not a report on the future. It is an invitation to reflect on both the present and the future (and perhaps even the past); to question our presuppositions regarding both technology and humanity in order to allow us to shape the future thoughtfully and imaginatively; to engage in ‘‘what if’’ questions, such as, ‘‘what if there is no difference between an ‘original’ and a ‘copy’’’ (it seems that some of the concerns that Walter Benjamin raised in his *The Work of Art in the Age of Mechanical Reproduction*93 can be easily applied to a world in which humans, and not only art, are mechanically reproduced)? What would be the impact of this supposition on the way we construct our reference groups? Is cultural diversity relevant to this question? What should be the legal status of clones if and when reproductive cloning is permitted by domestic and international law? How should clones be treated if cloning is successfully performed illegally? Implicitly, these very questions suggest that thinking about them merely along the dichotomy between ostensibly neutral means (technology) and political ends (‘‘progress’’; socio-economic and legal policy) is inadequate.

More broadly, technology raises serious questions concerning its interaction with human beings (how do we define a human? Can non-humans bear human rights?94). Science-fiction has been preoccupied with these questions, engaging their ontological, ethical and legal aspects, for decades. It may well assist us in thinking about them in a manner more nuanced and coherent than we currently do.95 Such questions are relevant not only to cloning technology (which at present international law generally rejects) but also to lethal robotic technology (which at present international law generally embraces, albeit with growing unease).

**3 Of humans, golems and lethal robots**

**a Controlling narratives**

The development of LARs is a technology designed to revolutionize human experience with war.96 The term ‘‘LAR’’ refers, in the present discussion, to a robotic system that can engage in lethal attacks without direct human input. The international legal discourse is yet to pay to the meaning and ramifications of this technology the attention it deserves. Thus far international legal attention has focused mainly on ‘‘warbots’’ currently in use (comprising drones, unmanned aerial vehicles (UAVs) or on unmanned combat vehicles (UCVs)), in a manner that essentially follows the footsteps of the debate over the legality of targeted killings.97 A welcomed addition to scholarship, focusing mainly on LARs, is contained in ‘‘*Losing Humanity: The Case against Killer Robots*.’’98 Still, the gap between the traditional debate and the potential impact of LARs remains. This is especially so in relation to the human experience with and understanding of war, and ergo on the major building-blocs of IHL – including the ontology of the ‘‘combatant’’ status, responsibility and accountability. This gap may well mirror the divorce between our knowledge (in the sense of ‘‘know how’’) and our thought, anticipated by Arendt.99 By contrast, imaginative literature (both folk-tales and science-fiction) has anticipated the knowledge and thought about its impact, highlighting a complexity to which, to the extent that we wish to halt rather than advance the process of separating our knowledge from our thought, we should pay attention.

LARs are a weapon; the cutting-edge product of military driven research and technology. Conceived to ‘‘take man out of the battle loop,’’ thus ostensibly generating, for the technologically advanced, a ‘‘risk-free’’ war, they are rapidly becoming ‘‘the only game in town.’’100 They are a technological response to ‘‘other minded’’ states and political entities that have used humans as weapons by ways of brainwashing, coercion, and programming (suicide bombers, Kamikaze pilots, etc.).101 That response, thus, appears to be more humane: machines, not men, are instruments of destruction, though only insofar as the perpetrators, not the victims are concerned.

But LARs are not only a weapon. They are also a late-modernity representation of a thick narrative, ancient as well as science-fictional. The narrative of human desire to create an artificial anthropoid, a *golem* endowed with the power to serve and protect its creator while being subservient to him – and its discontent – can be traced to early Judaism.102 Tellingly, like Adam, all ancient *golems* were created of mud.103 Like Adam, they too had the potential of disobedience, substituting freedom of choice and autonomy for submission. Echoing as it surely does the story of God’s creation of man, the hubristic nature of the enterprise may well explain why the narrative collapses the dream into a nightmare, with the *golem* turning against its creator and becoming a violent monster. Man was created in the image of God;104 the *golem* is created in the image of man.

The most famous such tale is of the *golem* created in the late sixteenth century by the Chief Rabbi of Prague in order to protect the Jews from pogroms.105 Upon creation, the Hebrew word ‘‘*emet*’’ (truth) was inscribed on the *golem*’s forehead. Once the *golem* became a murderous thug (either as a ‘‘natural’’ progression of its power or due to a broken heart, depending on the version, but at any rate in a manner that involves awareness of its capabilities as well as its potential for developing in ways unforeseen by its creator), the Rabbi was able to deactivate it by erasing the first letter, leaving the word ‘‘*met*’’ (dead).

With the advent of secularism and technology, the power to create artificial life was no longer reserved for men whose holiness approximated the divine. They have been replaced by ambitious scientists (*Frankenstein*),106 the uninitiated (*The Sorcerer’s Apprentice*)107 and the greedy (*R.U.R*.).108 The latter is the title of a 1920 science-fiction play written by Karel Čapek. The acronym stands for Rossum’s Universal Robots, a factory where robots (somewhat akin to ‘‘humanoids’’ or ‘‘clones’’) are manufactured. It tells the story of a robot rebellion culminating in the extinction of the human species. Imaginative, ‘‘intelligent design’’ thus generated, from its inception, the need to regulate the human/robot interaction.

**b Science-fiction laws of robotics**

The migration of a term-of-art from science-fiction to science also characterizes the term ‘‘robotics’’ (i.e., the technology that deals with the design, construction, manufacture and application of robots) introduced in Isaac Asimov’s 1941 short story ‘‘*Liar*.’’ This is also the story where Asimov stipulated the first of his famous ‘‘Three Laws of Robotics,’’ “a robot may not injure a human being or, through inaction allow a human being to come to harm.”109 The ‘‘liar’’ is Herbie, a robot who, due to a programming error, can read human minds. Herbie is a law abiding, well-intentioned liar: his telepathic power enables him to know what humans want to hear; his reading of the first law propels him to do so. The inevitable result is that Herbie injures the very humans he is programmed not to harm.

‘‘*Runabout*,’’ a short story published a year later, added two laws governing the human/robot interaction and impressed, almost without exception, in all robots, in a hierarchical order. The second law reads: “a robot must obey the orders given to it by human beings, except where such orders would conflict with the First Law.” The third law provides that “a robot must protect its own existence as long as such protection does not conflict with the First and Second Law.”110 Subsequently, Asimov introduced an additional law, which due to its normative superiority over the others is known as the Zeroth Law: “a robot may not harm humanity or, by inaction, allow humanity to come to harm.”111

Later writers modified Asimov’s laws and introduced others. Thus, for instance, in the trilogy *Caliban, Inferno* and *Utopia*, Roger MacBride Allen ***deleted*** the omission clause of the First Law; changed the Second Law to require cooperation in lieu of obedience; placed the Third Law on an equal normative footing with the Second Law so that a robot cannot be ordered to self-destruct and introduced a Fourth Law stipulating that a robot may do whatever it likes so long as this does not conflict with the first Three Laws.112 In *Icarus’ Ways*, Lyuben Dilov introduced a new Fourth Law: “a robot must establish its identity as a robot at all times.”113 In a short story entitled ‘‘*The Fifth Law of Robotics*’’ and revolving around a robot who violated the First and Fourth Law because he did not know he was a robot, Nikola Kesarovsky supplied a Fifth Law: “a Robot must know it is a robot.”114

These Laws of Robotics are grounded in an ethical basis quite similar to our own laws.115 This basis was first articulated by the main human character in Asimov’s robot stories, robot psychologist Dr. Susan Calvin in ‘‘*Evidence*’’, a short story revolving around the possibility of differentiating between a robot and a human being: the laws are what the normative world expects from human behavior, thereby equating ‘‘a very good man’’ with a robot.116 This does not mean that there is no difference between robots and humans (the misanthropic Dr. Calvin believes the two are “[W]orld different. Robots are essentially decent”117), but it does imply that the gap between the normative imperative and its realization and the difficulties which beset our legal systems persist when it comes to the laws of robotics, including the indeterminacy of laws and self-serving modifications and interpretations of laws. Such complexities are the main theme of Asimov’s stories.

Let us consider, for instance, the lack of a universal definition of the terms ‘‘human being’’ and ‘‘humanity.’’ Surely, without it, robots cannot be expected to apply the law. Indeed, in *Solaria*, robots are programmed to know that only people speaking with a Solarian accent are human. Consequently harming non-Solarian human beings is not a violation of the laws.118 The robots in *That Thou Art Mindful of Him* are inscribed with the Three Laws, but are also programmed to mimic organic life, simple animal behavior which does not require governance by the laws of robotics. They conclude that organic life is not required for qualifying as human and that given that they are the most intelligent beings on the planet, they are the only humans alive and hence the Three Laws apply exclusively to themselves.119 Conversely, interpretation of both the laws of robotics and human law in the previously mentioned ‘‘*Bicentennial Man*,’’ eventually allow a robot to become human. While the normative hierarchy makes it possible for a robot to deduce that it is permissible to harm a human being if the harm benefits humanity as a whole,120 multitude situations resurrect the familiar problems of risk management (e.g., is it permissible for a robot inscribed with the Three Laws to operate on a human being, an operation that may generate a greater harm?) and the weighing of alternatives.121

Asimovian robots inhabit a world starkly different from ours in one respect: it is peaceful. There is military driven research, but it takes place in space stations. Tellingly, this is the environment where a ‘‘top secret’’ modification of the First Law, has been effected. This is the focus of ‘‘*Little Lost Robot*’’:122 a few robots are not impressed with the proviso of the First Law. One of them was told by a scientist to ‘‘get lost’’ and, pursuant to the Second Law, did get lost by hiding himself among 62 otherwise identical robots. The reason for the modification of the First Law was that the work done on the planet did involve some risk to human beings, which the non-modified robots did not allow even when they were ordered to do so and even at a risk to themselves, because obedience and self-preservation are normatively lower than the First Law. The robots are intelligent, capable of developing, and consider themselves superior to the humans they serve. It is thus not surprising that they harbor resentment. This indeed is why the Three Laws are needed in the first place. It is Dr. Calvin’s task to find him (out). Horrified to learn that some robots have been manufactured with a modified First Law, her immediate solution is to destroy all 63 robots. Given that even in Asimov’s peaceful world, the marriage between military research and huge investments is sanctified, this suggestion is rejected.123

**c From science-fiction to science: the politics of law and technological fundamentalism**

The need, anticipated in science-fiction literature, to govern the human/robot interaction, is migrating from the world of science-fiction to the real world.124 The logic and impact of the technology, as imagined by Asimov and others, include, as even the brief tour above suggests, problems emanating from errors in programming and the unpredictability of technology; the inherent ambiguity and malleability of regulation inherent in all legal systems; lack of transparency and secret deviation from regulation in the name of security; economic considerations attached to huge investments and expected financial and political returns; attempts to respond to problems generated by the technology with more technology; and the relations between man and machine, ranging from forced labor and domination to interchangeability. Further and quite tellingly, science-fiction stories propose rules of robotics only to end up disproving their usefulness as reliable constraints on either robots’ or human behavior. The development of LARs generates similar problems.

LARs are designed, manufactured and programmed to kill human targets. In this sense they are a weapon, an effect of military technology. But a technology is never merely a scientific product. It is also political: located in a political and economic environment, it serves domination and profit. Knowing how to use the weapon requires technological literacy; knowing that the technology reflects as it advances a military culture inseparable from business interests requires critical public awareness.125 Reflecting, first on the nature and meaning of the technology, and then on its regulation in this environment is the international lawyers’ business.

The environment does not seem too amenable to regulating the technology. The facts are well known and it is thus sufficient to outline them briefly:126 the technology is increasingly prevalent in NATO and other countries, including China, India, Israel and South Korea.127 It is also reaching Iran.128 The value of the UAVs market is expected to grow within a decade to $70–80 billion.129 At present, given the numbers of remote pilots, communication and maintenance personnel, the systems are heavily manned. Still, the reference to UAVs, or rather UAS (unmanned aviation systems) and to LARs reflects where the wind is blowing more precisely than the term the military prefers: ‘‘remotely piloted air-systems.’’ The latter is designed to counter the perception that the systems operate automatically. It is, however, an increasingly accurate perception. Further, a multi aircraft control system, enabling one pilot to operate several UAVs simultaneously has been developed and is becoming operational.130 Interestingly, this development too was anticipated by science-fiction: *Ender’s Game*, an award-winning novel published in 1985 revolves around young Ender Wiggin who, believing he is merely playing a computer game and oblivious to the fact that he is participating in a battle, repels an alien invasion of Earth via the use of a fleet of military drones under his remote control.131 Earlier still, Asimov anticipated this capacity: Dave, the protagonist of ‘‘*Catch the Rabbit*’’ is a robot with six ‘‘fingers’’ which he uses for various simultaneous tasks. He is also mentally disturbed.132 Given reports that operators of lethal robots suffer from mental stress,133 and that while aware that their actions generate deaths, they nevertheless feel that they are playing a game,134 both stories become somewhat eerie.

Current technology is but a step in the long-term plans of both the US and the UK military to remove man from the battle-loop altogether.135 The direction is thus clear: developing systems that are not merely automatic but also capable of making their own decisions, that is, autonomous.136

The military is the major source of the huge funding the research and development of this technology require. The coupling of military eagerness with commercial enthusiasm indicates that international legal regulation that attempts to halt or limit this development is unlikely to be welcomed. Reflection on the feasibility of such regulation has led to the whimsical suggestion that the content of the Three Laws of Robotics our real world is likely to accept would stipulate as follows: ‘‘(1) a robot will not harm authorized Government personnel but will terminate intruders with extreme prejudice; (2) a robot will obey the orders of authorized personnel except where such orders conflict with the Third Law; (3) a robot will guard its own existence with lethal antipersonnel weaponry, because a robot is bloody expensive.’’137 The joke is on us: current legal doctrine in the US seems already quite prone to incorporating some version of these Laws. Thus, for instance, the question whether a robot has a right of self-defense – a question presupposing that it has a ‘‘self’’ to defend – already appears to have been answered positively by the US Air Force: the mere targeting of a drone, even with radar, generates the right to kill.138 In an ironic twist, military lawyers seem to be recognizing robot rights to an extent far broader than most science-fiction authors ever proposed.139

Technology contains both the promise of progress and the threat of regress. It offers amazingly creative solutions to problems as it exacerbates others and creates new risks. Our faith in technology generates the belief that technology will solve the problems it created. Designing ‘‘ethical’’ (rule based) LARs, programmed with ‘‘artificial consciousness’’ based on IHL is an effect of this technological fundamentalism.140 This effort seems to rest on some presuppositions: first, that current IHL is perfectly adequate to govern their use (e.g., that the distinction between a civilian and a combatant and the answer to the question ‘‘who is a civilian’’ are both clear and translatable to an algorithm); second, that humanity (inclusive of human discretion) can be reduced to algorithms; that the human is interchangeable with the machine. Other scientists consider that any variation of the laws of robotics is bound to fail as the laws cannot anticipate the myriad of challenges, both physical and mental the robots would encounter. Their solution is the development of yet another system where, when a decision becomes too complex, ‘‘a smooth transfer of control to another loop, machine or human’’ occurs.141 This solution too presumes the interchangeability of man and machine but couples it with another presumption related to an ability and willingness to relinquish control while ostensibly having the capacity to reclaim it.

The problem goes beyond the parameters of calculated decision-making. It concerns the ontology of deciding according to rules: the very existence of rule-based decision-making anticipates exceptions; the former can be successfully undertaken by computers, and in a manner superior to humans; the exception, however, requires discretion and ergo justification and accountability. Could it be that the wish underlying these solutions is to relieve human discretion from accountability? To outdo, while updating Raskolnikov’s fantasy of the ‘‘perfect crime’’?

Technology is seductive. It tempts us to believe in the possibility of providing neat solutions to complex problems and to discard the likely possibility that they will also be, quite simply, wrong. The impact of technology on who and how we are should not be confused with, indeed, reduced to technology. The insistence that technology will resolve the problems it creates settles for a *Deus ex machina* solution. The latter, as already noted by Aristotle,142 is a bad solution on stage. It is even worse in the theatre of real life: it is equally indicative of a failure of creative faculties (insofar as it substitutes faith in technological literacy for critical reflection) and it invites thinking in terms of paradigmatic extremes (either reject or embrace a certain technology). This is far too simplistic a conception of a complex reality. Recognizing and contemplating this complexity is the condition of possibility for legal regulation.

Responsible governmental and non-governmental agencies are considering, even if belatedly, the impact of this technology from a non-technological perspective.143 Such consideration has led some to call for a complete ban on LARs.144 Others expose the dangers inherent in the technology: a voluminous study commissioned by the American National Science Foundation concluded that technology has ushered in ‘‘the age of uncertainty’’ insofar as the future course of our sociopolitical culture and indeed identity is concerned.145 A study commissioned by the UK government equally concluded with a question-mark: ‘‘Is the technological genie already out of the ethical bottle, embarking us all on an incremental and involuntary journey towards a Terminator-like reality?’’146 The August 2010 Interim Report of the Special Rapporteur on extrajudicial, summary or arbitrary executions, noting that while new technologies have ‘‘transformed the world of the twenty first century … the human rights community often seems determined to remain firmly rooted in the twentieth century,’’147 proceeded to urge the Office of the UN High Commissioner for Human Rights to convene an interdisciplinary group of experts to consider, inter-alia, the type of new standards to be developed in regulating LARs technology.148 The time has come to rethink the viability of current IHL and International Human Rights (IHR) paradigms.

**d LARs’ legal discourse: content and discontent**

The development of LARs is yet to produce a meaningful legal discourse. Presently, the controversy focuses on the legality of the use of drones in a manner both narrow and predictable: it is mostly limited to the specific contours of the current theatres in which they are used and often rehashes the debate over the legality of targeted killings before it began to avail itself of this technology.149 Presupposing that the technology presents a quantitative rather than a quantum leap in the way we experience war, it recognizes neither a crisis nor a need for the shifting of paradigms. It is sufficient for our purposes to briefly present the discourse’s major building-blocks.

International lawyers enthralled by the technology posit that the use of killer drones is perfectly legal within the applicable IHL paradigm. The latter is applicable because the events of 9/11 were an armed attack triggering a US response in self-defense under Article 51 of the Charter. That response constitutes what is currently known as a ‘‘global war against specific transnational terrorist organizations,’’ comprising of al Qaeda, Taliban, associated forces and those who substantially support or harbor them.150 While opinions differ on the characterization of the conflict,151 there is general agreement that the legitimate targets are specific individuals and the targeting decision is case-specific and depends on detailed considerations including the imminence of the threat; the sovereignty of the State involved and the latter’s ability and willingness to suppress the threat on its own.152

Having determined that IHL is the applicable paradigm, the argument posits that robotic technology enables better compliance with the requirements of military necessity,153 distinction,154 proportionality155 and humanity156 than was previously possible.157 Whether those requirements were indeed met is subject to a case-specific assessment.158 Statistical data support this assessment.159

The international legal case against the use of lethal robots is essentially a mirror image of the above arguments:160 it posits that given that the operations are conducted outside the traditional, ***geographically*** limited, ‘‘hot’’ battlefield, the governing paradigm is law-enforcement rather than IHL. The ensuing applicability of the right to life under IHR renders the killings an assassination.161 Alternatively, if IHL does apply, lethal robots cannot detect surrender thus violating the prohibition on attacking *hors de combat*;162 killing a suspect generates no military advantage but resentment, and is therefore both counterproductive and in breach of the principle of military necessity; and, since the requirements of distinction and proportionality rest on a qualitative assessment, robots cannot meet them.163 Statistical data support this conclusion.164

The fight over statistics is quite indicative not merely of the lack of transparency of the operations,165 but also of their underlying meta-legal (mostly utilitarian) narratives: those who support the use of drones argue that it has been a most effective tool in the fight against terrorists, killing top leaders, disrupting terrorist networks, and breeding a sense of insecurity; that it does so with no risk to American soldiers, and that any other view is but an ‘‘appeasement policy.’’166 Those who oppose it, point to the resentment and anti-Americanism it feeds and aggravates, solidifying the power of extremists, generating political destabilization and a defeat in the battle over peoples’ minds.167

Both positions, reflecting as they inevitably do a mixed bag of political ideology, law, and technology, are as predictable as they are disappointing: both assume that technology is neutral; both display no cognitive estrangement in the face of the *novum* – the lethal, increasingly autonomous robot;168 both presume that the technology changes neither the experience of war nor the regulative paradigm that purports to regulate it. But what if this presumption is simply wrong? What if the technology, while ostensibly realizing the fantasy of a risk-free war, changes not merely how we fight but also the meaning of war and the identity of the fighter thereby bringing to an end the history of ‘‘[H]umankind 5000-year monopoly on the fighting of war,’’ and ergo our very experience with and understanding of war?169 What if, in substituting tactics for strategy, increasingly elastic legal distinctions for legal imagination and technology for its breeding environment, they inadvertently advance the dangerous process of separating our knowledge from our thought thus generating subservience to technology?170

Reflection on the ontology of a risk-free war is quite different from debating the rules of engagement relative to asymmetrical conflict. International legal scholarship has focused on the latter issue, but hardly on the former.171 Risk, however, has been inseparable from our experience with and consciousness of war, and ergo of its regulation, since time immemorial.

The war/risk paradigm is a ‘‘concept we live by.’’172 ‘‘War’’ is an insidious cultural metaphor, which shapes our perception of reality. Lakoff and Johnson demonstrate this pervasiveness of war in our everyday life with the conceptual metaphor ‘‘argument is war:’’ arguments can be defensible or indefensible; we attack the weak points in an argument; an argument can hit right on target (or miss it); one ***wins*** or loses an argument, and so on.173 Such metaphorical concepts, they argue, structure ‘‘what we do and how we understand what we are doing.’’174 We posit that the ‘‘risk-free war’’ is such a metaphorical concept: It is a metaphor for a war with no one. The elimination of risk entails the dehumanization of the enemy and its degradation to a ‘‘no one.’’ The international legal paradigm which regulates war, however, is predicated on a different imagination: the parties to a conflict are construed as equally human and thus vulnerable to mutual risk. It is this mutuality which justifies the combatants’ license to kill.175 The idea (and metaphor) of a riskless war erases this imagination and, *ipso facto*, flies in the face of the international legal project of humanizing war and minimizing its occurrence.176

The paradigm designed for the use of force that requires no symmetry (in the sense of mutuality of risk) provided the target is morally guilty, is law-enforcement.177 Alas, that paradigm, in denying the political nature of the conflict, also fails to capture it. Given that the war paradigm and the law enforcement paradigm (in their antecedent form) are mutually exclusive, and given further that both fail equally to reflect the reality they purport to regulate, the result is a paradigmatic crisis in the Khunian sense. The latter is evident in both the ambivalence currently replacing traditional distinctions that served as the building-blocks of the laws of war and peace, and in the resistance to acknowledge their significance.178 In the context of the ‘‘global war against specific transnational terrorist organizations,’’ these include a myriad of issues ranging from the temporal and spatial dimensions of war to the identity of the fighters. Lethal robots, though not necessarily confined to this type of war (or law enforcement) but nevertheless being used primarily in its course, have added another layer of obfuscation relative to the identity of the fighters, the nature of the weapon and the locus of accountability. Let us briefly consider these issues.

All positions, including legal norms, rest on presuppositions. The latter, while rarely explicit, inform the inner logic and coherence of the relevant legal regime. Thus, while IHL specifies neither a time limit nor a territorial limit on war, it does not follow that it does not assume them. Our political imagination, experience and expectations do differentiate between war-time and peace-time. In peace, we expect the sovereign to attend to our security and well being; in war we accept that we may be called to sacrifice both for the sovereign’s security; we conceive of our sovereignty as territorially defined by a border and indeed cannot imagine a war between states that enjoy an open border.179 We further distinguish between a home-front and a battle-front; a combatant and a civilian. So indeed do our laws: they conceive of peace as a rule; of war as an exception regulated by different rules. A situation where the exception is confused with and indeed substitutes for the rule indicates the terminus of the legal system.180

A war that takes place at all times in a distant location within a (normally, ‘‘failed’’) state, in the presence of only the killer robots and the targeted individual victims, with fear and pain attached only to the latter is experienced by neither the operator(s) of the robots nor by their fellow citizens as a real war; from their perspective, it is virtual. It certainly requires no sense of sacrifice, courage and chivalry,181 on the part of either the operators (formally combatants) or the civilians. Virtual wars are a game; easily confused with entertainment, which, in our imagination, is governed by rules other than IHL and requiring, perhaps, parental guardianship, not the International Committee of the Red Cross. For the victims it is a, well, deadly serious business. The gap between reality and the ostensibly applicable legal paradigm becomes all the more poignant when one considers that the law construes the operator as a combatant and the targeted victim as either an unprivileged belligerent (if the conflict is classified as an international armed conflict)182 or as an individual who engages in continuous combat function (if the conflict is classified as a non-international armed conflict).183 The operator, however, in as much as s/he is in the business of administering death, not risking it, is hardly the combatant the law was designed to privilege. The target, at least in the context of the ‘‘global war against specific transnational terrorist organizations,’’ is neither privileged as a combatant nor protected as a civilian. He is, for all practical purposes the ‘‘undecidable.’’184 Being excluded from the protection of established legal categories, his is a ‘‘bare life.’’185 How, in this context (but potentially also in others), is the LAR construed?

The point of departure in thinking about the LAR is that it is a weapon, albeit a new one which should be subject to review.186 The paucity of discussion concerning its nature indicates that the prevailing view is that the weapon represents but an incremental step in technological development.187 If it is a weapon the employment of which violates the basic tenets of IHL or is otherwise abhorrent, it should be banned. If it is not, there is no need to subject it to any specific weapon regime, let alone to ban it. When viewed from the end-point, however, this point of departure seems inadequate: given that the explicit objective of the technology is to replace combatants with lethal intelligent robots capable of making their own rational decisions about a target, the LAR changes not merely how we fight but who is fighting:188 in lieu of enemy combatants facing each other there is a human (albeit objectified and reified) target facing a technological *Deus ex machina*, a robot. The interchangeability between a robot and a combatant suggests that the LAR is not merely another weapon. It is that, but it is also something else.

Considering that ‘‘something else,’’ scholarship has focused mostly on the issue of accountability: assuming that robots become autonomous in the sense that they would be capable of making and executing a lethal decision that ultimately violates IHL without direct human input, who would be held responsible?189 The proper implications of the question require a few additional assumptions: that states ensure that the machines archive information that allows for an investigation; that safety standards have been built in; that their performance and reliability have been tested before deployment,190 and that they are programmed to comply with IHL standards191 – all somewhat far-fetched assumptions, but still such that the international legal project can reasonably be expected to require.192 Cleared of any criminal intention on the part of the state or an individual, the possibility that the robot would nevertheless violate IHL due to an error or a rationally calculated decision remains. Assigning responsibility to the manufacturer or the programmer is neither a feasible nor a desirable solution: fully aware (as is any owner of a PC) that a propensity towards unpredictability is not reserved merely to Asimov’s robots; that indeed the predictability of this unpredictability is augmented in complex systems comprised of millions of lines of codes written by different teams of programmers none of whom has the complete picture, and that the consequences of that propensity are serious, they would surely ascertain that they are not held responsible.193 Giving reassurances that there will always be a human decision involved is an attempt to circumvent the underlying assumption and to deny the rationale behind the whole enterprise: if the robot is indeed making autonomous decisions, there is no justification for holding anyone else responsible; and an intelligent robot will be far more efficient in making critical decisions than a human being thus rendering human intervention redundant.194 The logic of modernity (reflected in the very technology which construes speed as power)195 magnified by late capitalism defies that possibility.

The remaining possibilities are either that there would be no one accountable or that the responsibility is attached to the machine. The first option suggests that the LAR is a weapon that should be banned.196 This possibility, which would require IHL to shift its focus back from the use of the weapon to its nature,197 has nevertheless a forward-looking significance: it admits that it is no longer human decision (use), but the weapon that deserves special attention.198 As noted above, presently this does not seem to be a viable option.199 Nevertheless, international lawyers can advance a regulative framework designed to ensure first, that the above-mentioned assumptions regarding transparency and safety measures are transformed into legal expectations, and second, that there is a forum consisting of representatives from both the private and the public sector, where concerns regarding the advent of LARs are voiced; awareness is raised and cooperative practices are encouraged.200

The second option acknowledges that the LAR cannot be regarded as merely a weapon. It is something else. That possibility invites different responses ranging from endowing the LAR with a legal personality analogous to that of a corporation,201 to admitting that it is a moral agent; that indeed we are creating a *golem*, a lethal robo-sapiens and a potential subject of post-human obligations and rights. This option compels us to contemplate our understanding of humanity and its membership, a contemplation undertaken extensively by science-fiction.202

The irony attached to the possibility that a technology designed to ‘‘take man out of the battle loop’’ may lead not merely to the interchangeability of man and machine but also to the replacement of homo sapiens, cannot be missed. Indeed the stuff that, much like the launching of Sputnik, used to belong only to science-fiction. Science-fiction literature anticipated these developments in terms of technology, process and impact. It does not provide us with solutions, but it does invite us to engage our imagination in conceiving them. Such engagement offers a promising starting point for a responsive international legal paradigm.

**IV. Concluding Thoughts: Intelligent Design Strikes Forward**

The impact of technology on the human condition requires reflection on our being and on what do we want to become.203 That impact is not limited to cloning and to LARs. We chose to focus on these two issues because they exemplify what is perhaps the most revolutionary, and ironic turn in what we still refer to as the development of humanity: the metamorphosis of organic evolution by natural selection into evolution by intelligent design (through genetic engineering that creates new organisms; implantation of non-organic instruments into an organism in a manner that alters the latter’s capabilities, needs and identity; and genetic programming that imitates the methods of genetic evolution designed to generate completely artificial creatures programmed to evolve independently).204 Once these technologies become applicable to humans, homo-sapiens would become something else.205

These developments are no longer confined to science-fiction. They are science. Scientific evolution and technological innovations are a reflection of societal values.206 These values encourage or discourage the development, adoption or rejection of technologies.207 Yet the relationship between societal values and technology is reciprocal: these developments also alter values.208 The technology which stirred the amazing progress we associate with modernity, also enhanced, in the name of liberty, enormous inequalities and enabled systematic dehumanization processes on a vast scale.

Making machines more human-like is a process current technology complements with making humans more machine-like. The politically correct reference to the process is ‘‘human enhancement.’’ This terminology is misleading insofar as it capitalizes on our automatic equation of technological developments with human progress and situates the human as its proper subject while obfuscating the possibility that the ‘‘enhanced’’ human would no longer be human.

Science and technology interact not only with socio-cultural values, but also with law in general and, given their global scope, with international law in particular. They present new types of problems.209 Such problems, as we suggested, may require a solution that transcends existing regulating parameters, invite imaginative legal thinking, indeed a paradigm shift. When it comes to such technologies, analogies and mere adaptation of existing rules are often insufficient, and in failing to recognize, or simply turning a blind eye on the logic underlying technological developments and their potentially subversive impact, are even dangerous.

In his last report as Special Rapporteur on extrajudicial, summary or arbitrary executions, Philip Alston attributed the “general lack of attention” on the part of the international legal community to the impact of new technologies on human rights to various factors ranging from problems perceived as more immediate, to technological illiteracy, to the observation that ‘‘anything that smacks of science-fiction seems more at home in an Asimov novel or Terminator film rather than in a human rights report.’’210 This article extended an invitation to pay attention to the attention science-fiction has given to the man-machine interaction and its impact on the human condition.

Science-fiction provides representations of technologies. Some are imagined, like transporting (‘‘teleporting’’) people or objects from one point to another; others exist, but are not in use, such as cloning; still others are being used as they are further enhanced, such as lethal robots. International law also provides representations of certain technologies such as cloning and drones. It is important to deconstruct and challenge these representations in both disciplines and closely examine their interrelations, while taking account of the different responsibilities of each.

Modern normative paradigms normally focus on behavior that should be prohibited or otherwise constrained. Aesthetic paradigms often challenge the cultural presuppositions underlying limits on human behavior. The main thrust of scientific developments is geared towards what we can achieve; not what we cannot. It is not inconceivable that thinking about regulating these developments should also think in terms of possibilities, rather than limitations, provided such thinking encompasses the question what is it that we want to become.211 This is a normative question par excellence. Given that human will too is subject to engineering, reflecting on the question has acquired a particular urgency.

**Notes**

FundingThe author gratefully acknowledges the support of COMA’s President research fund.; 1.Clifford Geertz, “Local Knowledge: Fact and Law in Comparative Perspective,” in *Local Knowledge: Further Essays in Interpretive Anthropology* (New York: Basic Books, 1983), p. 184.; 2.And to the business interests propelling these innovations. See, e.g., Armin Krishnan, *War as Business: Technological Change and Military Service Contracting* (Burlington, VT: Ashgate, 2008).; 3.Hannah Arendt, *The Human Condition* (Chicago, IL: The University of Chicago Press, 1998), p. 3.; 4.Op. cit., pp. 1–2 (emphasis added).; 5.Carl Freedman, *Critical Theory and Science-Fiction* (Middletown, CT: Wesleyan University Press, 2000).; 6.Philosophers, aware that human interaction with technology affects the human condition in terms of both consciousness and experience in ways that an instrumental view of technology fails to appreciate, have already accepted this invitation. See, e.g., Michael Philips, ed., *Philosophy and Science Fiction* (Buffalo, NY: Prometheus Books, 1984); Steven M. Sanders, ed., *The Philosophy of Science Fiction Films* (Lexington, KY: The University Press of Kentucky, 2009); Edward James and Farah Mendelsohn, eds, *The Cambridge Companion to Science Fiction* (Cambridge: Cambridge University Press, 2003).; 7.Canonic examples are found in Biblical legal stories the normative meaning of which is not merely inseparable from, but is articulated by the narrative. See Robert. M. Cover, “The Supreme Court 1982 Term: Foreword: Nomos and Narrative,” 97(4) *Harvard Law Review* 4 (1983), pp. 19–25.; 8.James Boyd White, *The Legal Imagination: Studies in the Nature of Legal Thought and Expression* (Boston, MA: Little, Brown and Co., 1973). White’s later contributions include *Heracles Bow: Essays on the Rhetoric and Poetics of the Law* (Madison, WI: University of Wisconsin Press, 1985); *Acts of Hope: Creating Authority in Literature, Law and Politics* (Chicago, IL: University of Chicago Press, 1994).; 9.For a general review of the law and literature project see, e.g., Gary Minda, *Postmodern Legal Movements: Law and Jurisprudence at Century’s End* (New York: New York University Press, 1995), pp. 149–66; Gary Minda, “Law and Literature at Century’s End,” 9(2) *Cardozo Studies in Law and Literature* 245 (1997); Ian Ward, *Law and Literature: Possibilities and Perspectives* (Cambridge: Cambridge University Press, 1995), pp. 3–27.; 10.See, e.g., Sanford Levinson, “Law as Literature,” 60 *Texas Law Review* 373 (1982); Sanford Levinson and Steven Mailloux, eds, *Interpreting Law and Literature: A Hermeneutic Reader* (Evanston, IL: Northwestern University Press, 1988); Stanley Fish, *Is There a Text in This Class? The Authority of Interpretive Communities* (Cambridge, MA: Harvard University Press, 1980).; 11.Cover’s “Nomos and Narrative” lay the foundation for this approach. See also Paul Gewirtz, “Narrative and Rhetoric in the Law,” in Peter Brooks and Paul Gewirtz, eds, *Law’s Stories: Narrative and Rhetoric in the Law* (New Haven, CT: Yale University Press, 1996), pp. 2–13; Julie Stone Peters, “Literature, the ‘Rights of Man,’ and Narratives of Atrocity: Historical Backgrounds to the Culture of Testimony,” 17 *Yale Journal of Law & the Humanities* 253 (2005).; 12.See, e.g., Richard H. Weisberg, “Family Feud: A Response to Robert Weisberg on Law and Literature,” 1 *Yale Journal of Law & the Humanities* 69 (1988).; 13.The argument that the law and literature movement is searching for the ‘‘Holy Grail,’’ equally confusing the myth with the ‘‘real,’’ has been provocatively made by Julie Stone Peters, “Law, Literature and the Vanishing Real: On the Future of an Interdisciplinary Illusion,” 120(2) *Proceedings of the Modern Language Association of America* 442 (2005). For reactions to this argument, see the Roundtable Discussion “Where Is Law & Literature Headed,” in “Symposium: The Power of Stories: Intersections of Law, Literature, and Culture,” 12 *Texas Wesleyan Law Review* 485 (2005), pp. 487–91.; 14.E.g., Paul W. Kahn, *The Cultural Study of Law: Reconstructing Legal Scholarship* (Chicago, IL: University of Chicago Press, 1999).; 15.E.g., Richard K. Sherwin, *When Law Goes Pop: The Vanishing Line Between Law and Popular Culture* (Chicago, IL: The University of Chicago Press, 2000).; 16.Theodor Meron, *Henry’s Wars and Shakespeare’s Laws: Perspectives on the Law of War in the Later Middle Ages* (Oxford: Clarendon Press, 1993); Theodor Meron, Bloody Constraint: *War and Chivalry in Shakespeare* (New York: Oxford University Press, 2000).; 17.Meron defines ‘‘chivalry’’ as a set of ideal norms, including “honour, loyalty, courage, mercy, commitment to the community and the avoidance of shame and dishonor,” Meron, Chivalry, Op. cit., pp. 11–12. See also Elizabeth L. Hillman, “Gentlemen under Fire: The U.S. Military and ‘Conduct Unbecoming’,” 26 *Law & Inequality: A Journal of Theory and Practice* 1 (2008).; 18.Meron, *Chivalry*, Op. cit., pp. 203–204.; 19.Ed Morgan, *The Aesthetics of International Law* (Toronto: University of Toronto Press, 2007).; 20.Op. cit., p. 176.; 21.Joseph R. Slaughter, *Human Rights Inc.: The World Novel, Narrative Form, and International Law* (New York: Fordham University Press, 2007).; 22.The genre focuses on a youth’s coming of age, understood as building of a sense of self – and as a self-regulating subject of rights – in a journey from adolescence to maturity. The book offers close reading of Bildungromans as diverse as Daniel Defoe, *Robinson Crusoe, Goethe, Wilhelm Meister’s Apprenticeship, Marjorie Oludhe Macgoye, Coming to Birth, Tsitsi Dangarembga, Nervous Conditions and Mario Roberto Morales, Face of the Earth, Heart of the Sky*.; 23.See, e.g., Susan Tiefenbrun, “The Failure of the International Laws of War and the Role of Art and Story Telling as a Self-Help Remedy for Restorative Justice,” 12 *Texas Wesleyan Law Review* 91 (2005).; 24.Slaughter, *Human Rights*, p. 55.; 25.See, e.g., Susan Ayres, “The Hand That Rocks the Cradle: How Children’s Literature Reflects Motherhood, Identity, and International Adoption,” 10 Texas Wesleyan Law Review 315 (2004); Gina Heathcote, “Article 51 Self-Defense as a Narrative: Spectators and Heroes in International Law,” 12 *Texas Wesleyan Law Review* 131 (2005); Gary Minda, “Narratives of International Law and Literature After 9/11,” 11 *ILSA Journal of International & Comparative Law* 435 (2005); Richard H. Weisberg, *Vichy Laws and the Holocaust in France* (New York: New York University Press, 1996); Orna Ben-Naftali, “Human, All Too Human Rights: Humanitarian Ethics and the Annihilation of Sodom and Gomorrah,” in Ulrich Fastenrath et al., eds, *From Bilateralism to Community Interest* (Oxford: Oxford University Press, 2011), p. 419.; 26.William Shakespeare, *The Tragedy of Hamlet, Prince of Denmark* act 2, sc. 2.; 27.Cited in Aeon J. Skoble, “Technology and Ethics *in The Day the Earth Stood Still,”* in Sanders, *Philosophy of Science Fiction*.; 28.The film *The Day the Earth Stood Still* (directed by Robert Wise in 1941) was based on the short story Farewell to the Master by Harry Bates. See Skoble, Op. cit. Interestingly, a 2009 remake of the film replaces Angst over nuclear weapons with concern for environmental damage.; 29.On the debate concerning the legality of anticipatory and preventive self-defense, see Mary Ellen O’Connell, *The Myth of Pre-emptive Self-defense*, American Society of International Law Task Force on Terrorism (2002), [*http://asil.org/taskforce/oconnell.pdf;*](http://asil.org/taskforce/oconnell.pdf;) John Yoo, “International Law and the War in Iraq,” 97 *American Journal of International Law* 563, (2003), pp. 571–5; Richard N. Gardner, “Neither Bush nor the ‘Jurisprudes’,” 97 *American Journal of International Law* 585 (2003).; 30.Questions that have interested political philosophers since 1651, when Hobbes presented us with the ‘‘quasi’’ science-fiction thought experiment known as Leviathan. Skoble suggests that what appears at first sight to be a Hobbesian exchange of absolute sovereignty for absolute security, is in fact based on Mill’s On Liberty (1859) harm principle, and that Klaatu’s ultimatum implies that “the only freedom lost in this arrangement is the freedom to act in ways we don’t have a right to in the first place,” Skoble, ‘‘Technology and Ethics,’’ p. 97 (discussion at 95–8).; 31.The impact of the development of LARs on war and its regulation is discussed in Part III.3.; 32.Situations in which human beings place computers endowed with artificial intelligence (AI) in control of the fates of human beings have been contemplated by famous science-fiction literature and films, such as, 2001: A Space Odyssey (Stanley Kubrick, Dir., MGM 1968) which was later published as a book, see Arthur C. Clarke, 2001: *A Space Odyssey* (New York: New American Library, 1968); *Dr. Strangelove or How I Learned to Stop Worrying and Love the Bomb* (Stanley Kubrick, Dir., Columbia Pictures Co. 1964); *The Terminator* (James Cameron, Dir., Hemdale Films 1984).; 33.Aldous Huxley, *Brave New World* (London: Chatto & Windus, 1932). See discussion in section 3.b.; 34.Anthony Burgess, *A Clockwork Orange* (London: William Heinemann, 1962), and its 1971 film adaptation by Stanley Kubrick.; 35.For a complete inventory see Michael P. Scharf and Lawrence D. Roberts, “The Interstellar Relations of the Federation: International Law and ‘Star Trek: The Next Generation’,” 25 *The University of Toledo Law Review* 577 (1994). See also Robert H. Chaires and Bradley S. Chilton, eds, *Star Trek Visions of Law and Justice* (Dallas, TX: Adios Press, 2003).; 36.William Gibson, *Neuromancer* (London: Victor Gollancz, 1984).; 37.Jack Womack, *Terraplane* (New York: Grove Press, 1988).; 38.Philip K. Dick, Do *Androids Dream of Electric Sheep?* (Garden City: Doubleday, 1968) and the film based on it, Blade Runner (Ridley Scott, Dir., Warner Bros. Studios 1982), provide a well-known example.; 39.The point is made with respect to science-fiction by Farah Mendelsohn, “Introduction: Reading Science-Fiction,” in James and Mendelsohn, *Cambridge Companion*, and by Freedman, *Critical Theory*, p. 22.; 40.Examples of such engagement include Ward, *Law and Literature*, who discusses works by Margaret Atwood, George Orwell, and Jonathan Swift; *The Handmaid’s Tale* is discussed in Derrick Bell, “Justice Marshall and the Handmaid’s Tale,” in *Afrolantica Legacies* (Chicago, IL: Third World Press, 1997), p. 123; Elizabeth Villiers Gemmette, ed., *Law in Literature: Legal Themes in Short Stories* (New York: Praeger, 1992) discusses short stories by Isaac Asimov, Edgar Allen Poe and Kurt Vonnegut, Jr.; Kieran Tranter, “Terror in the Texts: Technology – Law – Future,” 13(1) Law & Critique 75 (2002) discusses the works of Asimov, Frederik Pohl and Cyril M. Kornbluth; Lolita K. Buckner Inniss, “Bicentennial Man – The New Millennium Assimilationism and the Foreigner Among Us,” 54 *Rutgers Law Review* 1101 (2002) uses the movie Bicentennial Man (based on Asimov’s story); Sage Leslie-McCarthy, “Asimov’s Posthuman Pharisees: The Letter of the Law Versus the Spirit of the Law in Isaac Asimov’s Robot Novels,” 3(3) *Law, Culture & the Humanities* 398 (2007) discusses *The Robot Novels* of Isaac Asimov; see in general, Bruce L. Rockwood, “Law, Literature and Science Fiction: New Possibilities,” 23(3) *Legal Studies Forum* 267 (1999) and the Symposium on “Law, Literature and Science Fiction,” 23(3) *Legal Studies Forum* 267 (1999), pp. 267–348.; 41.Scharf and Roberts, ‘‘Interstellar Relations,’’ provide the notable exception, though their interest seems to be limited to pedagogy.; 42.The saying “the golden age of science fiction is twelve” has been attributed, inter-alios, to science-fiction writers Isaac Asimov and Terry Carr. See Norman Spinrad, “On Books: The Pulp Tradition,” 23 *Asimov’s science fiction* 131 (1999) and Thomas M. Ditch, *The Dreams Our Stuff is Made of: How Science Fiction Conquered the World* (1998), p. 1. These references are noted by Rockwood, ‘‘Law, Literature and Science Fiction,’’ p. 269, footnote 12.; 43.The common ‘‘literary’’ perception of science-fiction tends to be blind to subtleties, including the irony with which highly intelligent scientists, like Asimov or Lem, described their engagement in science-fiction; dismissive of the huge appeal of the genre to a wide-ranging, heterogeneous and often quite sophisticated, readership; oblivious of its impact on both popular attitudes to contemporary problems, including law and justice, and on the minds of decision-makers. The two notorious examples are US Presidents Truman and Reagan, whose respective decisions regarding the launching of the atomic bomb and the SDI project (tellingly dubbed ‘‘Star War’’) have reportedly been influenced by their reading of science-fiction.; 44.Farah Mendelsohn, “Introduction: Reading Science-Fiction,” in James and Mendelsohn, *Cambridge Companion*, p. 4 (noting that its quality as a thought experiment distinguishes it from other literary genres and easily accommodates philosophical and theological issues).; 45.Freedman, *Critical Theory*, pp. 2–13.; 46.Darko Suvin, *Metamorphoses of Science Fiction* (New Haven, CT: Yale University Press, 1979), p. 7.; 47.Op. cit., p. 6.; 48.The estrangement principle is similar to Brecht’s notion of alienation (*Verfremdung*). See, e.g., Bertolt Brecht, *The Messingkauf Dialogues*, trans. John Willett (London: Methuen, 2012), pp. 21–7.; 49.See Freedman, *Critical Theory*, p. 18. Freedman refines this definition by distinguishing between the cognition effect of the text and cognition proper. Note that estrangement differentiates science-fiction from realistic literature; cognition differentiates it from myth and fantasy.; 50.Martti Koskenniemi, *From Apology to Utopia: The Structure of International Legal Argument, Reissue with a new Epilogue* (Cambridge: Cambridge University Press, 2005); Karen Knop, “Utopia without Apology: Form and Imagination in the Work of Ronald St. John Macdonald,” *The Canadian Yearbook of International Law* (2002), p. 287, discusses Macdonald’s unique contribution to international legal scholarship, highlighting the affinity between the utopian form (or style) in international law as a speculative, imaginative genre and attempts to radicalize international law to bring about desired substantive changes.; 51.Post WWII political philosophy has virtually abandoned utopia largely due to the critiques of Berlin, Rawls and Oakeshott. See Isaiah Berlin, “The Pursuit of the Ideal,” in Henry Hardy, ed., *The Crooked Timber of Humanity* (New York: Knopf, 1991), pp. 1–19, and Isaiah Berlin, “Decline of Utopian Ideas in the West,” Op. cit., pp. 20–48 (arguing that the attempt to make people agree on a set of values rather than accept pluralism is a recipe for violence); John Rawls, *A Theory of Justice* (Cambridge, MA: Harvard University Press, 1971) (the teleology of a shared goal collapses individual desires and violates human rights); Michael Oakeshott, On Human Conduct (Oxford: Oxford University Press, 1975) (positing the danger to discursive practices posed by utopian robotic, managerial problem-solving focus). The point is discussed in Clair P. Curtis, “Rehabilitating Utopia: Feminist Science Fiction and Finding the Ideal,” 8(2) *Contemporary Justice Review* 147 (2005), proposing that the vacuum left by philosophy has been filled by science-fiction writers whose utopian visions take count of these critiques and are thus characterized as skeptical or ambiguous, such as Ursula K. Le Guin, *The Dispossessed: an Ambiguous Utopia* (London: Granada Books, 1975).; 52.Farah Mendelsohn, “Introduction: Reading Science-Fiction,” in James and Mendelsohn, *Cambridge Companion*, p. 4.; 53.Isaac Asimov, “The Bicentennial Man,” in Michael Philips, ed., *Philosophy and Science Fiction* (Buffalo, NY: Prometheus Books, 1984), p. 183.; 54.Op. cit., p. 210.; 55.Op. cit., p. 211.; 56.Adiv Zelony, “Don’t Throw the Baby Out with the Bathwater: Why a Ban on Human Cloning Might be a Threat to Human Rights,” 27 *Loyola of Los Angeles International & Comparative Law Review* 541 (2005), p. 541.; 57.Denis Campbell, “Doctors’ radical plan to tackle organ shortage,” *The Guardian*, February 13, 2012.; 58.See, e.g., Margaret Jane Radin, “Contested Commodities,” in Martha M. Ertman and Joan C. Williams, eds, *Rethinking Commodification: Cases and Readings in Law and Culture* (New York and London: New York University Press, 2005), pp. 81, 86. This dilemma resonates an earlier debate on the definition of the moment of death. See e.g.: “Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain-death,” 205(6) *Journal of the American Medical Association* 337 (1968) discussed in Shai Lavi, “Introduction: Law Facing Science and Technology,” in Shai Lavi, ed., *Technologies of Justice: Law, Science and Society* (The Buchman Faculty of Law Series, Tel-Aviv University, 2003) (Hebrew), pp. 9–12.; 59.The idea that certain things cannot be traded originated from Roman Law. Rudolf Sohm, *The Institutes: A Textbook of the History and System of the Roman Private Law* (Leipzig: Duncker & Humblot, 1901), pp. 320–23.; 60.Council of Europe, *On Harmonisation of Legislation of Member States relating to Removal, Grafting and Transplantation of Human Substances*, Resolution 78(29) (Adopted by the Committee of Ministers on 11 May 1978 at the 287th meeting of the Ministers’ Deputies), art. 9.; 61.Yosuke Shimazono, “The State of the International Organ Trade: a Provisional Picture based on Integration of Available Information,” 85(12) Bulletin of the World Health Organization 955 (2007), p. 956.; 62.Op. cit., pp. 956–7.; 63.World Health Organization, *Resolution on human organ and tissue transplantation*, WHA 57.18 (May 22, 2004), available at: [*http://www.who.int/transplantation/en/A57\_R18-en.pdf*](http://www.who.int/transplantation/en/A57_R18-en.pdf).; 64.Transplantation of Human Organs Act, India Code. Act No. 42 of 1994.; 65.Ji Minhua and Zhang Yingguang, “Beijing Mulls New Law on Transplants of Deathrow Inmate Organs,” *Caijing*, November 28, 2005; D. A. Budiani-Saberi and F. L. Delmonico, “Organ Trafficking and Transplant Tourism: A Commentary on the Global Realities,” 8 *American Journal of Transplantation* 925 (2008), p. 927; David Matas, “Emerging Challenges in International Law: Organ Transplant Abuse in China,” Paper for the Queensland University of Technology Human Rights and Governance Colloquium, Brisbane, Australia, November 26, 2011, [*http://www.david-kilgour.com/2011/matas\_11262011.pdf*](http://www.david-kilgour.com/2011/matas_11262011.pdf).; 66.David Matas and David Kilgour, *Bloody Harvest: The Killing of Falun Gong for their Organs* (Woodstock, ON: Seraphim Editions, 2009), available at: [*www.organharvestinvestigation.net*](http://www.organharvestinvestigation.net).; 67.See, e.g., Jennifer M. Krueger, “Life Coming Bravely out of Death: Organ Donation Legislation across European Countries,” 18 *Wisconsin International Law Journal* 322 (2000), p. 328.; 68.Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, 2010 O.J. L 207/14.; 69.Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Jan. 24, 2002 (ETS No. 186). As of June 2013, 33 states are party to the convention; 12 are party to the protocol.; 70.Anne-Maree Farrell, “Adding Value? EU Governance of Organ Donation and Transplantation,” 17 *European Journal of Health Law* 51 (2010), p. 64.; 71.Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine, art. 16.; 72.Erica Teagarden, “Human Trafficking: Legal Issues in Presumed Consent Laws,” 30 *North Carolina Journal of International Law & Commercial Regulation* 685 (2004–2005), p. 719.; 73.Jodi Picoult, *My Sister’s Keeper* (New York: Atria, 2004). The book was adapted to a movie in 2009 (Dir. Nick Cassavetes). This book (and all other books discussed as examples) was extremely successful, translated into dozens of languages and selling millions of copies worldwide). See interview with Picoult on the BBC’s *World Book Club*, September 1, 2012, available for download at: [*http://www.bbc.co.uk/podcasts/series/wbc*](http://www.bbc.co.uk/podcasts/series/wbc).; 74.The McGowan Institute for Regenerative Medicine at Pittsburgh University has a program for growing artificial organs: [*http://www.mirm.pitt.edu*](http://www.mirm.pitt.edu) (last visited June 14, 2013). See also *60 Minutes: Growing Body Parts* (CBS News, July 25, 2010), [*http://www.cbsnews.com/video/watch/?id=6711905n&tag=contentBody;storyMediaBox*](http://www.cbsnews.com/video/watch/?id=6711905n&tag=contentBody;storyMediaBox).; 75.Kazuo Ishiguro, *Never Let Me Go* (New York: Knopf, 2005).; 76.See, e.g., Kerry Lynn Macintosh, *Illegal Beings: Human Clones and the Law* (Cambridge: Cambridge University Press, 2005), p. 27; Zelony, ‘‘Human Cloning,’’ pp. 559–63.; 77.An interesting analogy has been suggested between the stigma attached to ‘‘clones’’ and the one that was attached to illegitimate children. The latter ended in severe human rights violations. Zelony, Op. cit. Ishiguro’s novel strengthens the analogy: regarded as mere instruments and discarded once they are no longer of use, their suffering echoes that of the Dickens’s novels’ illegitimate children.; 78.Michael H. Shapiro, “I Want a Girl (Boy) Just Like the Girl (Boy) that Married Dear Old Dad (Mom): Cloning Lives,” 9(1) *Southern California Interdisciplinary Law Journal* 1 (1999), pp. 6–7.; 79.Chamundeeswari Kuppuswamy et al., *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance* (United Nations University – Institute of Advanced Studies Report, 2007), p. 7.; 80.Instruments that attempt to ban mainly reproductive cloning include art. 11 of the UNESCO Declaration on the Human Genome and Human Rights (UNESCO G.C. Res. 29 C/17, UNESCO GC, 29th Sess. (1997)); (adopted by the UN General Assembly, G.A. Res. 53/152, U.N. Doc. A/RES/53/152, (Dec. 9, 1998)); World Health Organization, *Ethical, Scientific and Social Implications of Cloning in Human Health*, WHA 51.10 (May 16, 1998). On the acceptance of therapeutic, as opposed to reproductive cloning, see, e.g., Adrienne N. Calhoun Cash, “Invasion of the Clones: Animal Cloning and the Potential Implications on the Future of Human Cloning and Cloning Legislation in the United States, the United Kingdom, and Internationally,” 82 *The University of Detroit Mercy Law Review* 349 (2005), pp. 372–5.; 81.Macintosh, *Illegal Beings*, p. 3; Debora L. Spar, *The Baby Business: How Money, Science and Politics Drive the Commerce of Conception* (Watertown, MA: Harvard Business School Press, 2006), pp. 143–5.; 82.Macintosh, Op. cit.; Roberto Andorno, “Biomedicine and International Human Rights Law: In Search of a Global Consensus,” 80 *Bulletin of the World Health Organization* 959 (2002), p. 961.; 83.Macintosh, Op. cit.; 84.Among the US states that have banned human cloning are Arkansas, Iowa, Michigan, North Dakota, and South Dakota. See Macintosh, Op. cit., pp. 75–89; Spar, *Baby Business*, pp. 151–3.; 85.Council of Europe Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Jan. 12, 1998 (ETS No. 168).; 86.G.A. 59/280 U.N. Doc. A/RES/59/280 (March 23, 2005). See also *Report of the Ad Hoc Committee*, [*http://www.un.org/law/cloning*](http://www.un.org/law/cloning). On the non-binding status of the Declaration, see Arnold N. Pronto, “Consideration at the United Nations of an International Prohibition on the Cloning of Human Beings,” 20 *Leiden Journal of International Law* 239 (2007), pp. 247–52.; 87.George J. Annas, Lori B. Andrews and Rosario M. Isai, “Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations,” 28 *American Journal of Law & Medicine* 151 (2002), p. 169.; 88.This is the second version of her creation (Genesis 2: 22); in the first, God created them both at the same time, and Eve was not a derivative of Adam (Genesis 1: 27).; 89.See *Evans v. United Kingdom*, 2007-I Eur. Ct. H.R. (App. No. 6339/05).; 90.Huxley, Brave New World.; 91.Nazi regime provides a monstrous manifestation of the eugenic movement. See, e.g., Benno Müller-Hill, *Murderous Science: Elimination by Scientific Selection of Jews, Gypsies, and Others in Germany*, 1933–1945 (New York: Oxford University Press, 1988).; 92.Ira Levin, *The Boys from Brazil* (Boston, MA: G. K. Hall, 1976). The movie was released in 1978 (Dir. Franklin J. Schaffner).; 93.Walter Benjamin, *The Work of Art in the Age of Mechanical Reproduction*, J. A. Underwood trans. (London: Penguin Books, 2008).; 94.The growing recognition of animal rights is a case at point. See, e.g., Tom Regan, “The Case for Animal Rights,” in Steven M. Cahn, ed., *Exploring Ethics: an Introductory Anthology* (New York: Oxford University Press, 2009), p. 310.; 95.See the discussion in section II.3.; 96.On the development of the technology and its potential impact on human monopoly over war, see generally, Peter W. Singer, *Wired for War: the Robotics Revolution and Conflict in the Twenty-first Century* (New York: Penguin Press, 2009).; 97.For a comprehensive study, see Directorate-General for External Policies of the Union, Policy Department, *Human Rights Implications of the Usage of Drones and Unmanned Robots in Warfare*, EXPO/B/DROI/2012/12 (May 2013).; 98.Human Rights Watch & the International Human Rights Clinic, Human Rights Program at Harvard Law School, *Losing Humanity: The Case Against Killer Robots*, Nov. 2012 [hereinafter: Losing Humanity].The Report classifies robotic weapons according to their level of autonomy into three categories: Human in the Loop; Human on the Loop and Human out of the Loop weapons, focusing mainly on the latter. Op. cit., p. 2.; 99.Arendt, The Human Condition.; 100.Attributed to then-CIA Director Leon Panetta, *U.S. Air Strike in Pakistan Called “Very Effective”*, CNN.Com, May 18, 2009, cited in Ryan J. Vogel, “Drone Warfare and the Law of Armed Conflict,” 39(1) *Denver Journal of International Law & Policy* 101 (2010), p. 104, footnote 15.; 101.‘‘Human conditioning’’ is an old phenomenon: taking advantage of psychological methods of brainwashing, coercion and other forms of conditioning, humans have been manipulated and ‘‘re-programmed’’ to be used as weapons for generations. See, Mako Sasaki, “Who Became Kamikaze Pilots, and How Did They Feel towards Their Suicide Mission?” *The Concord Review* 176 (1999); Emiko Ohnuki-Tierney, *Kamikaze Diaries: Reflections of Japanese Student Soldiers* (Chicago, IL: University of Chicago Press, 2007); Mohammed M. Hafez, *Manufacturing Human Bombs: The Making of Palestinian Suicide Bombers* (Washington, DC: US Institute of Peace Press, 2006).; 102.See Moshe Idel, *Golem: Jewish Magical and Mystical Traditions on the Artificial Anthropoid* (Albany, NY: State University of New York Press, 1990).; 103.According to the *Talmud, Tractate Sanhedrin* 38B, Adam, his dust “kneaded into a shapeless husk,” was initially created as a golem.; 104.Genesis 1:27.; 105.The Rabbi is Judah Loeb Ben Bezalel (the Maharal). For the various versions of the story, see, Yudl Resenberg, *The Golem and the Wondrous Deeds of the Maharal of Prague*, Curt Leviant, ed. & trans. (New Haven, CT: Yale University Press, 2007).; 106.Mary W. Shelley, *Frankenstein* (London: Bloomsbury, 2006) (1818). The book is considered the first science-fiction book since it first added technology (the *novum*) to the cognitive estrangement produced by the fantasy of a man-made living creature.; 107.Goethe’s poem, *Der Zauberlehrling*, was made universally popular in the 1940 Disney animation ‘‘Fantasia,’’ and ‘‘Fantasia 2000.’’; 108.Karel Čapek, R.U.R., Paul Selver trans. (Mineola, NY: Dover Publications, 2001).; 109.Isaac Asimov, “*Liar*,” in I, Robot, pp. 91–111.; 110.Op. cit., pp. 25–45.; 111.Isaac Asimov, *Robots and Empire* (Garden City, NY: Doubleday, 1985). The Zeroth law resonates substantively with the ‘‘Martens Clause.’’ On the theoretical significance of the latter, see Theodor Meron, “The Hague Peace Conference: The Martens Clause, Principles of Humanity and the Dictates of Public Conscience,” 94 *A.J.I.L.* 78 (2000).; 112.Discussed in Don D’Ammassa, “Allen, Roger MacBride,” in *Encyclopedia of Science Fiction* (New York: Facts On File, 2005), pp. 6–8.; 113.Lyuben Dilov, “Icarus’s Ways,” referred to in Valentin Ivanov, *Lawful Little Country: The Bulgarian Laws of Robotics* (June 16, 2011), [*http://worldsf.wordpress.com/2011/06/15/lawful-little-country-the-bulgarian-laws-of-robotics*](http://worldsf.wordpress.com/2011/06/15/lawful-little-country-the-bulgarian-laws-of-robotics).; 114.Op. cit.; 115.Note that the cultural perception of human/robot interaction in non-Western technological societies, primarily Japan, is different and accordingly promulgates other laws of robotics. See Jennifer Robertson, “Robo Sapiens Japanicus: Humanoid Robots and the Posthuman Family,” 39(3) *Critical Asian Studies* (2007), pp. 369–98.; 116.Asimov, I, Robot, p. 182.; 117.Op. cit., p. 178.; 118.Isaac Asimov, *Foundation and Earth* (Garden City, NY: Doubleday, 1986).; 119.Isaac Asimov, “That Thou Art Mindful of Him,” in *The Complete Robot* (London: Grafton Books, 1983). Discussed in Wikipedia, [*http://en.wikipedia.org/wiki/Three\_Laws\_of\_Robotics*](http://en.wikipedia.org/wiki/Three_Laws_of_Robotics) (last visited June 14, 2013).; 120.Isaac Asimov, “The Caves of Steel,” in *The Robot Novels* (New York: Ballantine Books, 1988).; 121.*Wikipedia*, [*http://en.wikipedia.org/wiki/Three\_Laws\_of\_Robotics*](http://en.wikipedia.org/wiki/Three_Laws_of_Robotics) (last visited June 14, 2013).; 122.Isaac Asimov, “Little Lost Robot,” in I, *Robot*, pp. 112–43.; 123.Op. cit., p. 116.; 124.The realization that lethal (though not yet autonomous) robotic technology presents, inter-alia, regulatory problems, is already migrating from the real world to popular culture, thereby underscoring the social impact of the technology. Thus an episode of the courtroom drama ‘‘The Good Wife’’ featured the trial of a soldier facing 12 counts of murder for sending drones to fire on unarmed citizens in Afghanistan, sitting at her desk in an air force base in the US. *The Good Wife: Season 3, Episode 9* (CBS, November 20, 2011).; 125.Aaron A. Toscano, “Using I, Robot in the Technical Writing Classroom: Developing a Critical Technological Awareness,” 28(1) *Computers & Composition* 14 (2011).; 126.For a succinct exposé of the technologies see ‘‘Losing Humanity,’’ pp. 6–19.; 127.Special Rapporteur on extrajudicial, summary or arbitrary executions, U.N. Doc. A/65/321, § 22, footnotes 36–38 (Aug. 23, 2010) (Philip Alston).; 128.E.g., the Missile Technology Control Regime and the Wassenaar Arrangement. Some litigation in the US indicates that in this context too greed overpowers legal prohibitions. See, e.g., the case of Aviation Services International BV (an aircraft company in the Netherlands whose director and sales manager, Robert and Neil Kraaipoel pled guilty in the US District Court in Washington DC to the charges of conspiracy to export UAVs to Iran), see *United States v. Kraaipoel et al.*, No. 09-cr-00220 & 1:09-cr-00219 (D. D. C., Sept. 24, 2009).; 129.The International Institute for ***Strategic*** Studies, “Cyberspace: Assessing the Military Dimension,” 111(1) *The Military Balance* (2011), pp. 27–32; 130.Alston noted in 2010 that it is expected to become operational within a year (Alston, Special Rapporteur, § 25). This expectation is being met. See, e.g., Cory Doctorow, *London Think-tank has already lofted a fleet of swarming file-sharing drones* (Mar. 21, 2012), [*http://boingboing.net/2012/03/21/london-thinktank-has-already-l.html*](http://boingboing.net/2012/03/21/london-thinktank-has-already-l.html).; 131.Orson Scott Card, *Ender’s Game* (New York: TOR Books, 1985). On the nexus between this novel and current technology, see Steve Tarlow, “Fully automated killer drones changing face of warfare,” *NewsyType* (Sept. 20, 2011), [*http://www.newsytype.com/11606-automated-killer-drones/*](http://www.newsytype.com/11606-automated-killer-drones/).; 132.Isaac Asimov, “Catch the Rabbit,” in I, *Robot*, pp. 68–90.; 133.See, e.g., ‘‘Drone pilots on the edge of collapse,” *RT* (Dec. 20, 2011), [*http://rt.com/usa/news/drone-pilots-us-stress-193;*](http://rt.com/usa/news/drone-pilots-us-stress-193;) Robert Sparrow, “Building a Better WarBot: Ethical Issues in the Design of Unmanned Systems for Military Applications,” 15(2) *Science & Engineering Ethics* 169 (2009).; 134.In interviews, drone operators express their experience as follows: “It is like a video game. It can get a little bloodthirsty. But it’s fucking cool,” cited in Sparrow, Op. cit., p. 184; “[We] can coolly pick out targets as if playing a video game … We do things in the virtual world, daring and violent things, that we would never do if we were there in perso,.” cited in Peter Singer, “Military Robots and the Laws of War,” 23 *The New Atlantis* 25 (2009), p. 42. Similar sentiments are expressed by Israeli drone operators as well, see, e.g., “It’s like taking a joystick like play-station and killing,” *Ha’Aretz*, July 2, 2010, [*www.haaretz.co.il/hasite/spages/1177375.html*](http://www.haaretz.co.il/hasite/spages/1177375.html) (Hebrew).; 135.United States Air Force, *Unmanned Aircraft Systems Flight Plans 2009–2047*, US Air Force Headquarters (May 18, 2009); The UK Approach to Unmanned Aerial Systems, UK Ministry of Defence, Joint Doctrine Note 2/11 (Mar. 30, 2011).; 136.See, e.g., Alston, Special Rapporteur, §§ 27–8; Peter Singer, “War of the Machines,” 303(1) *Scientific American* 56 (2010).; 137.David Langford, *Starcombing: Columns, Essays, Reviews and More* (Rockville, MD: Cosmos Books, 2009), p. 119.; 138.Peter Singer, *The 2009 William C. Stutt Ethics Lecture*, the Vice Admiral James B. Stockdale Center for Ethical Leadership, US Naval Academy: Ethical Implications of Military Robotics (Mar. 25, 2009).; 139.The point, however, should not be overstated: attacking robots is not essentially different from attacking other military objects. The attack exposes the perpetrator to retaliation under the self-defense doctrine (provided it amounts to an ‘‘armed attack’’ within the meaning of U.N. Charter art. 51) as well as under IHL which perceives participators in hostilities as legitimate targets. See the Geneva Convention Relative to the Treatment of Prisoners of War, art. 4, Aug. 12, 1949, 6 U.S.T. 3316, 75 U.N.T.S. 135; Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflicts (Protocol I), art. 43, 1125 U.N.T.S. 3 (entered into force Dec. 7, 1978) [hereinafter API]; art. 51(3) of API, id.; Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of Non-International Armed Conflicts (Protocol II), art. 13(3), 1125 U.N.T.S. 609 (entered into force Dec. 7, 1978) [hereinafter APII]).; 140.See Ronald C. Arkin, *Governing Lethal Behavior in Autonomous Robots* (Boca Raton, FL: CRC Press, 2009). For a critic, see Vivek Kanwar, “Post Human Humanitarian Law: The Law of War in the Age of Robotic Weapons,” 2 *Harvard National Security Journal* 616 (2011), pp. 626–7.; 141.Ben Austen, “The Terminator Scenario: Are We Giving Our Military Machines Too Much Power?” *POPSCI* (Jan. 13, 2011), [*http://www.popsci.com/technology/article/2010-12/terminator-scenario?page=2*](http://www.popsci.com/technology/article/2010-12/terminator-scenario?page=2).; 142.Aristotle, *Poetics*, S.H. Butcher, trans. (CreateSpace, 2011), p. 26.; 143.See e.g., ICRC Rep., *International Humanitarian Law and the Challenges of Contemporary Armed Conflicts* (2011), pp. 36–40, available at: [*http://www.icrc.org/eng/assets/files/red-cross-crescent-movement/31st-international-conference/31-int-conference-ihl-challenges-report-11-5-1-2-en.pdf*](http://www.icrc.org/eng/assets/files/red-cross-crescent-movement/31st-international-conference/31-int-conference-ihl-challenges-report-11-5-1-2-en.pdf).; 144.See ‘‘Losing Humanity,’’ pp. 46–8.; 145.Helga Nowotny et al., *Re-Thinking Science: Knowledge and the Public in an Age of Uncertainty* (Cambridge: Polity Press, 2001).; 146.The UK Approach to Unmanned Aerial Systems, § 521.; 147.Alston, Special Rapporteur, § 45. Alston attributed the fact that law lags behind technological development to two factors: first, the perception that “[O]ther humanitarian or human rights issues – disastrous floods in Pakistan … or gang killing in Mexico – seem far more immediately pressing”; second that “anything that smacks of science fiction seems more at home in an Asimov novel or Terminator film rather than in a human rights report.” Op. cit., § 18. This 1980s science-fiction film which casts the then yet-to-be-governor of California Arnold Schwarzenegger in the role of ‘‘The Terminator,’’ a humanoid sent back in time to earth to prevent the birth of a human who would otherwise lead a successful revolt of human beings against humanoids, is the standard metaphor used in scholarly writing to describe the direction of current robotics. In making the same reference, Singer further notes that The Terminator is the only character that ended up in the 2003 list of Hollywood’s hundred greatest villains and heroes of all times in both categories. Singer, *Wired for War*, p. 428.; 148.Alston, Op. cit., §§ 47–8.; 149.On that debate see, e.g., Orna Ben-Naftali and Keren Michaeli, “We Must Not Make a Scarecrow of the Law: A Legal Analysis of the Israeli Policy of Targeted Killings,” 36(2) *Cornell International Law Journal* (2003); David Kretzmer, “Targeted Killing of Suspected Terrorists: Extra-Judicial Executions or Legitimate Means of Defence?” 16(2) *European Journal of International Law* 171 (2005); Jordan J. Paust, “Self-Defense Targeting of Non-State Actors and Permissibility of U.S. Use of Drones in Pakistan,” 19(2) *Journal of Transnational Law & Policy* 237 (2010).; 150.And similar terms with which the Obama administration replaced the Bush administration’s “global war on terror”. See Scott Wilson and Al Kamen, “‘Global War on Terror’ is Given New Name,” *Washington Post*, Mar. 25, 2009, [*http://www.washingtonpost.com/wp-dyn/content/article/2009/03/24/AR2009032402818.html*](http://www.washingtonpost.com/wp-dyn/content/article/2009/03/24/AR2009032402818.html).; 151.The debate centers on whether this transnational armed conflict is international (Yoram Dinstein, *The Conduct of Hostilities under the Law of International Armed Conflict* (Cambridge: Cambridge University Press, 2010), pp. 56–7; Dapo Akande, “Classification of Armed Conflicts: Relevant Legal Concepts,” in Elizabeth Wilmshurst, ed., *International Law and the Classification of Conflicts* (Oxford: Oxford University Press, 2012), p. 32), or non-international (Hamdan v. Rumsfeld 548 US 557 (2006)). Since the determinants of the legality of the use of drones are equally applicable in both kinds of conflict, the classification in the present context matters little.; 152.See, e.g., Harold Hongju Koh, *Keynote Speech at the Annual Meeting of the American Society of International Law: The Obama Administration and International Law* (Mar. 24, 2010), available at: [*http://faisalkutty.com/editors-picks/full-text-of-harold-koh%E2%80%99s-address-to-asil-mar-25-2010/;*](http://faisalkutty.com/editors-picks/full-text-of-harold-koh%E2%80%99s-address-to-asil-mar-25-2010/;) Harold Hongju Koh, “The Lawfulness of the U.S. Operation Against Osama Bin Laden,” *Opinio Juris* (May 19, 2011), [*http://opiniojuris.org/2011/05/19/the-lawfulness-of-the-us-operation-against-osama-bin-laden/;*](http://opiniojuris.org/2011/05/19/the-lawfulness-of-the-us-operation-against-osama-bin-laden/;) Kenneth Anderson, “Targeted Killing and Drone Warfare: How We Came to Debate Whether There is a ‘Legal Geography of War’,” in Peter Berkowitz, ed., *Future Challenges in National Security and Law* (Stanford, CA: Hoover Institution, Stanford University, 2011), available at: [*www.futurechallengesessays.com*](http://www.futurechallengesessays.com); John O. Brennan, *Remarks on the Efficacy and Ethics of the President’s Counterterrorism Strategy*, the Woodrow Wilson International Center for Scholars, Washington, DC (April 30, 2012), available at: [*http://www.wilsoncenter.org/event/the-efficacy-and-ethics-us-counterterrorism-strategy*](http://www.wilsoncenter.org/event/the-efficacy-and-ethics-us-counterterrorism-strategy).; 153.API, art. 52; Regulations concerning the Laws and Customs of War on Land, Annex to Hague Convention (IV) respecting the Laws and Customs of War on Land, art. 23, Oct. 18, 1907, 205 C.T.S. 277 [hereinafter Hague IV]; Rome Statute of the International Criminal Court, art. 8, July 17, 1998, 2187 U.N.T.S. 90 [hereinafter ICCST].; 154.API, art. 48, 51 & 52; APII, art. 13; ICCST, art. 8(2)(b)(i), (ii), (iv), (v) & 8(2)(e); Hague IV, art. 22, 24(1), 25 & 26.; 155.API, art. 51(5) & 55; ICCST, art. 8(2)(a)(iv) & 8(2)(b)(iv).; 156.Hague IV, art. 22 & 23; API, art. 35; Convention on Prohibitions or Restrictions on the Use of Certain Conventional Weapons Which May Be Deemed to Be Excessively Injurious or to Have Indiscriminate Effects, Preamble, Oct. 10, 1980, 1342 U.N.T.S. 137.; 157.See, e.g., Vogel, ‘‘Drone Warfare.’’; 158.Koh, *Obama Administration*; Vogel, ‘‘Drone Warfare.’’; 159.See, e.g., C. Christine Fair, “Drone Wars,” *Foreign Policy*, May 28, 2010; Bill Roggio and Alexander Mayer, *Long War Journal* (conclude that between 2006–2012 “2,227 leaders and operatives from Taliban, Al Qaeda, and allied extremist groups killed and 138 civilians killed”), available at: [*http://www.longwarjournal.org/pakistan-strikes.php*](http://www.longwarjournal.org/pakistan-strikes.php); Peter Bergen and Katherine Teidelman, “The Year of the Drones: An Analysis of U.S. Drone Strikes in Pakistan, 2004–2010,” *New American Foundation* (concluding ‘‘that the 114 reported drone strikes … have killed between 830 and 1,210 individuals of whom around 550 to 850 were described as militants by reliable press accounts, about two thirds of the total on average. Thus, the true civilian fatality rate according to our analysis is approximately 32 percent’’). For starkly different data see *infra* note 164.; 160.‘‘Losing Humanity’’ provides a good example: its call for a ban on the development of autonomous killer robots essentially revolves around the inability of fully autonomous weapons to meet the international legal standards of distinction (at 30–32); proportionality (at 32–34); military necessity (at 34–35) and humanity (at 35–36).; 161.See, e.g., Anthony Dworkin, “Drone Attacks: Why New Wars Need New Rules,” *European Council of Foreign Relations* (Oct. 14, 2010), available at: [*http://ecfr.eu/content/entry/Drone\_Attacks\_Why\_New\_Wars\_Need\_New\_Rules;*](http://ecfr.eu/content/entry/Drone_Attacks_Why_New_Wars_Need_New_Rules;) “Osama Bin Laden: Statement by the UN Special Rapporteur on Summary Executions and on Human Rights and Counter-Terrorism,” *U.N. High Commissioner for Human Rights* (May 6, 2011), available at: [*http://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=10987&LangID=E*](http://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=10987&LangID=E).; 162.See Hague IV, art. 23(c); API, art. 41. Violating this rule is a war crime under the ICCST, art. 8(2)(b)(vi). It is also prohibited to conduct hostilities effecting a policy of no-survivors (Hague IV, art. 23(d); API, art. 40), and violation of this rule is a war crime under the ICCST, art. 8(2)(b)(xii) & 8(2)(e)(x). On robots’ inability to detect surrender, see Gary E. Marchant et al., “International Governance of Autonomous Military Robots,” 12 *Columbia Science & Technology Law Review* 272 (2011), p. 282; Noel Sharkey, “Saying ‘No!’ to Lethal Autonomous Targeting,” 9(4) *Journal of Military Ethics* 369 (2010), p. 378.; 163.Markus Wagner, “Taking Humans Out of the Loop: Implications for International Humanitarian Law,” 21 *Journal of Law Information & Science* 1 (2011). See generally, Directorate-General for External Policies of the Union, Human Rights Implications.; 164.E.g., David Kilcullen and Andrew McDonald Exum, Op-Ed., “Death From Above, Outrage Down Below,” *New York Times*, May 17, 2009 (estimating that over the years, drones had killed 14 ‘“terrorist leaders’ at the price of some 700 civilians in Pakistan,” pointing that “This is 50 civilians for every militant killed. A hit rate of 2%”). For a critique of the methodology used by Bergen and Teidelman, ‘‘Year of the Drones,’’ see an interview with Madiha Tahir (a journalist in Karachi), “Killer Drones: Counting the Human Cost,” *The Asia Pacific Forum* (WBAI 99.5FM, March 28, 2011) (noting that it is based on anonymous sources or local stringers who themselves cannot access the relevant areas).; 165.The CIA, a civilian agency the actions of which are covert, is involved in these operations. For a comprehensive study of the issue and the accountability problems it generates, see Philip Alston, “The CIA and Targeted Killings Beyond Borders,” 2 *Harvard National Security Journal* 283 (2011).; 166.See, e.g., Adam Entous et al., “Drone attacks Split US Officials,” *The Wall Street Journal*, June 4, 2011; Kenneth Anderson, “Targeted Killing is Legitimate and Defensible,” *Weekly Standard*, June 6, 2011.; 167.See, e.g., Kilcullen and McDonald Exum, ‘‘Death From Above’’; Singer, *Wired for War*, pp. 304–14.; 168.See the definition of science-fiction at supra text and notes 46–49.; 169.Singer, ‘‘War of the Machines,’’ p. 63; Singer, *Wired for War*, p. 41.; 170.Arendt, *The Human Condition*.; 171.See e.g., Toni Pfanner, “Asymmetrical Warfare from the Perspective of Humanitarian Law and Humanitarian Action,” 87(857) *International Review of the Red Cross* 149 (2005); Michael N. Schmitt, “21st Century Conflict: Can the Law Survive?” 8(2) *Melbourne Journal of International Law* 443 (2007); Andreas Paulus and Mindia Vashakmadze, “Asymmetrical War and the Notion of Armed Conflict – A Tentative Conceptualization,” 91(873) *International Review of the Red Cross* 95 (2009); Eyal Benvenisti, “The Legal Battle to Define the Law on Transnational Asymmetric Warfare,” 20 *Duke Journal of Comparative & International Law* 399 (2010).; 172.George Lakoff and Mark Johnson, *Metaphors We Live By* (Chicago, IL: University of Chicago Press, 2003), p. 3.; 173.Op. cit., p. 4.; 174.Op. cit., p. 5.; 175.Paul W. Kahn, “The Paradox of Riskless Warfare,” 22(3) *Philosophy and Public Policy Quarterly* 2 (2002), pp. 4–8; Paul W. Kahn, “Criminal and Enemy in the Political Imagination,” 99 *The Yale Review* 148 (2011). IHL prohibition on killing people who are *hors de combat* (Common Article 3 of the Geneva Conventions) emanated from the fact that they no longer present a risk; it is the risk combatants and civilians who take direct part in hostilities pose, that justifies that putting them at risk. Noting that the new face of war engages a shift from focusing on status based on group-membership (combatants/civilian) to focusing on individuals and that neither the war nor the law enforcement paradigms are adequate, the need for creating a military environment that is more adjudicative-like is being suggested. See Samuel Issacharoff and Richard H. Pildes, “Drones and the Dilemma of Modern Warfare,” Public Law & Legal Theory Research Paper Series Working Paper No. 13-34 13 (forthcoming in Peter Bergen and Daniel Rothernberg, eds., *Drone Wars: The Transformation of Armed Conflicts and the Promise of Law* (Cambridge: Cambridge University Press, 2013)).; 176.Insofar as the decision to engage in war is made in the light of the risks entailed. See, e.g., Alston, Special Rapporteur, § 4.; 177.Kahn, *Paradox of Riskless Warfare*, p. 182.; 178.The move to apply concurrently IHL (reflecting the war paradigm) and IHR (reflecting the law enforcement paradigm) has generated much writing, attesting in and of itself to the shifting of paradigmatic grounds. See, e.g., Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion, 1996 I.C.J. 226-593 ¶ 25 (July 8); Legal Consequences of the Construction of the Wall in the Occupied Palestinian Territory, Advisory Opinion, 2004 I.C.J. ¶ 106 (July 9); Armed Activities in the Territory of the Congo (D.R.C. v. Uganda) 2005 I.C.J. 116 ¶ 119 (Dec. 19); Orna Ben-Naftali, ed., *International Human Rights and Humanitarian Law: Collected Courses of the Academy of European Law* (Oxford: Oxford University Press, 2011); Roberta Arnold and Noelle Quénivet, eds., *International Humanitarian Law and Human Rights Law: Towards a New Merger in International Law* (Leiden: Martinus Nijhoff, 2008); *Ruti Teitel, Humanity’s Law* (Oxford: Oxford University Press, 2011).; 179.Kahn, Paradox of Riskless Warfare, pp. 16–18.; 180.Carl Schmitt, *Political Theology: Four Chapters on the Concept of Sovereignty*, George D. Schwab trans. (Chicago, IL: University of Chicago Press, 2004), p. 15; Giacomo Marramao, “Schmitt and the Categories of the Political: The Exile of the Nomos: For a Critical Profile of Carl Schmitt,” 27 *Cardozo Law Review* 1567 (2000).; 181.In reference to Meron, *supra* text and notes 16–19.; 182.The question whether these individuals should be classified as protected persons according to GC IV with regard to detention is discussed in e.g., Derek Jinks, “The Declining Significance of POW Status,” 45 *Harvard International Law Journal* 367 (2004). Dinstein, *Conduct of Hostilities*, pp. 33–9.; 183.ICRC, *Interpretive Guidance on the Notion of Direct Participation in Hostilities under International Humanitarian Law* (2009), available at: [*www.icrc.org/eng/assets/files/other/icrc-002-0990.pdf;*](http://www.icrc.org/eng/assets/files/other/icrc-002-0990.pdf;) but cf. some commentators suggest to classify individuals who can be targeted in non-international armed conflicts on the basis of their membership in the armed group, see Yoram Dinstein et al., *The Manual on the Law of Non-International Armed Conflict: With Commentary* § 1.1.2 (2006), reprinted in 36 *Israel Yearbook of Human Rights* (2006).; 184.Jacques Derrida, *Dissemination*, Barbara Johnson trans. (London: Athlone Press, 1981), pp. 71, 99.; 185.Giorgio Agamben, *Homo Sacer: Sovereign Power and Bare Life*, Daniel Heller-Roazen trans. (Stanford, CA: Stanford University Press, 1998).; 186.API, art. 36. The ICRC position since 1987 is that the “automation of the battlefield” should be subject to the review regime of new and modified weapons because “if man does not master technology, but allows it to master him, he will be destroyed by technology.” See ICRC, *Commentary on the Additional Protocols of 8 June 1988 to the Geneva Conventions* of 12 August 1949 (1987), pp. 427–8. Human Rights Watch proceeds from the same premise, see ‘‘Losing Humanity,’’ pp. 21–6.; 187.See, e.g., Issacharoff and Pildes, ‘‘Drones,’’ p. 13.; 188.Singer, *Wired for War*, pp. 327–43.; 189.Alston, Special Rapporteur, § 34; ‘‘Losing Humanity,’’ pp. 42–5.; 190.Alston, Special Rapporteur, § 48.; 191.Oren Gross, “When Machines Kill: Criminal Responsibility for International Crimes Committed by Lethal Autonomous Robots” (forthcoming. A draft from the Institute of Advanced Studies, the Hebrew University of Jerusalem, is available at: [*http://micro5.mscc.huji.ac.il/~gharpaz/admins/uploads/Oren\_Gross\_reading.pdf*](http://micro5.mscc.huji.ac.il/~gharpaz/admins/uploads/Oren_Gross_reading.pdf)).; 192.API, art. 36, distinguishes between a first and a second phase analysis of weapons: the former looks at the nature of the weapon; the latter at its use. In practice, current IHL focuses on the use of weapons, rather than on their nature to determine their legality, requiring that the use comply with its fundamental principles of distinction, proportionality and humanity. See Legality of the Threat or Use of Nuclear Weapons Case, Advisory Opinion 1996 I.C.J. Rep. 226 §§ 78, 88 (July 8).; 193.Robert Sparrow, “Killer Robots,” 24(1) *Journal of Applied Philosophy* 62 (2007), pp. 70–71.; 194.Op. cit., p. 70.; 195.In the sense that the speediest controls space/time thereby becoming the most powerful. See Paul Virilio, *Vitesse et Politique: Essay de Dromologie* (Paris: Galilée, 1977).; 196.Sparrow, ‘‘Killer Robots,’’ p. 66.; 197.API, art. 36.; 198.Kanwar, ‘‘Post Human Humanitarian Law’,’’ p. 624.; 199.See supra text at note 137. At the same time, the observation that the time for a certain regulation is yet to come does not mean that it will not come, the prime example being the adoption of the CCW.; 200.Along the lines of the Vienna Convention for the Protection of the Ozone Layer, Mar. 22, 1985, 1513 U.N.T.S. 324. For this and similar proposals, see Marchant et al., ‘‘International Governance.’’; 201.That analogy would still situate the LAR within that amazingly successful fiction wrought by the legal imagination.; 202.See discussion in Parts III.1 and 2 above.; 203.Martin Heidegger, *Being and Time*, John Macquarrie & Edward Robinson trans. (London: SCM Press, 1962).; 204.Yuval Harari, *A Brief History of Mankind* (Israel: Kineret, Zmora–Bitan, Dvir, 2011) (Hebrew), pp. 392–408.; 205.E.g., presently, military-driven technology enables the ‘‘spy-fly’’: implanting insects (and whales) with devices that allow a human or robotic operator to remotely control their movements and receive and transmit information. Research is geared towards implanting devices that would allow for artificial hearing and sight. In the future, cyborgs may be able to link the human brain directly to a computer, changing our understanding of memory, communication and cognition, i.e., our very being. Harari, *Brief History*, p. 401, and footnotes 118 & 119.; 206.Gaia Bernstein and Zvi Triger, “Over-Parenting,” 44 *University of California Davis Law Review* 1221 (2011), pp. 1236–7.; 207.Op. cit.; See also David Elliott and Ruth Elliott, *The Control of Technology* (London: Wykeham Publications, 1976), pp. vii, 1–3; Marcel Chotkowski Lafollette and Jeffrey K. Stine, “Contemplating Choice: Historical Perspectives on Innovation and Application of Technology,” in Lafollette and Stine, *Technology and Choice*, Op. cit. But cf. Jacques Ellul, “The Technological Order,” in Carl Mitcham and Robert Mackey, eds, *Philosophy and Technology: Readings in the Philosophical Problems of Technology* 86 (New York: Free Press, 1972), p. 88. On the need to design technologies to reflect social values, see e.g., Batya Friedman and Peter H. Kahn, Jr., “Human Agency and Responsible Computing: Implications for Computer System Design,” in Batya Friedman, ed., *Human Values and the Design of Computer Technology* (Cambridge: Cambridge University Press, 1997), p. 221.; 208.See Elliott and Elliott, *Control of Technology*, p. 10; Andrew Feenberg, *Alternative Modernity: The Technical Turn in Philosophy and Social Theory* (Berkeley: University of California Press, 1995), pp. 227–8.; 209.See, e.g., Joseph W. Dellapenna, “Law in a Shrinking World: The Interaction of Science and Technology with International Law,” 88 *Kentucky Law Journal* 809 (1999–2000).; 210.Alston, Special Rapporteur, § 18.; 211.Harari, *Brief History*, p. 409, concludes that given that what is being engineered is human will, and given further that presently it is still humans who do the engineering, the real question is ‘‘what do we wish to wish,’’ and that s/he who is not terrified by the question, probably did not give it enough thought.

**Load-Date:** March 29, 2024

**End of Document**



[***Federal budget and dual citizenship: four MPs quit after high court ruling - as it happened; Labor grills government over tax plan, while reeling over resignations sparked by Katy Gallagher being ruled ineligible. Follow all the day's events, liveSign up to receive the latest news in Australian politics every weekday***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5S8S-GW71-F021-653W-00000-00&context=1516831)

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**Section:** AUSTRALIA NEWS; Version:19

**Length:** 14771 words

**Byline:** Amy Remeikis

**Body**

block-time published-time 8.38am BST

Now that the gremlins have been tamed, we're going to wrap up the blog for tonight - because we have another big day ahead of us tomorrow.

That's right, it is budget reply day, where Bill Shorten will lay out Labor's economic plan. That will happen later in the evening, and then he'll head to 7.30.

We'll be back with that, and everything else that happens tomorrow bright and early, so make sure you get your rest.

For anyone who missed it, we are heading to a super Saturday of byelections, probably on 16 June, where Labor will fight to keep Perth, Fremantle (where the Greens may pose a threat) Braddon and Longman (which will be the big contest) and the Liberals will attempt to wrestle Mayo from Centre Alliance. The campaigning has begun.

The budget seems like it was delivered a lifetime ago.

No doubt we will be back on it tomorrow though. Won't that be exciting? I know I can't wait.

A big thank you to Mike Bowers, for dragging my carcass through the day, and to the Guardian brains trust.

As always, a big thank you to you for reading, and for sticking through our technical difficulties. I am not kidding when I say we called the UK office to fix it.

Have a wonderful night, rest up - and take care of you.

block-time updated-timeUpdated at 8.42am BST

block-time published-time 8.21am BST

Malcolm Turnbull is explaining to 2GB that the 200,000 migrant cap is a "ceiling, not a target".

"We don't take in anyone that we don't need, or we don't want," he says.

That's based on the budget line which showed there were no changes to the migration limit - despite people \*cough Tony Abbott cough\* agitating for it to be lower.

Pauline Hanson has already jumped on it, judging by her social media.

block-time updated-timeUpdated at 8.27am BST

block-time published-time 8.17am BST

Now we are back, I can show you some more of what Mike Bowers was up to this afternoon:

Bill Shorten confers with his front bench during question time. Photograph: Mike Bowers for the Guardian Prime Minister Malcolm Turnbull during question time. Photograph: Mike Bowers for the Guardian

From the citizenship press conferences:

Rebekha Sharkie resigns from Parliament. Photograph: Mike Bowers for the Guardian ***Opposition*** leader Bill Shorten and the manager of ***opposition*** business Tony Burke discuss the Labor resignations. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 8.26am BST

block-time published-time 8.09am BST

Malcolm Turnbull says you can't trust " Bill Shorten on citizenship and you can't trust him with your money."

Slow clap for whoever workshopped that segue.

block-time updated-timeUpdated at 8.22am BST

block-time published-time 8.08am BST

Tim Storer is delivering his maiden speech to the Senate.

His entry into the Senate, as part of the section 44 merry-go-round, was a trial by fire, having dealt with the government's company tax bill in the first two weeks he was in parliament - and then killing it off (for now).

He says everything he does is underscored by a foundation of integrity.

block-time updated-timeUpdated at 8.21am BST

block-time published-time 8.06am BST

(from earlier, but it was ***deleted*** as part of the attempts to fix the blog)

The Greens, who are the only party who had MPs who resigned as soon as being made aware they were dual citizens, have weighed in on the latest round of section 44 resignations: Rebekha Sharkie and the three Labor MP's who ceded to the high court have done the right thing by resigning. Had the Greens pushed for a full audit of Parliament taken on board months ago, we wouldn't be in this mess today. How many more MPs will have to be crowbarred out of their positions - kicking and screaming for months - rather than doing the right thing. On a day when we should have been talking about how the budget impacts on Australians, politicians were talking about themselves. Today's resignations will not be the end of this ongoing crisis: there are several Liberal MPs that still have a cloud over their heads, and Malcolm Turnbull now needs to do the right thing and refer them to the high court to put an end to this uncertainty. The only long-term solution is to abolish this outdated law through a referendum to make sure that Australians of all backgrounds can give back to their communities through parliamentary service.

block-time updated-timeUpdated at 8.20am BST

block-time published-time 8.05am BST

Tony Abbott rang in to deliver his regular 2GB nuggets of gold. He thinks the Liberals are a chance to ***win*** in Mayo.

Malcolm Turnbull will also speak to 2GB. He's due to be on air any moment now.

block-time published-time 8.01am BST

A big thank you to the boffins who just fought all of the gremlins, in mortal combat, to bring the blog back from the brink.

block-time updated-timeUpdated at 8.04am BST

block-time published-time 7.00am BST

Susan Lamb's whole speech to the chamber:

Speaker in February this year, I explained in detail to the Parliament - to the people of Australia, and of course the wonderful people in my electorate of Longman - the steps I took to renounce any entitlement to citizenship that I may have held.

Mr Speaker today a ruling made by the High Court of Australia has set a new precedent of course, giving a new interpretation on the "reasonable steps" test which has been in place for more than two decades.

Now in light of this judgment, I'll be resigning as the Member for Longman and I will re-contest my seat in a byelection because, Mr Speaker, I am not done yet.

I put my hand up to represent people who were just like me.

To represent the workers in Narangba who rely upon on a job. A good job, a secure job, a safe job with fair pay.

I put my hand up to be a voice for parents in Morayfield with families who need schools that deliver an education that their children need.

And of course to stand up for affordable and accessible health care that the good people on Bribie Island, and in fact every person in Australia, deserves.

After nearly two years of having the privilege of taking up this fight - I am not done.

While there is $80 billion worth of taxpayers' money still going to banks and big businesses instead of the pockets of people in Burpengary and Caboolture - I am not done.

And while there is still a housing crisis, elderly waiting for aged care packages, and an unreliable NBN connecting us with the rest of the world - I am not done.

Because in Longman, we deserve a government that's fair, a government that cares and just as I have done since the 2016 election and for many, many, many years before that, I will keep fighting because, Mr Speaker, I am not done.

Speaker this is not a valedictory speech, let me be very clear. I'm putting the government on notice that, while ultimately the decision will be in the hands of the amazing people of Longman, I intend to be back.

block-time updated-timeUpdated at 8.18am BST

block-time published-time 6.57am BST

The phone calls to electors in the Labor electorates heading to byelections are due to begin in a couple of hours. The campaign has officially begun.

No one is resigning, officially, until Friday though.

block-time updated-timeUpdated at 8.12am BST

block-time published-time 6.49am BST

The crew at Buzzfeed very kindly allowed me to spew out words in between blog posts for their Buzzfeed OzPol show - if you ever wanted to know what a slightly manic, two-hours' sleep, over-caffeinated Amy looked like, you are in for a treat. (Spoiler: not great)

enltr. [*@AmyRemeikis*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) says the plan to put people on $41k & $200k on the same tax rate in seven year's time is a batshit crazy idea. "I could say in seven years I'm going to be living in Beyoncé's mansion!"   [*#BFOzPol*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*pic.twitter.com/dKNnKx6ox1*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- BuzzFeedOz Politics (@BuzzFeedOzPol) [*May 9, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 8.11am BST

block-time published-time 6.41am BST

After the day that has been, we all deserve a little treat.

Today, [*I offer you this gem*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) from the Chaser (thanks to Gareth Hutchens for the find) - which explains how Mark Latham was all a prank set up by the Chaser, which went terribly wrong. Watch out for the cameos, Ed Husic among them.

block-time updated-timeUpdated at 8.10am BST

block-time published-time 6.14am BST

Here is Justine Keay's whole statement to the chamber:

The greatest honour of my life was being elected as the member for Braddon in 2016.

In my first speech in this House, I said the people of West Coast and North West of Tasmania, and of course King Island, they're a resilient lot. Ours is a community that genuinely cares for each other. We come together in challenging times, we're generous of spirit, we're always willing to pitch in and help one another.

I chose to put up my hand up for my community because the need to stand up for workers, for pensioners and those trying to make ends meet, convinced me that they deserved a progressive voice in Canberra fighting for them.

I'm also here to give my kids, and kids right across my electorate, the decent, secure jobs they deserve in the beautiful part of Tassie they know and love.

I want to make it very clear to every member of my community, and every member of this House, that I am not done working and fighting on behalf of those who sent me here.

This citizenship issue has been a difficult time for my family, friends, supporters and staff and of course, myself. It's been a character building experience.

But I can hold my head high for being upfront and honest with my electorate. I have nothing to fear or hide, you just need to look at my disclosure for that. I've been criticised for being too honest. Bit of an oxymoron for a politician perhaps. People have commented that while I don't have an allegiance to the United Kingdom, that perhaps I have an allegiance to my family. Well if they are my flaws, then so be it.

I am a seventh generation Tasmanian. A town in the Huon Valley bears my mother's family's name. I am proud of my heritage from both my mother and father, as I would expect all Australians are proud of theirs.

I've always been upfront about the fact that before nominating for Parliament I acted on the best available legal advice, which indicated that I had satisfied the eligibility requirements under the Constitution as they had been interpreted for 25 years.

Today, the High Court has set a new precedent. This is a new rule, and I respect this new rule without qualification.

As a consequence of today's decision, I will be resigning my seat as the Federal Member for Braddon. I will be writing to you, Mr Speaker to advise you of my resignation.

I will nominate for preselection to contest the election in the seat of Braddon. The people in my community deserve a representative that cares about them, respects them and listens to them. This is what I have done and I will continue to do.

I am proud of the fact that one of the first things I was able to achieve after being elected was to successfully advocate on behalf of local farmers for an inquiry to get to the bottom of the floods that devastated the livelihoods and the lives of my local communities.

I am proud of the fact my office has been able to assist hundreds if not thousands of people in Braddon.

I am proud of the fact I have been the first Member of Parliament in my electorate in generations to take mobile offices to our outlying communities in the far North West and West Coasts.

I am proud of the fact I have been able to advocate on behalf of our local fishers, farmers, miners, foresters and industry and of course our pensioners and people who feel they don't have a voice.

But I also know there is much more to be done.

The people of Braddon deserve a government that invests in them and puts them first. This is what a Shorten Government will do.

I have been privileged to have been given roles and responsibilities within the Shorten ***Opposition*** Caucus as Deputy Chair of the Parliamentary Committee on Agriculture and Water Resources and Secretary of Labor's Caucus on Australian Jobs Taskforce. I want to thank my caucus colleagues for their unwavering support and mentoring a united and awesome Labor team.

I have been supported by a passionate labour movement in Tasmania, party members, union members and of course, my staff who go beyond what is required and to support me and to help the people of my electorate. This has been hard on them and on my family and has taken a personal toll on all of us.

But we will keep fighting - this is bigger than us, it is about giving a voice to those who feel they don't have one. It's about helping people. That's why I'm here. It's about making our region, as wonderful as it is, better and better.

block-time updated-timeUpdated at 6.41am BST

block-time published-time 6.13am BST

Even the prime minister has given up on question time. It ends.

block-time published-time 6.11am BST

The Parliamentary Budget Office has released its budget snapshot.

For some facts and figures, [*head here*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time published-time 6.08am BST

Chris Bowen to Scott Morrison :

How does the treasurer expect this Parliament to support policies when he doesn't know or won't say how much they cost?

Morrison: IT IS $140 BILLION. GOSH! THE BUDGET IS AWESOME

(I assume) He is yelling like he's being swept up in a cyclone and there is a lot of pointing and fist-shaking and honestly, I am too tired to go through this for a millionth time today.

block-time updated-timeUpdated at 6.13am BST

block-time published-time 6.04am BST

Bill Shorten to Malcolm Turnbull :

The government has refused to say the separate cost of all three steps of its personal income tax scheme, and refused to provide the year-by-year cost of its income tax scheme. Is it that the government does not know what these numbers are, or that it is refusing to provide the answer?"

Scott Morrison takes it, because he just hasn't got his yelling-at-Labor quota in today (and someone in his office has been very busy researching).

"The Leader of the ***Opposition*** may be very used to changing the rules to suit himself in the union movement and the ***opposition***. This is what the former finance minister said in the government of which he formed apart. This is Penny Wong in 2012: 'We do not release 10-year costings.' The treasurer Wayne Swan stood at the same National Press Club and talked about 10-year projection as being unreliable, and he said to Fran Kelly on 20 March 2012, 'We do not do those 10-year estimates'. Mr Speaker, it is always one rule for the Labor Party and one rule for everyone else. One rule for their union mates, one rule for everyone else. You can't change the rules..."

He withdraws the union mates comment and ends his question.

Peter Dutton takes his daily dixer on how safe you are. VERY, VERY SAFE and now even safer because of the awesome budget.

block-time updated-timeUpdated at 6.23am BST

block-time published-time 6.00am BST

Bill Shorten tries again to get Scott Morrison to say the corporate tax cuts will cost $80 billion, but Morrison is not having any of it.

And I really don't think I have the energy at this stage to type out another answer saying nothing. It's been a rough day.

block-time published-time 5.57am BST

Michael McCormack is yelling at the ***opposition*** because he is talking about infrastructure funding that is "ABOUT SAVING PEOPLE'S LIVES" (he is talking about the upgrade of the Cooroy-to-Curra section of the Bruce Highway, which is a particularly deadly section of road.

Anthony Albanese has a point of order to say they didn't yell anything out.

Peter Dutton gets up to accuse Anne Aly of having made an unparliamentary remark, which Bill Shorten laughed at. She denies it, we move on.

block-time published-time 5.52am BST

And Chris Bowen has another go:

This morning the treasurer introduced legislation to implement the government's entire seven-year personal income tax gain.

Already today at the National Press Club, the treasurer refused to say what the year-by-year cost of that scheme because he said those costings were unreliable. If the Treasurer won't say what the year-by-year cost of the scheme is, and he also says the costing is unreliable, how could the Treasurer of the parliament vote for it?"

Scott Morrison :

The answer is simple. The cost of the measure is $140 billion over the next 10 years. That is more than twice the relief that has been provided to companies under our enterprise tax plan. We are putting the priority on ensuring the tax relief is provided to those on low and middle incomes... If the ***opposition*** wants to deny Australians lower taxes, then they should just be honest about it. They should not come in here looking for excuses, Mr Speaker. They will look for any excuse not to reduce taxes for Australians. The bill is on the table. Vote for it or oppose it. Whichever way you do it, then the Australian people know where you sit on tax and where they sit on tax. Higher tax on Labor, low under the Liberal and National Party and you are making that clear to the Australian people."

block-time updated-timeUpdated at 5.58am BST

block-time published-time 5.46am BST

Chris Bowen tries again:

What is the year by year cost of the budget's new personal income tax scheme over those seven years?"

Scott Morrison:

Page 33 of budget paper two, which sets out the costings, and as I have indicated the full cost is $140 billion over 10 years."

So, still no answer.

He says Labor didn't provide the year-by-year estimate beyond the forward estimates for its retiree tax, which is basically the "your face is" argument.

block-time updated-timeUpdated at 5.50am BST

block-time published-time 5.41am BST

Chris Bowen to Scott Morrison :

This morning the treasurer introduced legislation to reform the income tax scheme. He refused to say what the year-by-year cost of the scheme would be. Will you tell the Parliament what is the year-by-year cost of the government's personal income tax scheme over those seven years?"

Morrison: The shadow treasurer will be well aware of the process for putting together budgets. He was once a treasurer. If not for very long, and we will work very hard on this side of the house to ensure he doesn't get that opportunity again, because of a lack of understanding that he has demonstrated in this place about how budgets are put together. I have made it very clear that the cost of that measure over the medium term is $140 billion."

#theministerdoesnotanswerthequestion

block-time updated-timeUpdated at 5.47am BST

block-time published-time 5.37am BST

Chris Bowen to Scott Morrison :

The budget includes a seven-year personal income tax scheme. The budget papers outlined three separate steps of the scheme, and the government this morning introduced legislation to implement all three steps of the scheme. Will the treasurer immediately release the separate cost of each step of its personal income tax scheme?"

Morrison: The cost of the plan over 10 years is $140 billion.

We should move to another dixer, but whoever it was supposed to be on the government side doesn't get up in time, and Bowen jumps up to fill the gap with another question.

"My question is for the PM. Will the PM release a separate cost of each step of the government's seven-year income tax plan?"

Turnbull: The Treasurer has answered that question very well. The question that the member for McMahon and his leader can't answer is what is going to happen to the Australian economy and thousands of jobs if they were able to manage their tax plan, which is putting up taxes on businesses, on families, grabbing the cash out of retirees..."

He's told to sit down, because Tony Burke has a point of order, but then decides he has already said enough and concludes his answer.

We move on to the Member for Bonner, Ross Vasta, who gets a cheer for remembering to stand up, and another dixer on "how amazing is this budget, oh really amazing, I had no idea" is uttered. Craig Laundy gets this one. He is really looking forward to heading to Queensland this Friday to talk more budget amazingness, apparently.

block-time updated-timeUpdated at 5.43am BST

block-time published-time 5.32am BST

Bill Shorten tries again:

Prime Minister, is the total cost of corporate tax cuts over 10 years from July 1, 2018 both legislated and proposed to be legislated by this government, is it more than or less than $100 billion?"

Malcolm Turnbull : The honourable member, by the year 2027-2028, the full enterprise tax plan, were it all to be legislated, will have been in full operation for two years. So asking what company tax receipts will be 10 years from now is effectively asking, "What will be the profitability of the corporate sector 10 years from now?" Medium-term estimate has been provided.

Scott Morrison in his latest effort of describing the budget as the greatest thing since Cronulla, refers to the ***opposition*** as "you muppet".

That is ruled unparliamentary.

block-time updated-timeUpdated at 5.37am BST

block-time published-time 5.28am BST

Bill Shorten to Malcolm Turnbull :

I missed the whole question, but it basically amounts to WHAT IS THE TOTAL OF CORPORATE TAX CUTS FROM JULY 1 2018 OVER THE 10 YEARS, OMG JUST SAY $80 BILLION

The prime minister does not say $80 billion.

I refer him to the earlier answer. The medium term cost of the unlegislated component of the enterprise tax plan currently before the Senate is $35.6 billion over the period from 2016-17 to 27-28. And in 27-28 the projected cost of that is around $9.8 billion."

As Shorten's eye begins to twitch, Scott Morrison moves on to the latest dixer, where the budget reaches Collingwood-magically-gets-all-its-greatest-players-from-the-past-100-years-onto-one-roster levels of awesome.

block-time updated-timeUpdated at 5.33am BST

block-time published-time 5.23am BST

The next #deathtodixers puts the budget at if-a-unicorn-married-a-mermaid-and-held-the-reception-inside-the-world's-sparkliest-wedding-cake-on-Atlantis-as-Billy-Joel-sang-Elton-John-songs levels of awesome.

block-time updated-timeUpdated at 5.34am BST

block-time published-time 5.22am BST

Cathy McGowan has the independent's question - it is on mobile phone blackspots:

"My question is what is the long-term plan to deliver mobile phone coverage to regional Australia? The budget overlooks the challenge of mobile connectivity in regional areas and there is no commitment for future rounds in the mobile phone blackspot program. What is your message to the 200 plus communities in Indi and across regional Australia that will be forced to go without this essential service?"

Malcolm Turnbul l: [it's under review, essentially]

I can also advise the house that the regional telecommunications review has been brought forward and the minister has asked them to hand down their recommendations to the government before the end of the year. The outcomes of the review will show how regional communication looks in the future. It will provide direction on where we need to focus our efforts to ensure contemporary communications in regional and rural Australia. We are committed to fixing the mobile blackspots."

block-time updated-timeUpdated at 5.34am BST

block-time published-time 5.18am BST

Paul Fletcher apparently said something interesting. I missed it, but it was enough for Tony Smith to ask him to stop interjecting, and for Tanya Plibersek to start her question to Scott Morrison again:

"When the Treasurer answered the exact same question last year, why was the treasurer refusing to tell Australians how much his corporate tax cuts cost over the next 10 years? So I ask, what is the total cost of corporate tax cuts over 10 years from 1 July 2018, both legislated and proposed to be legislated by the government?"

Morrison: [after being told to stick to the point, and responding with the parliamentary version of 'I was totally gunna!']

"Before the point of order was taken, the point I was about to make about the bank levy was how banks are major companies in this country who pay corporate tax and by the time that the major banks in this country would receive a corporate tax rate of 25%, they will have paid in the bank levy more than $16 billion in bank levy back to the government. But the figure... Look, get your calculator out and get a pen. Write it down and I will help you with the maths. Add $9.8 billion to the cost. It is that simple. I know maths is not your strong suit and no-one on that side can help you. Just add 9.8. It is simple!"

block-time updated-timeUpdated at 5.21am BST

block-time published-time 5.12am BST

Back to a #deathtodixers and in this answer, the budget is basically if Rihanna and Beyonce had a baby and it was raised in a commune with all the Hemsworths.

block-time updated-timeUpdated at 5.14am BST

block-time published-time 5.11am BST

Chris Bowen to Scott Morrison :

Following last year's budget, when asked what is the total cost of tax cuts both legislated and proposed to be legislated by the government, the treasurer answered $65.4bn. One year on, I ask, what is the total cost of the corporate tax cuts legislated and proposed to be legislated by the government?

Morrison, who looks like he is revving up to screaming-at-the-television-in-golden-point-time-yelling levels answers:

The... medium-term cost of the unlegislated component of the enterprise tax plan, which is currently before the Senate, is $35.6bn. Over the period from now until 2027-2028. The last year of that, the cost is $9.8bn, which includes the cost of that measure as it applies economy-wide, so I will let the shadow treasurer add up if he can. But the point is this, the point is this, Mr Speaker, is that the costings I have just set out is for the unlegislated tax cuts. They would know that once a measure is legislated, it is legislated, so it begs this question Mr Speaker. It begs this question as to why they want to know. Why would you want to know the cost of tax legislation that has already been legislated for small- and medium-sized businesses, unless you wanted to reverse it? Unless you wanted to rip away the tax cuts given for small- and medium-sized businesses in this country, I will tell you! $25bn is the cost to revenue of what those legislated tax cuts gave to small- and medium-sized businesses over 10 years. And you will be out $25bn, $25bn unless you reverse those tax cuts in your plan. Because you went to the last election and you said... Beating your chest, over there, the great man from McMahon, you are going to reverse the whole enterprise tax plan. You be honest with small businesses, and you tell them, are you going to rip away your tax cuts that have been legislated by this parliament? Or you going to strip it away?"

block-time updated-timeUpdated at 5.18am BST

block-time published-time 5.06am BST

Question time begins

Holy moly, we haven't even had question time today.

This is insane.

Here we go:

Bill Shorten to Malcolm Turnbull:

What is the total cost of corporate tax cuts over 10 years from the 1 July 2018, proposed to be legislated by the government?" (Labor has begun using a $80bn figure for it - they are now trying to get the government to say it.)

Turnbull: (after a bit of argy bargy over relevance):

The treasurer advises that the cost of the unlegislated tax relief business is $35bn, and the cost in the final year that is outside of the medium term, figures for which were given at the last budget, is just under $10bn. But Mr Speaker, what the Labor party is demonstrating in its questions, and a reference to an $80bn figure, to which they have simply added $15bn to $65bn, has no financial basis.

"What they have indicated is that their plan is to repeal all of the legislated tax cuts for Australian business. What they want to do is not simply oppose the unlegislated tax cuts for larger businesses, but repeal the tax cuts for Australian-owned, family-owned businesses up to $50m turnover, which employed 6.8 million Australians. That is what Labor wants to do, undermine the investment, the optimism, the entrepreneurship that is driving record jobs growth that we have seen. 415,000 jobs last year, the record jobs growth, the strong economy that is enabling us to deliver the outcomes for Australian families, 10 million Australians will receive tax relief from the treasurer's budget, and we will move to a personal income tax system that is simpler and fairer."

We move on to a dixer, the first of a series I am going to call: "Just exactly how amazing is this budget on a scale of Rhianna to Beyonce?" which, no offence to Trevor Evans, gives me a chance to run to the bathroom for the first time all day.

block-time updated-timeUpdated at 5.16am BST

block-time published-time 5.01am BST

So, in the meantime, I have made some calls.

In Longman, the LNP don't have a candidate ready as yet. And that worries them, because they don't want the optics of losing a Queensland seat this close to the election. Because they need to hold Queensland to have any chance of holding on to power, and they are in danger of losing a whole bunch of them. Labor is less worried, but also aware they aren't guaranteed to hold the seat. And given the amount of time Bill Shorten has spent in Queensland, vying for those votes, and talking fairness (a big deal in the lower- and middle-income seat of Longman), Labor would like a little more certainty that they will ***win*** it.

In short, both parties are feeling pressure - and that this is a test for the coming election. And neither of them are particularly happy about it.

block-time updated-timeUpdated at 5.09am BST

block-time published-time 4.56am BST

Here is what Josh Wilson had to say:

The high court's decision in the case of Katy Gallaghe r has changed the way the law is understood and interpreted in relation to eligibility under section 44 of the constitution. Until today's decision the 'reasonable steps' test had been accepted for more than 25 years. It continues to be the basis of the Australian electoral commission's advice to candidates (in the current candidate's handbook), and was the guidance I followed when I nominated in 2016.

The new interpretation of the law means the question of whether a person took all 'reasonable steps' to renounce foreign citizenship simply doesn't exist for dual Australian-British citizens, irrespective of the administrative delay in the process (which is generally two to four months). Under the new interpretation, any prospective candidate must have their British citizenship deregistered before the close of nominations. In my case, that was effectively impossible.

I was endorsed as a late replacement Labor candidate in Fremantle on 12 May 2016 and completed the requisite UK Home Office paperwork to renounce my British citizenship on that day. I mailed the renunciation form and attached documents on Friday 13 May, using express registered post. I received confirmation that the documents had been received by the UK Home Office on Monday 16 May. The processing fee for renunciation was withdrawn from my bank on 6 June. I nominated the following day, two days before the close of nominations. I received a letter from the UK Home Office dated 24 June saying that my British citizenship had been deregistered, with a copy of the renunciation form stamped 29 June 2016.

I was elected on 2 July 2016. I have not served a single day as anything other than an Australian citizen.

I was born in London when my parents were on a working holiday. My mum was expecting me when they travelled to the UK, and I returned home with them at the age of one after we'd travelled in Europe for six months in a Kombi van. Both my parents were born in Australia. My great-great-grandfather came to Fremantle as a convict in the 1860s. I have never lived in the UK, and have only visited there twice, in 1998 and 2012, for a few weeks each time.

In any case, the high court's interpretation of the law has changed and I respect that ruling. That means I must resign as the member for Fremantle and contest the forthcoming byelection.

As I said in my first speech, I can't imagine a more meaningful kind of work than to represent the community where I've lived virtually all my life. Every opportunity I am given to ask the people of Fremantle to trust me with the responsibility of being their representative in the national parliament is an opportunity I will relish.

I am looking forward to once again seeking that trust and responsibility in the weeks to come, and I am happy to be considered by voters in the Fremantle electorate on the basis of my character, principles, work-ethic, and record.

block-time updated-timeUpdated at 5.08am BST

block-time published-time 4.55am BST

Georgina Downer ( Alexander Downer's daughter) looks like the strongest Liberal candidate to run against Rebekha Sharkie in Mayo.

Alexander Downer held that seat for 24 years, up until 2008.

block-time published-time 4.49am BST

Tony Burke says the case of Jason Falinski should be referred to the high court:

As you know last year, I did move for all of these cases to be referred to the high court, for all the ones where there could be considered any level of grey. The reason this court case doesn't change anything for the Liberals involved, they are all people that took absolutely no steps. Absolutely no steps. So the reasonable steps test never helped them. There is still a cloud over their citizenship. The right thing for them to do, under, and this is all based on what they made public and what they left in doubt, with Jason Falinski being the one where the evidence appears strongest based on entry in 1958 and Polish passports there. We're not saying he should leave the parliament tomorrow, but that is one case which should be referred to the court."

block-time updated-timeUpdated at 4.53am BST

block-time published-time 4.47am BST

Bill Shorten said his MPs did not resign, because they were waiting on the reasonable steps decision:

I'm giving you the answer. We relied on our advice that says all reasonable steps. Now what the high court has said is that all reasonable steps has to include the bureaucratic processing systems of a foreign government. That hasn't been the advice we received. Whether or not we like what the high court has decided, they made that decision and we're going to get on with it. Australians want to get on with debating what is the right sort of budget for the country.

block-time updated-timeUpdated at 4.51am BST

block-time published-time 4.45am BST

Will Susan Lamb be ready (as in have her British citizenship null and voided by the time of the byelection)

Well, as we saw with more recent Coalition members, it would appear that British authorities are speeding up their responsiveness to resolving these citizenship matters."

Tony Burke adds to that:

Since this issue has blown up even in the last few months, if you look at Fiona Nash, when that happened, the renunciation took place in three days. So the processes now are quite different. For the reference made earlier about the previous high court decision last year, as to why we didn't have a response from that, that didn't test reasonable steps. Because the people who were before the court then were people who had taken no steps to renounce. We have reasonable steps being tested and when you say, oh, what about the legal advice, can I just say, the Australian electoral commission had the same conclusion as the Australian Labor party, and kept that in the candidates' hand book, even as recently as the Batman byelection."

block-time updated-timeUpdated at 4.50am BST

block-time published-time 4.42am BST

Bill Shorten says the Labor party won't release its legal advice, but he says that he did check to make sure it was still sound when all the section 44 stuff started up again - and it was.

block-time updated-timeUpdated at 4.46am BST

block-time published-time 4.41am BST

Susan Lamb has not yet renounced her British citizenship. Bill Shorten said he is "sure" she will have completed all the necessary steps by the time of any byelection.

Does he feel like "a goose"? (Don't @ me, it was a question asked by a reporter at the press conference and I present it so you have the context for his response.)

At all times, the Labor party has acted in good faith. I have replied upon the legal advice provided to me by the Labor party, the same advice provided to Labor leaders since the mid-90s. Our quality candidates have relied on this advice. After asking all candidates to comply with the processes we thought were appropriate, the high court has set a stricter test. Legal experts such as Prof George Williams say they are surprised by this decision. The Australian electoral commission's hand book for prospective candidates spells out [that] candidates, if they're a dual national, have to take all reasonable steps. The high court has made the decision, these are the facts we've got to deal with, and that's why all three of these quality candidate will be recontesting at the earliest possible date, and this provides, I must say, although this wasn't the plan, it provides an early opportunity for Australians to pass a view about giving away $80bn to big business, of which $17bn alone goes the banks."

block-time updated-timeUpdated at 4.45am BST

block-time published-time 4.38am BST

Tony Burke on the details:

I met with the speaker and have explained to the speaker the situation, particularly for the members wanting to make sure, as good local members, they don't want any of the constituent matters they have been dealing with to be disadvantaged in any way. They won't be returning to the house of representatives until after they come back from the byelections. And they will be spending the next couple of days finalising different constituent matters they have to deal with [so] the resignations themselves will take effect on Friday. And I understand that Tim Hammond's resignation will be received on the same day."

block-time updated-timeUpdated at 4.42am BST

block-time published-time 4.37am BST

Bill Shorten :

The high court has set a new precedent for the eligibility of candidates to nominate and still be constitutionally acceptable under section 44. In good faith, our candidates and the Labor party and I have relied on advice that's been the same advice for over 20 years.

But the high court has looked at the facts in Senator Gallagher's matter, they have developed a new test, a stricter test, and we have accepted that.

I'm pleased to announce today that all three candidates, members who have fallen into the section 44 problems which have taken many other people, they have all agreed to renominate, so at these byelections which weren't sought, it's an early opportunity for Australians to cast their view on Mr Turnbull's proposal to give $17bn to the big banks."

block-time updated-timeUpdated at 4.40am BST

block-time published-time 4.31am BST

Mike Bowers was there to catch those resignations (except for Justine Keay, because while he is incredible, even he can't be in two places at once).

Independent MP Rebekha Sharkie resigns from parliament. She leaves Parliament House accompanied by her fellow Centre Alliance party members MPs Stirling Griff and Rex Patrick along with independents Cathy McGowan, Andrew Wilkie and Bob Katter in Canberra this afternoon. Photograph: Mike Bowers for the Guardian Josh Wilson, the member for Fremantle (WA), resigns in the House of Representatives. Photograph: Mike Bowers for the Guardian Susan Lamb, the member for Longman (Qld), resigns in the House of Representatives. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 4.37am BST

block-time published-time 4.22am BST

Bill Shorten is holding a press conference in about 10 minutes.

A reminder that we still have question time ahead of us.

Oh, and Scott Morrison is still answering questions at the press club, but I might have to come back to that in a bit.

block-time published-time 4.11am BST

So since Scott Ludlam was made aware of his New Zealand dual citizenship and resigned on 13 July last year, and everyone in the government jumped up and down about how disorganised the Greens were, after Larissa Waters looked into her Canadian birth and found she too was a dual citizen, we have lost or held byelections for:

Barnaby Joyce Fiona Nash Stephen Parry John Alexander Malcolm Roberts Jacqui Lambie Skye Kakoschke-Moore David Feeney Katy Gallagher Josh Wilson Justine Keay Susan Lamb

block-time updated-timeUpdated at 4.14am BST

block-time published-time 4.03am BST

Queensland and Western Australia are also the two states the Coalition are desperate to ***win*** - or at least hold on to - at the next election.

So the "fuck" message I just received from a Coalition source makes sense in that context - the government might enjoy Labor having to eat some humble pie from the section 44 mess, but they are not overly excited about holding a bunch of byelections they may not ***win***, when we are talking about the next election in terms of months, not years.

block-time updated-timeUpdated at 4.08am BST

block-time published-time 4.01am BST

Out of all of those battles, Longman in Queensland will shape up as the one to watch. Susan Lamb holds that seat by 0.8%. It was one of the surprises of the 2 July 2016 election when she took it from Wyatt Roy and the demographics there are a little strange - it is a mix of working class and older residents, with some young families in pockets.

block-time updated-timeUpdated at 4.04am BST

block-time published-time 3.59am BST

It does not seem like Scott Morrison is having a great time keeping the attention of the crowd on his National Press Club address:

enltrI think every single person at this post budget address is on their mobile [*@AmyRemeikis*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*#auspol*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Katharine Murphy (@murpharoo) [*May 9, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 4.01am BST

block-time published-time 3.57am BST

Susan Lamb resigns

Completing the trio, the member for Longman also announces her intention to resign.

That means we are set for byelections in Longman (Qld), Braddon (Tas), Fremantle (WA) and Mayo (SA) as well as Perth (WA).

Lamb says she is "not done yet" and will recontest the byelection.

This Super Saturday is shaping up as quite the test for both the government and the ***opposition***. The campaign starts now, I am told.

block-time updated-timeUpdated at 4.00am BST

block-time published-time 3.55am BST

Josh Wilson said he will recontest the byelection.

block-time published-time 3.54am BST

Josh Wilson resigns

The member for Fremantle Josh Wilson has announced he will also resign.

Wilson said he was endorsed on 12 May 2016 and filled out his forms that same day, and sent them on 13 May. He said he received confirmation that the forms were received, the funds were taken out of his bank account on 16 May. But the confirmation did not come through until after the nominations closed, on 29 June, with the election on 2 July.

But the high court ruling today means filling out the paperwork doesn't end it - it is the timing as well.

Susan Lamb is expected to follow suit.

block-time updated-timeUpdated at 3.55am BST

block-time published-time 3.50am BST

We now officially have byelections planned for Perth, Mayo and Braddon.

block-time published-time 3.49am BST

Justine Keay says she will re-contest the byelection and will write to the Speaker later today.

block-time published-time 3.48am BST

Justine Keay resigns

The first of the Labor MPs has taken to the floor of parliament to announce: "I am not done working and fighting on behalf of those who sent me here."

"I have nothing to fear or hide, you just need to look at my disclosure for that."

She says she is a seventh generation Tasmanian, and operated under the best available legal advice.

She announces her resignation.

block-time updated-timeUpdated at 3.51am BST

block-time published-time 3.44am BST

Rebekha Sharkie has resigned

The Mayo MP said she has done everything right, but the high court ruling is "quite clear".

She will resign today and is seeking re-election. She wants the byelection held as early as possible - which would be 16 June.

block-time updated-timeUpdated at 3.46am BST

block-time published-time 3.30am BST

David Smith, the director of Professionals Australia's ACT branch, is the certain beneficiary of the high court's ruling on Katy Gallagher's ineligibility.

He was Labor's second ACT candidate and will ***win*** the seat on a recount.

Smith told Guardian Australia he would keep the seat because "we can't afford to have any interruptions in the representation of the ACT in the Senate" and it was "not a great look" to resign for Gallagher to resume her seat because it would be "seen to be trying to get around the high court decision".

Smith thinks Gallagher would make a "great member" for the third seat in Canberra, presumably because he wants to avoid fighting her off in a preselection battle.

block-time updated-timeUpdated at 3.45am BST

block-time published-time 3.20am BST

Labor is still working out its next move. And so is Katy Gallagher. There is some pressure on her to move to the lower house, but then there are others who want to see her back in the Senate.

Penny Wong has already stated the party wants her back (in so many words)

block-time published-time 3.17am BST

It's worth noting that if Rebekha Sharkie resigns, it is going to put even more pressure on the Labor MPs.

And right before question time too.

If anyone remembered or still cares about the budget, Scott Morrison is about 15 minutes out from his National Press Club address.

block-time updated-timeUpdated at 3.21am BST

block-time published-time 3.15am BST

If we do go to a byelection in Braddon, Jacqui Lambie won't be on the ticket:

enltrStatement regarding the decision handed down by the High Court today. [*#auspol*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*#politas*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*pic.twitter.com/6A0rxYrTt3*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Jacqui Lambie (@JacquiLambie) [*May 9, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time published-time 3.14am BST

Rebekha Sharkie has called a press conference for 12.45

block-time updated-timeUpdated at 3.20am BST

block-time published-time 3.13am BST

For everyone asking 'what about' the government MPs who have questions over their citizenship status, it is complicated.

International citizenship law is varied and complicated and while not all MPs put forward their documents, we can't force them. The government has the numbers in the house, and would need to refer its members. The high court has put a 30-day limit on when electors can challenge an election.

So in short, yes there are questions, but we can't answer them for you, or force them to provide answers.

block-time published-time 3.07am BST

As I have just been reminded, the committee looking into section 44 is [*a joint committee*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw). My apologies.

block-time updated-timeUpdated at 3.16am BST

block-time published-time 3.06am BST

Barnaby Joyce says he would have had sympathy for the Labor MPs who look like being forced to resign, "if they had left when I did".

Talking to Sky, he says once his ruling was done, Labor should have sent their MPs through as well.

block-time published-time 3.03am BST

And a handy reminder of what we are talking about:

The constitution

Section 44 (i) of Australia's constitution bars "citizens of a foreign power" from serving in parliament, including dual citizens, or those entitled to dual citizenship. But the provision was very rarely raised until July 2017, when the Greens senator Scott Ludlam [*suddenly announced he was quitting parliament*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) after discovering he had New Zealand citizenship.

That sparked a succession of cases, beginning with [*Ludlam's colleague Larissa Waters*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw), as MPs and senators realised their birthplace or the sometimes obscure implications of their parents' citizenship could put them in breach.

The Citizenship Seven

By October, seven cases had been referred by parliament to the high court, which has the final say on eligibility. They were Ludlam and Waters; the National party leader [*Barnaby Joyce*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw), deputy leader   [*Fiona Nash*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) and minister   [*Matt Canavan*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) ; One Nation's   [*Malcolm Roberts*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) ; and independent   [*Nick Xenophon*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw).

The court [*found that five of the seven had been ineligible to stand for parliament*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw), exonerating only Canavan and Xenophon. That meant the senators involved had to be replaced by the next candidate on the ballot at the 2016 federal election, while the sole lower house MP - Joyce - would   [*face a byelection*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) on 2 December in his New South Wales seat of New England. Joyce renounced his New Zealand citizenship   [*and won the seat again*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw).

Further cases

After the court ruling the president of the Senate, the Liberal Stephen Parry, also [*resigned on dual citizenship grounds*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw). Then   [*MP John Alexander quit*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw), triggering a   [*byelection in his Sydney seat of Bennelong*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)  - which he won. Independent   [*Tasmanian senator Jacqui Lambie*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) became the next casualty and   [*NXT senator Skye Kakoschke-Moore*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) soon followed. Labor MP    [*David Feeney*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)  also had to quit, but Ged Kearney    [*won his seat of Batman*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)  back for the ALP.

Legal implications

The case of senator Katy Gallagher [*tested the interpretation*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) relied on by Labor that taking 'reasonable steps' to renounce citizenship was enough to preserve eligibility. In May 2018 the   [*high court ruled against her*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw), forcing a further three Labor MPs - Justine Keay, Susan Lamb and Josh Wilson - to quit, along with Rebekha Sharkie of the Centre Alliance (formerly NXT). The major parties have agreed that all MPs and senators must now   [*make a formal declaration of their eligibility*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw), disclose foreign citizenship and steps to renounce it. But the constitution   [*cannot be changed without a referendum*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw).

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block-time published-time 2.47am BST

There is a senate committee which is looking into how they fix the section 44 issue. It is due to report next week.

The obvious (and only way, really) is a referendum. It is in the constitution. The constitution can only be changed by referendum.

However there is some chatter that there is another fix/bandaid in the works, which would improve vetting processes. We will see.

block-time updated-timeUpdated at 2.55am BST

block-time published-time 2.44am BST

The Coalition is really doubling down on the ' Bill Shorten needs to force his MPs to resign' thing.

From Christian Porter and Christopher Pyne's statement:

While Bill Shorten had many opportunities to refer each of his three Labor members to the high court and was urged to do precisely this to avoid unnecessarily politicising this issue, he repeatedly failed to do the right thing and make these referrals.

The situation now is that any referral to the high court of any of these members would do no more than cause a further delay and expense to the taxpayer before reaching a conclusion that now is beyond doubt. The time for the referral of this group has passed and the only course of action is their immediate resignations to allow for byelections to be held as soon as possible.

While it is never too late to do the right thing, it is now clear that both Bill Shorten and his shadow attorney-general, Mark Dreyfus, have deliberately mischaracterised the application of previous high court decisions to their own members of parliament and have misled Australians for months as part of a cynical delaying tactic.

Bill Shorten initially claimed that none of his MPs were dual citizens because of Labor's 'extremely stringent vetting process' ( [*Bill Shorten press conference 21 August 2017*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) ; The Australian 21 August 2017) and that the difference between Katy Gallagher and the cases of Barnaby Joyce and Fiona Nash were as different as 'night and day' (Canberra Times, 5 December 2017).

Dreyfus claimed Gallagher '... took the reasonable steps that the high court has spoken of in repeated decisions' ( [*Sydney Morning Herald, 10 December 2017*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) ).

These statements were deliberately designed to mischaracterise high court decisions and mislead the Australian people and what is now going to be tested is Mark Dreyfus's claim that '...Labor care about the constitutional legitimacy of the Australian parliament' (Sydney Morning Herald, 10 December 2017).

If Labor does care about the constitutional legitimacy of the Australian parliament, they must now accept the outcome of the high court decision and finally do the right thing and demand the resignations of the three Labor members who are in clear breach of the constitution so that the people in their electorates can elect a legitimate representative to the parliament.

block-time updated-timeUpdated at 3.27am BST

block-time published-time 2.20am BST

Christian Porter :

They were delaying, they were obfuscating, and they did so at enormous expense to the Australian taxpayer and radically, they tried to take everyone for mugs and there was always going to be a day of reckoning and here it is, and where are they?

Christopher Pyne says the government sees no reason for the Labor party to refer its other MPs to the high court:

They will be wasting more taxpayer money, more time in order to run this protection racket around their caucus.

block-time updated-timeUpdated at 2.27am BST

block-time published-time 2.16am BST

Neither Christian Porter or Christopher Pyne will say if the government will use its numbers (and break a longstanding convention) and force the MPs to the high court. They say it is up to Bill Shorten "demanding, requiring and effecting the resignation" of his three MPs.

block-time updated-timeUpdated at 2.18am BST

block-time published-time 2.14am BST

Christian Porter says Rebekha Sharkie's case is no different from the Labor cases and she should also resign.

block-time updated-timeUpdated at 6.40am BST

block-time published-time 2.11am BST

Christian Porter went through a list of Labor claiming its MPs were fine, because of the reasonable steps test, over the last six months.

Christopher Pyne, rewriting history a little bit, says the Coalition MPs who were in question, "did the right thing and resigned".

When we understood that members of our side of the house had a cloud over them, they were referred to the high court, or they resigned. In fact, quite a number - Fiona Nash, Matt Canavan, who was cleared by the high court, Barnaby Joyce, who wasn't, and faced the byelection that he won.

John Alexander, when he couldn't satisfy himself that he didn't have dual citizenship, he resigned, faced the byelection. On our side, we did the right thing. When there was a problem, we responded to it, methodically, sensibly, as a good government would, faced byelections, and the people re-elected those two members."

Which is not exactly true. The government held out until the last moment. And then after the ruling, Stephen Parry, the former Senate president, discovered he was in the same position. Then John Alexander discovered his.

block-time updated-timeUpdated at 2.16am BST

block-time published-time 2.06am BST

The government says the four lower house MPs 'must resign'

Christian Porter :

It means that there four other dual citizens- in fact all dual citizens of Great Britain - who were dual citizens after the close of nominations, who are presently ineligible to sit in the federal parliament, and who should not be sitting in the federal parliament.

And those four people must resign. They must resign today. Bill Shorten must require the resignation of those three Labor members today, and that must occur before close of business today.

block-time updated-timeUpdated at 2.15am BST

block-time published-time 2.04am BST

Christian Porter and Christopher Pyne have opened their press conference looking quite pleased.

Pyne gestured to Porter to speak first and he did, opening with an attack on Bill Shorten:

If I might start by saying that Bill Shorten said something very curious on Channel Nine yesterday. 'If the high court today set the new precedent, the Labor Party will deal with it.' He then, when pressed, said, if the interpretation of the law changes, we will consider what we have got to do.

I want to make it clear from the outset that this decision is not a reinterpretation or a change of the law, it is a crisp and crystal clear clarification of the law as it was stated in the Canavan decision last year, and anyone, Bill Shorten, Mark Dreyfus or anyone else, who says this is a reinterpretation or a change, is talking absolute rubbish.

block-time updated-timeUpdated at 2.14am BST

block-time published-time 1.52am BST

So I have spent the last couple of weeks chatting to both parties about the possibilities of byelections, and I can tell you that neither is either enthused by the prospect.

Mostly because they are expensive and we are a year (less than a year?) out from a general election. But also because neither want a test so close to the election.

block-time updated-timeUpdated at 2.13am BST

block-time published-time 1.51am BST

Christian Porter, the attorney general, has called a press conference in the Blue Room - the fancy one where ministers hold their "we have something important to say" pressers.

He is expected to say the four MPs need to stand down. Christopher Pyne will be with him.

And just like that, we are no longer talking about the budget.

block-time updated-timeUpdated at 2.13am BST

block-time published-time 1.49am BST

B ill Shorten says it's a new precedent - what he means there is Labor had interpreted the reasonable steps ruling from Skyes v Cleary to mean that as long as you filled out your forms and met all your own personal obligations to divest yourself of your dual citizenship before you nominated for parliament, then you were eligible.

The high court has now ruled that it is not just the taking of the actions - it is also the timing. Which means just filling in and sending off the forms is not enough, you have to take into account the time to send it off and receive your confirmation.

The only one of the four who are in question who might have a case on the timing issue is Josh Wilson - he was a late pre-selected candidate, who moved to divest his British citizenship on the day he was nominated. It just didn't come back as confirmed until after the election. Not sure how much quicker he could have acted, but the high court may not care.

block-time updated-timeUpdated at 2.12am BST

block-time published-time 1.44am BST

Bill Shorten has released a statement:

I am deeply disappointed for Katy Gallaghe r today.

This is a loss to the Senate, and a loss for Labor. We are a better parliament with Katy in it, and a stronger party with Katy in our caucus.

Katy has always acted on the best available legal advice, which indicated that she had satisfied the eligibility requirements under the constitution.

Today, the high court has set a new precedent.

I know this period of uncertainty has been tough for Katy and her family. She has shown great resilience and grace in difficult circumstances.

As a community worker, as a disability advocate, as chief minister and as a senator, Katy has always served others. She has made a valuable contribution to the Australian parliament, and to our shadow ministerial team.

Katy is a key part of Labor's Senate leadership team. She is too good to lose from public life - and I know we won't lose her. Katy has a lot more to contribute to Labor and to Australia.

The Labor party will now consider what further implications today's decision by the high court may have.

block-time updated-timeUpdated at 2.11am BST

block-time published-time 1.43am BST

The questions in this reference turn upon one issue - whether British law operated to irremediably prevent an Australian citizen applying for renunciation of his or her British citizenship from ever achieving it. An affirmative answer cannot be given merely because a decision might not be provided in time for a person's nomination. The exception is not engaged by a foreign law which presents an obstacle to a particular individual being able to nominate for a particular election.

That's the paragraph which has implicated the lower house MPs.

Does the British system stop Australians from being able to nominate for parliament? The court can't be sure. So Katy Gallagher is out - and the others may be made to resign by the party.

Josh Wilson sent off his documents the day he was preselected. It wasn't confirmed until after nominations closed. This could have even more layers but, as we have now seen, this high court bench is very black letter. It may not matter.

block-time updated-timeUpdated at 2.11am BST

block-time published-time 1.36am BST

Given that Malcolm Roberts held on to the very, very last second, even insisting that he was "choosing to believe" that he was never British, and was basically forced into being referred to the high court, I am not sure Pauline Hanson should be the arbiter of what other parties in the same position should do.

enltrNow that Katy Gallagher has been thrown out it is time for Susan Lamb to stop stalling and resign. -PH [*#auspol*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Pauline Hanson ???? (@PaulineHansonOz) [*May 9, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 2.10am BST

block-time published-time 1.35am BST

Katy Gallagher has issued her own statement:

Today the high court sitting as the court of disputed returns has ruled that I am ineligible to sit as a senator in the Australian parliament.

I am very disappointed by this outcome but I respect the decision of the court.

I have spent the last 17 years of my life representing the people of the Australian Capital Territory, firstly in the ACT legislative assembly and more recently in the Senate.

It has been an absolute honour to hold elected office.

I have always performed my duties to the ACT community with honesty, integrity and a desire to make Canberra and Australia a better place for all of us.

I have always acted on the best available legal advice, which at all times, indicated that I satisfied the eligibility requirements under the constitution. However, today the high court has made its decision, and I respect the outcome.

To the people of the ACT, I'm very sorry that this disruption has occurred to one of your federal representatives.

To have my place in the Senate end like this today is very deeply disappointing but I believe that I have more to contribute to public life and I will take the time to talk with Labor party members on how I can do this over the months ahead.

It has been a privilege to serve the Canberra community and the Australian Labor party in both the ACT and federal parliaments for almost two decades.

block-time updated-timeUpdated at 2.09am BST

block-time published-time 1.34am BST

Here is the bit from the ruling which looks like the others will be forced to resign:

enltrHigh court confirms in this par that Labor has been quoting only one half of the reasonable steps test. The foreign law must IRREMEDIABLY PREVENT renunciation. [*#auspol*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*#auslaw*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Paul Karp (@Paul\_Karp) [*May 9, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time published-time 1.33am BST

This isn't the last we'll see of Katy Gallagher - you may remember that the ACT had a new seat drawn up in the boundary redistributions? She is expected to run for the lower house seat.

block-time published-time 1.32am BST

Rebekha Sharkie, the Centre Alliance MP for Mayo in South Australia, said she was investigating her options and seeking "urgent legal advice":

I acknowledge today's ruling of the high court regarding the citizenship status of Labor Senator Katy Gallagher.

Based on the recent high court judgment, I will now take urgent legal advice.

It is my belief that the particulars of my circumstances are materially different to Senator Gallagher's case.

My paperwork was lodged and received by the UK Home Office before the election was called.

My paperwork was returned before the election was held.

Once I have received legal advice I will be in a position to comment further.

block-time updated-timeUpdated at 2.08am BST

block-time published-time 1.31am BST

The Senate president, Scott Ryan, has made a statement to the chamber:

He has announced the Katy Gallagher ruling and said he would table the ruling.

Penny Wong says the Australian Labor party will respect the decision of the court (meaning that Gallagher will resign):

First thing she is a woman of great integrity who always acted in accordance with the advice given to her... she has always acted in good faith ...

She is an outstanding senator, an outstanding representative of the people of the ACT and she is an outstanding member of the Labor team, and she is too good to lose.

block-time updated-timeUpdated at 2.08am BST

block-time published-time 1.29am BST

Summary

The high court website appears to have crashed.

Probably because everyone in this building is now trying to access it.

block-time updated-timeUpdated at 2.07am BST

block-time published-time 1.23am BST

Antony Green is speaking on the ABC about dates - if it turns out that the others all have to resign as well.

The first date for the byelections would be the 16 June and that would mean potentially the new members could be sworn in before the parliament rises at the end of the budget session at the end of June.

If they do not, that is if the byelection is not called by next Monday, if it was the following Monday, it is the 23rd. Other than that, it could be held in July and they could not be sworn in until the next session starts in mid August, which is getting quite close to the next election.

block-time updated-timeUpdated at 1.40am BST

block-time published-time 1.21am BST

If we do go to a byelection bonanza, you might find this handy to bookmark.

enltrFor those interested, here are my guides to the seats of Braddon, Longman and Fremantle (will require some small tweaks to turn them into by-election guides if needed): [*https://t.co/YblAiUW4UI*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*https://t.co/I6ToyPPgGW*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*https://t.co/DhlMapdZL*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Ben Raue (@benraue) [*May 9, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 2.06am BST

block-time published-time 1.21am BST

Katy Gallagher ruled ineligible to sit in parliament

We are waiting on the decision details - Paul Karp is running out of the court - but if "reasonable steps" include that candidates need to have the divestment of dual citizenship confirmed before they nominate for parliament, then we are off to Super Saturday.

That potentially means we will see byelections in Fremantle, Longman and Braddon (as well as Perth) for Labor and in Mayo for Rebekha Sharkie for Centre Alliance.

Gallagher will have to resign from the Senate though. She will be replaced and will most likely be back after the next election.

block-time updated-timeUpdated at 2.06am BST

block-time published-time 1.18am BST

enltr [*#breaking*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) the High Court has unanimously ruled Katy Gallagher is INELIGIBLE to sit in parliament. Seems the "reasonable steps" defence is not the cure-all Labor has claimed.   [*#auspol*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*#auslaw*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*#citizenshipXX*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Paul Karp (@Paul\_Karp) [*May 9, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time published-time 1.14am BST

The high court is almost back in session.

We'll bring you that result as soon as it happens. Paul Karp's fingers are POISED, I tell you. POISED.

block-time published-time 1.13am BST

What's in the box? Some Mike Bowers magic, this is.

Malcolm Turnbull, Christopher Pyne and Josh Frydenberg investigate the contents of the dispatch box as the House of Representatives resumes this morning. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 1.18am BST

block-time published-time 1.09am BST

John Howard is very popular as a draw card for the post-budget breakfast - this time round he was the headline speaker at the PwC Melbourne event.

And even HE thinks its time to raise Newstart.

enltrFormer PM John Howard says its time to increase the Newstart Allowance. "I actually think there is an argument about that, I do. I was in favour of freezing that when it happened, but I think the freeze has probably gone on too long". There was no change in the budget.

- Henry Belot (@Henry\_Belot) [*May 8, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

Full disclosure, I have been on Newstart. And it was bloody hard. I managed, but only because I had flatmates, didn't drive, and was, at the time, quite ill, so I never actually did anything. I had lost my casual job because of the illness, and was still too sick to return to work. I was very, very lucky that nothing went wrong - no unexpected bill, no massive need to outlay cash - but I still got into a credit card debt, which took years to pay off. I get it, it's difficult and I'm in and was in, a relatively privileged position compared with so many others.

Living on $40 a day, even with a bit of extra help from rent assistance, or whatever, is cruel.

block-time updated-timeUpdated at 1.11am BST

block-time published-time 1.03am BST

Back in 2005, both Bill Shorten and Malcolm Turnbul l had plans to fix the tax system - Rob Harris from the Herald Sun has dug up this Fairfax report:

enltrThis 2005 story was actually quite incredible in hindsight [*https://t.co/fR8f8zasyE*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)   [*pic.twitter.com/UJjejbeaDL*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- rob harris (@rharris334) [*May 8, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 1.10am BST

block-time published-time 1.00am BST

Chris Bowen was on Radio National this morning, talking about the tax package Scott Morrison just introduced in parliament:

We think that is worthy of some examination. We don't make 10-year tax plans in 10 minutes. The government might just be happy not to have the figures in the budget, not to have the analysis of who ***wins*** who loses et cetera. We take a different approach. 2024, I'm not sure what you'll be doing in 2024, I'm not sure what I'll be doing in 2024, I'm not sure what the economy will be doing in 2024.

Normally you would vote on 2024 tax cuts in 2024 or 2023. The government is saying that you can't have the tax cuts in 2018 unless you get the tax cuts in 2024. He's holding a gun to the head of the 2018 tax cuts and now that's just silly.

block-time updated-timeUpdated at 1.09am BST

block-time published-time 12.55am BST

Malcolm Turnbull was on Sunrise this morning as part of his media blitz. He says the government knows what it is doing in terms of turning around the debt:

Well, the net debt is going to actually peak this year as a percentage of our economy, of GDP and then it will starts to decline. So we have actually turned the corner on debt. Then after a decade, it will be down to about 3.8% of GDP. So we're both paying down debt and once we get back into balance, which is in 2019-20 of course, we're not adding to the debt. So the debt declines in dollar terms and absolute terms and it also declines of course, because it's not growing and the economy is growing.

So we are bringing down the debt, we've turned the corner on debt.

block-time updated-timeUpdated at 1.09am BST

block-time published-time 12.53am BST

Presented without comment:

undltr [*pic.twitter.com/oEoOoQyn89*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Josh Taylor (@joshgnosis) [*May 8, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time published-time 12.52am BST

The government wants to extend the budget tax bill debate, which is outside of convention, and Labor has given a "yeah, nah", first with attitude, and now with an official no.

Chris Bowen : "Seriously guys, this is pathetic. What a joke. What a joke."

The government did not call for a division so it seems it wasn't overly into it either. Just wanted to stir the pot.

block-time updated-timeUpdated at 1.02am BST

block-time published-time 12.50am BST

The parliamentary Twitter accounts are having fun celebrating the building's birthday.

It has officially entered its dirty 30s.

enltrParliament first sat on 9 May 1901, following Federation and elections. Tom Roberts captured the Opening of the First Parliament of the Commonwealth of Australia in this piece, otherwise known as The Big Picture. [*pic.twitter.com/w4tlyoRC4R*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Australian House of Representatives (@AboutTheHouse) [*May 8, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

enltrLooking forward to it!! [*https://t.co/mz4jdY2Opn*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

- Australian Senate (@AuSenate) [*May 8, 2018*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 1.01am BST

block-time published-time 12.46am BST

A bit of Mike Bowers from this morning:

Malcolm Turnbull talks to the media in the press gallery. Photograph: Mike Bowers for the Guardian Turnbull at the temporary breakfast TV studios on the lawns out the front of Parliament House. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 12.51am BST

block-time published-time 12.42am BST

Scott Morrison is entering his bill into the house. His speech includes the line "the snake eating itself from the tail".

For something new.

Our plan will deliver a personal income tax system that is lower, that is simpler, that is fairer, consistent with Liberal party beliefs.

He is racing through this. He is going so fast that the Coalition MPs can barely get in a "hear hear".

Julia Banks and Ann Sudamalis, who sit behind the dispatch box, are nodding for their lives. Luke Howarth is doing his absolute best to look extremely interested, while simultaneously concerned. It's their art. They don't have to explain their art to you.

block-time updated-timeUpdated at 12.50am BST

block-time published-time 12.35am BST

Actually, we can tell you exactly when the treasurer will be entering his bill - 9.40.

And we know that because the chief whip, Nola Marino, has just sent an email to all Coalition MPs asking them to be in the chamber to "please support the treasurer in the house".

Thank you to the secret squirrel who passed that on. Your work is appreciated.

Coalition MPs reading this, you are needed in the chamber. Please, and thank you.

block-time updated-timeUpdated at 12.48am BST

block-time published-time 12.33am BST

Speaking of the treasurer, he is getting ready to enter his tax bill into parliament.

That should happen in the next few minutes.

block-time published-time 12.32am BST

The budget fight over the surplus is also continuing. Scott Morrison says he is on track to return the budget to balance -and then a surplus the next year.

Not surprisingly, Bill Shorten isn't as sure:

But the point about it is, and you understand that you're a student of economics, if China decided not to buy all of our minerals tomorrow, there goes the surplus. The reality is this government has no plan to pay down debt.

Debt is north of half a trillion dollars. Put in plain English, this government has run up a debt bill for every man, woman and child in Australia of $20,000.

These people aren't economic managers, they just lurch from crisis to crisis, and, in the meantime, the only thing they do is their DNA hardwired reaction, look after the top end of town and just feed crumbs to other people.

block-time updated-timeUpdated at 12.47am BST

block-time published-time 12.24am BST

The [*Senate*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) will open at 9.30 with a message from the Queen.

She's acknowledging the 30th anniversary of the opening of Parliament House.

block-time updated-timeUpdated at 12.47am BST

block-time published-time 12.19am BST

Scott Morrison will address the National Press Club just after lunch.

That's being held in parliament, because parliament is still being held. Despite us talking about everything other than parliament.

block-time published-time 12.17am BST

We have a BUSY morning.

We are all waiting on the high court. And while, publicly, Labor has been keeping its chin up, privately the party is preparing for the worst-case scenario - Katy Gallagher's case fails - and sending people to the electorates "just in case".

My sources tell me key campaigners are being placed around the states - Queensland, Tasmania and WA, so the party can hit the ground running if it turns out that Susan Lamb, Justine Keay and Josh Wilson also have to resign.

But no one really knows which way the high court will fall on this. The prime minister has learnt not to make such proclamations after the whole Barnaby Joyce will be fine "and the high court will so hold" thing.

block-time updated-timeUpdated at 12.46am BST

block-time published-time 12.13am BST

"This isn't a change to bracket creep, this is a total rewriting of Australia's tax system," Di Natale says.

He also has a problem with the lack of movement for Newstart. Just a reminder that it hasn't moved in real terms in almost 25 years. Di Natale says it is not just the Greens urging this, and noting that the business and welfare sectors have been calling for the same thing for years.

He wants the Labor party to "draw a line in the sand" and say they won't support the tax changes.

block-time updated-timeUpdated at 12.43am BST

block-time published-time 12.11am BST

Richard Di Natale has picked up this morning where he left off last night - criticising the budget.

He says it will "turbo-charge inequality". He's talking about the 2024 plan to put those on $41,000 on the same tax rate as someone earning $200,000.

We think someone earning that sort of salary [$200,000] deserves to pay a little bit more than someone earning $41,000.

block-time updated-timeUpdated at 12.41am BST

block-time published-time 12.08am BST

Just further from what Paul Karp told you on foreign aid, here's a bit more from Penny Wong:

At a time when we know Australia's influence in the region is diminishing. At a time when the government's own white paper talks about the importance of soft power, what does Julie Bishop preside over? She presides over yet another cut to Australia's overseas development assistance.

Yet another cut to aid on top of the $11bn that she has presided over in cuts to date. Another $140m and a new low. So, we're already at a record low in terms of how much of our national income we give to the nations of our region and the poorer nations of the world. Well, we're getting even lower, 19 cents in every $100 of national income.

That's what Julie Bishop and Malcolm Turnbull are delivering at the same time as they are giving the banks a tax cut.

block-time updated-timeUpdated at 12.40am BST

block-time published-time 12.07am BST

While Malcolm Turnbull continues his media blitz (which includes no fewer than three denials there will be an early election), [*Greg Jericho*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) has had a look at all those future   [*implications of the $140bn total tax plan.*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

You know, the one in the never-never. Seven years from now. Which is almost two budgets and two elections away.

block-time updated-timeUpdated at 12.39am BST

block-time published-time 12.03am BST

The major non-budget story around this morning is news that Donald Trump has [*announced he will impose "the highest level of economic sanctions"*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) on Iran, violating an international nuclear agreement and a UN resolution, breaking decisively with US allies in Europe, and potentially triggering a new crisis in the Gulf.

On Radio National, Malcolm Turnbull responded:

We regret the decision of the US. Of course, President Trump had foreshadowed that for a long time. We encourage all parties to continue to comply with the deal. And we certainly are trying to support that.

Turnbull said he had "some optimism" that an Iran deal could survive without the United States because there was still commitment from European parties.

Asked about Iran's reaction, he said Tehran "have certainly indicated that they will show restraint so far".

block-time updated-timeUpdated at 12.39am BST

block-time published-time 11.58pm BST

Another point of attack against the budget has been the $140m cut to foreign aid.

Labor's foreign affairs spokeswoman, Penny Wong, said: "The Turnbull government has continued on its disastrous path of cuts to aid, and lessening influence which can only further weaken Australia's standing."

But while Labor claims it will spend more on foreign aid than the Turnbull government, it is very short on specifics.

On Sky News Bill Shorten said:

There's no doubt the economic circumstances since the [global financial crisis] have changed what people hoped they could do. But I will put this general principle about foreign aid: foreign aid is also good politics.

We all saw the shock and outrage about discussions between Vanuatu and China about possibly putting a new base in Vanuatu. One of the issues is: it's not China's fault or Vanuatu's fault, but if Australia abandons the region we create a vacuum others will fill.

So I just say to some of the people who say foreign aid is a waste of time - it is not only a good thing to do to help people, it's good [for] ***strategic*** foreign relationships.

Pressed on specifics, Shorten replied: "We're going to crunch our numbers and see what we can do."

block-time updated-timeUpdated at 12.38am BST

block-time published-time 11.49pm BST

A lot of stakeholders have been out criticising the fact the budget has not lifted the Newstart allowance for jobseekers, stuck at just under $40 a day for singles.

Senator Tim Storer noted that both the Business Council and welfare groups want it lifted because they all recognise "it's very important for this group to be able to present themselves for work".

The Australian Council of Social Services chief executive, Cassandra Goldie, said " it's shameful that the government hasn't found the money required to lift the Newstart payment" because that would be the best policy to help some of the 3 million people living below the poverty line.

On Sky News Malcolm Turnbull said the government "believes the setting is right" because Newstart is a "safety net to support people while they're looking for work".

It's not like disability or aged pension which is entitled to be a substitute for employed income.

Asked about people struggling to live on $40 a day, Turnbull noted the "vast majority are in receipt of other benefits as well".

It's a more complex picture than that. The important thing is that they're looking for work.

block-time updated-timeUpdated at 12.35am BST

block-time published-time 11.41pm BST

Malcolm Turnbull is out selling the budget's centrepiece income tax cuts - framing them as hip-pocket relief for workers who haven't had a pay rise.

He told Radio National:

We know that tax should be no higher than it needs to be in order to deliver and guarantee our essential services. We want to ensure that Australians, particularly those on middle incomes, you know, a nurse and a teacher, they will be, next year, over $1,000 better off as a result of these reforms as a couple. This is ensuring that at a time when wage growth has been slow... this is giving more money, enabling people to hang on to keep more of the money they have. It's their money.

On Sky News Turnbull said: "It's an income tax plan - we're asking the parliament to support it all."

He warned that if the top tax bracket of $180,000 were not lifted it would soon capture workers such as school principals and police superintendants - not just the "millionaires" that Bill Shorten targets with his rhetoric.

Turnbull described the budget as "very realistic", arguing it was not built off record commodity prices but rather hard work and good policies. "We've made our own luck," he said.

block-time updated-timeUpdated at 12.33am BST

block-time published-time 11.27pm BST

The Business Council of Australia's Jennifer Westacott is largely happy with the economic plan though.

She told the ABC that she expected the $530 tax offset to help boost spending - which is what Scott Morrison said was the intention last night.

And of course, she would still like to see the business cut plan passed.

Well I think people are underestimating the impact of this personal tax cut. First of all, you are targeting those low- to moderate-income earners, for an average couple, that's $1,000. That's a lot of money to a lot of people.

But, you know, as it goes out, which is, kind of, fiscally calibrated and quite sensible, you know, you're taking out a whole tax bracket. You're taking out one of the great incentive sapping parts of our tax system. This bracket creep. You're simplifying it, you're allowing people from 40,000 onwards, to not have that constant anxiety that they're going to pay more in tax.

I think, most people want more money in their pocket than in the government's pocket. So, you know, I think the challenge now is not to reverse course. The challenge is to stay the course. The challenge is to get the business conditions working.

One thing that's changed, is that other countries have put their tax rates down, particularly, the US. Yeah, we've got to make sure that we now make our economy more resilient to external factors like commodity prices, lift our productivity, lift our competitiveness. That's why we need the full enterprise tax plan to be passed. And we've also got to remember, and I keep reminding people of this, that $100bn, I want it to be 120 but, you know, if it's 65 or 80, we've got a very different budget in four years' time.

block-time updated-timeUpdated at 12.31am BST

block-time published-time 11.24pm BST

The new cuts to the ABC are also raising eyebrows.

Michelle Rowland wants to know what happened to that 2014 commitment. You know - the one with Tony Abbott's face in front of a giant board which promised no cuts to the ABC.

This budget lays bare the utter contempt the Liberals and Nationals have for the Australian people and the ABC services they trust and rely on. The Liberals promised there would be "no cuts to the ABC" on the eve of the 2013 election. Yet on top of $254min cuts they have imposed since 2014, this budget contains a further $127m in cuts.

The Liberals have frozen indexation of the ABC's operational funding - amounting to a cut of $83.7m - to "ensure the ABC continues to find back-office efficiencies". The reality is this government knows full well this means cuts to jobs, content and services at the ABC.

The Liberals and Nationals complain the ABC isn't doing enough news coverage, yet these hypocrites have left a $43m hole in funding for ABC news and current affairs.

The Liberals gifted $30m to Fox Sports and relieved commercial broadcasters of $90m in spectrum license fees, yet they are imposing swingeing cuts on the ABC."

block-time updated-timeUpdated at 12.28am BST

block-time published-time 11.18pm BST

The Greens have also been discussing issues they have found with the budget. The extension of robodebt isn't winning any fans on that side of the political fence.

Rachel Siewert is worried about the plan to take money out of welfare payments, for those who have court ordered fines:

I have deep concerns about plans by the government to make compulsory deductions from income support recipients struggling to pay back fines.

This will disproportionately affect the most vulnerable in our community and I will be chasing up the detail in Senate estimates.

block-time updated-timeUpdated at 12.23am BST

block-time published-time 11.16pm BST

Good morning and welcome to the hard sell

Scott Morrison and Malcolm Turnbull have been out and about since the crack of dawn selling their message - they are very happy with the budget and think you should be too.

"The economic plan is to deliver strong economic growth," Turnbull said this morning. "That's the plan we're working on, and what that is doing is ensuring that more hard-working Australian families can keep more of what they earn."

Bill Shorten has also been out and about very early as well - and he is less happy with the budget.

"The real problem is with this budget, even though it was only one line in a speech last night, as to Morrison is giving away $80bn to the top end of town and, in the meantime, cuts to schools and pensioners being backed into the budget. They are pretty out of touch and I thought last night was uninspiring. What they are basically saying is, 'Let's get $80bn to the top end of town and, in the meantime, we might give you $10 a week.'"

Labor will support the July 1 tax changes - the ones that give workers up to $530 as a tax offset when they do their tax NEXT year, but doesn't appear overly into the seven-year total plan, which includes a flat rate tax in 2024, meaning all earners between $44,000 and $200,000 would pay the same amount.

It'll never happen, but Morrison plans on legislating it all together as a package, so prepare for that battle.

Meanwhile, Labor is keeping one eye on the high court this morning, with the justices [*handing down their decision*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) on whether Katy Gallagher is eligible to remain in parliament because she took reasonable steps to divest herself of her dual citizenship.

The Labor senator didn't receive her confirmation until after she had nominated. If the court rules reasonable steps are not enough when foreign law doesn't "irremediably prevent" renunciation, then Susan Lamb, Justine Keay and Josh Wilson will have to resign, sparking byelections in Longman, Braddon and Fremantle. Centre Alliance's Rebehka Sharkie would also find herself headed for a byelection. Throw in Tim Hammond from Perth, who resigned to spend more time with his family, and that is potentially, quite the super Saturday.

We'll bring you that as soon as it happens - 10.15am is the scheduled judgment delivery, and Paul Karp will be at the court.

Mike Bowers is out and about - follow his adventures at [*@mpbowers*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) and   [*@mikepbowers.*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw)

You'll find me in the comments, but more directly at [*@amyremeikis*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw) or   [*@pyjamapolitics*](https://twitter.com/AmyRemeikis?ref_src=twsrc%5Etfw).

Ready to get going? I have had three coffees already, so I am BUZZING!

Let's get into it!

block-time updated-timeUpdated at 12.22am BST

**Load-Date:** May 9, 2018

**End of Document**



[***MPs discuss huge scale of Grenfell Tower inquiry - Politics live; Rolling coverage of the day's political developments as they happenDowning Street lobby briefing - SummaryLunchtime summaryEarly evening summary***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5SB0-95P1-JCJY-G3VN-00000-00&context=1516831)

The Guardian(London)

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**Section:** POLITICS; Version:20

**Length:** 19336 words

**Byline:** Andrew Sparrow (earlier) and Mattha Busby (now)

**Body**

block-time published-time 7.48pm BST

On the Grenfell silent walk in west London, there are moving scenes as marchers embrace some of the firefighters who fought June's blaze and have lined Cambridge Gardens for the occasion.

enltrVery moving scenes as those taking part in the [*#Grenfell*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) silent walk kiss and hug firefighters   [*pic.twitter.com/v7lzfkab9N*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Kathryn Snowdon (@Kathryn\_Snowdon) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 7.52pm BST

block-time published-time 7.46pm BST

The Grenfell Tower inquiry debate reaches its conclusion

Paul Scully, the Conservative party vice chair for London, is now winding down this evening's proceedings.

He pays tribute to the campaigners and notes how the contributions of four Cabinet ministers demonstrates the importance that the government has placed on solving the situation and bringing justice to the people most affected.

The debate ends upon his remarks as he stresses that "action is needed".

block-time updated-timeUpdated at 7.50pm BST

block-time published-time 7.37pm BST

The timetable for the inquiry

MPs are now discussing the sheer scale of the task at hand for the inquiry, which includes 547 core participants, including 519 individuals from the Grenfell community.

On 27 April, the inquiry published a timetable for its first hearings which will focus on the factual narratives of events on 14 June 2017.

Before then, evidentiary hearings begin on the 4 June and there will be two weeks of hearings beginning on 21 May, commemorating all those who lost their lives.

The counsel to the inquiry has said that: "By starting the public hearings in this way, we can ensure that however technical and scientific the issues may become, and they will. However dry, however legal, we will never lose sight of who our work is for and why we are doing it."

The hearings will hear evidence from the inquiry's expert witnesses and London fire brigade personnel, scheduled to last until the end of July.

There will be no hearings in August as the inquiry prepares to hear evidence from the bereaved, survivors and local residents, which will run throughout September before further expert evidence will be heard ahead of closing statements in late October.

An interim report will then be drawn up before the second phase of the inquiry.

block-time updated-timeUpdated at 7.55pm BST

block-time published-time 7.23pm BST

This morning, our front page bore the names of a number of the victims of the Grenfell Tower fire.

The Guardian has been finding out about the lives of these Londoners. We have talked to as many families as were willing to speak, and asked friends and colleagues for anecdotes and their favourite memories.

Here are some of their stories.

Related: [*Grenfell: the 71 victims, their lives, loves and losses*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

block-time updated-timeUpdated at 7.36pm BST

block-time published-time 7.19pm BST

Emma Dent-Coad has posted a video of her formidable speech from earlier this evening in case you missed it.

block-time published-time 7.13pm BST

Richard Burgon, the Labour MP for Leeds East, has made made a powerful intervention to the debate in Westminster Hall, where he warned against mistakes of the past repeating themselves.

Far too often in this country politics seems to act as a dam, actually holding back justice rather than helping justice to flow. Hillsborough, Stephen Lawrence, Bloody Sunday - examples of when the state did not use its great powers to deliver truth and justice but instead blocked truth and justice for years and years.

In all of these instances, the state was accused of cover up by those affected, in all of these instances, distrust was sowed. We can't allow Grenfell to join that list. Race and class and power is at the heart of this. Justice delayed is justice denied, so it's essential that this enquiry gets it right first time.

block-time updated-timeUpdated at 7.50pm BST

block-time published-time 7.09pm BST

Grenfell silent walk begins

Hundreds of people gathered for [*tonight's silent walk for Grenfell*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) which left from Notting Hill methodist church in Lancaster Road at 7pm.

There was also a [*sister protest in Oxford*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) earlier, in solidarity with protesters on Parliament Square in Westminster.

Another march is planned for 16 June on the first anniversary of the Grenfell Tower tragedy.

Tonight's [*#Grenfell*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) silence begins   [*@GrenfellUnited*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*pic.twitter.com/CNq3Q3fvpQ*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Gregory\_ldr (@ldr\_gregory) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Updated at 7.12pm BST

7.00pm BST

The Grenfell rally is [*continuing on Parliament Square*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) where survivors demanded the urgent removal of flammable cladding from hundreds of tower blocks across the country.

Rob Booth has the full story.

Related: [*Grenfell rally demands urgent removal of flammable cladding*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Earlier, Labour MP Richard Burgon said solicitors acting for bereaved families and survivors were "concerned that they have only had access to 0.5% of relevant documentation".

That raises concerns about what they're not seeing."

Among the crowd was actor Michael Sheen, who said he wanted to see that "pressure is kept on" authorities and that "voices of residents are heard".

The shadow home secretary, Diane Abbott, welcomed the expanded panel to include two experts in an effort to improve its diversity, but said it was "not enough".

We need to know who they're going to be. If they just have puppets on the panel that is not going to help anybody."

Updated at 7.13pm BST

6.53pm BST

Good evening all, we're heading back to the debate on the Grenfell Tower inquiry in Westminster Hall.

Earlier, Emma Dent-Coad, the MP for Kensington, gave an impassioned speech which detailed the litany of undelivered reassurances that the government offered in the wake of the Grenfell Tower fire.

The former housing minister guaranteed that every household would be rehoused within the area - not delivered," she said. "The PM promised three 3 weeks for everyone affected to be rehoused - commitment not delivered."

Seventy-two households remain in hotels, 11 months on from the tragedy, despite various promises to the contrary.

David Lammy associated himself with her remarks and dedicated his speech to Khadija Saye and her mother, Mary Mendy, who died in the fire.

He explained how the state must regain the trust of Grenfell Tower survivors, given their dependence on the public sector to survive.

If you live on the 22nd floor of a tower block, the state literally has your life in their hands. It's the state that has told you to stay put. It is the state who has failed to ensure there are working fire alarms."

Other MPs, from across the house, have said how far too little has been done for those living in blocks like Grenfell.

Andy Slaughter called for action to ensure justice for Grenfell and to ensure the safety of people living in the dozens of cladded tower buildings across the country.

Is it unreasonable that we only use non-combustible cladding? We need buildings with more than one means of escape. We need sprinkler systems and we need to stop this farce of desktop studies."

The debate then moved towards identifying who was to blame for the tragedy. Bill Grant, the Conservative MP for Ayr, Carrick and Cumnock, said:

It's quite clear that a series of failings led to the needless deaths of 72 individuals last year. In November 2016, I understand the Grenfell Action Group raised concerns of poor fire safety standards at Grenfell and they predicted a catastrophe. It's quite clear that no-one listened when they predicted catastrophe, and the question is, who didn't listen."

Updated at 7.15pm BST

6.48pm BST

Early evening summary

* Peers have inflicted a fresh defeat on the government by voting to legislate for a new Leveson-style press inquiry by a majority of 39. This majority is 10 higher than the majority for a Leveson two inquiry in the Lords when peers first defeated the government on this in January, suggesting there is no evidence peers are minded to back down. If anything, they may have been encouraged by the fact that the government majority on this topic in the Commons when MPs debated it last week was just nine.

1. Theresa May and Jeremy Corbyn have led heartfelt tributes in the House of Commons to the former cabinet minister Tessa Jowell, who died of brain cancer at the weekend.
2. EU ministers have been told by Michel Barnier, the EU's chief Brexit negotiator, that "no significant progress" has been made in the Brexit talks since March. (See 6.18pm.)

That's all from me for tonight.

My colleague Mattha Busby is taking over now.

6.40pm BST

May defeated in Lords as peers back new Leveson-style press inquiry by majority of 39

The government has lost the vote by 252 votes to 213 - a majority of 39. That means have voted in favour a new Leveson-style press inquiry.

But the bill has to go back to the Commons, where the government is almost certain to try to take the amendment out. Last week in the Commons [*the government won a vote on this topic by a majority of nine.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

6.34pm BST

My colleague Jennifer Rankin has more from what Michel Barnier, the EU's chief Brexit negotiator, has been saying this afternoon.

Michel Barnier on Brexit state of play: with 10 months to go "negotiations on the future [relationship] with the UK have not started". Sufficient progress was agreed in December.

- Jennifer Rankin (@JenniferMerode) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

"A close partnership" on defence and security "is in our mutual interest" says Michel Barnier, who says solidarity is not to be negotiated against trade.

- Jennifer Rankin (@JenniferMerode) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Barnier: "We will keep the door open for close cooperation" on security and foreign policy. Warm words for "ambitious" p/ship out of Theresa May phrasebook. Now the but. "The UK will not have the same rights as member states."

- Jennifer Rankin (@JenniferMerode) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Michel Barnier says EU is not pushing UK out of Galileo: UK "decided unilaterally and autonomously to withdraw from the EU", therefore need new basis for co-operation on programme.

- Jennifer Rankin (@JenniferMerode) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

How much progress on Brexit talks? "I would say a little, not very little," says Michel Barnier in reply to "the famous" [*@adamfleming*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) Nobody should underestimate the "key rendezvous" of June.

- Jennifer Rankin (@JenniferMerode) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

6.24pm BST

What the amendment calling for new Leveson-style inquiry says

You can read the text of the amendment [*here (pdf).*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) It is amendment 62A (which would trigger amendment 62B).

And here is an extract.

Insert the following new Clause-

"Data protection breaches by national news publishers

(1) The Secretary of State must, within the period of three months beginning with the day on which this Act is passed, establish an inquiry under the Inquiries Act 2005 into allegations of data protection breaches committed by or on behalf of national news publishers and other media organisations...

(3) The terms of reference for the inquiry must include requirements-

(a) to inquire into the extent of unlawful or improper conduct by or on behalf of national news publishers and other media organisations in respect of personal data;

(b) to inquire into the extent of corporate governance and management failures and the role, if any, of politicians, public servants and others in relation to failures to investigate wrongdoing at media organisations within the scope of the inquiry;

(c) to review the protections and provisions around media coverage of individuals subject to police inquiries, including the policy and practice of naming suspects of crime prior to any relevant charge or conviction;

(d) to investigate the dissemination of information and news, including false news stories, by social media organisations using personal data;

(e) to consider the adequacy of the current regulatory arrangements and the resources, powers and approach of the Information Commissioner and any other relevant authorities in relation to-

(i) the news publishing industry (except in relation to entities regulated by Ofcom) across all platforms and in the light of experience since 2012;

(ii) social media companies;

(f) to make such recommendations as appear to the inquiry to be appropriate for the purpose of ensuring that the privacy rights of individuals are balanced with the right to freedom of expression, while supporting the integrity and freedom of the press, and its independence (including independence from Government)

6.20pm BST

Lady Hollins, the crossbencher who has tabled the amendment calling for a new Leveson-style inquiry into the press, has just moved her amendment. She said she did not think the press had learnt enough lessons from what went wrong in the past.

Peers are voting now.

6.19pm BST

Lord Keen of Elie, the advocate general for Scotland and a Ministry of Justice spokesman in the Lords, wound up for the government in the Lords debate. He said the government ruled out a Leveson part two inquiry in the Conservative election manifesto. And he said the data protection bill was all about looking forward. An inquiry would be about looking to the past, he said.

6.18pm BST

'No significant progress' in Brexit talks since March, EU ministers told

Turning to Brexit for a moment, EU ministers were told today that "no significant progress" had been made in the Brexit talks since March. The comment came from Ekaterina Zaharieva, the foreign minister of Bulgaria (current holder of the EU's six-month presidency) who was speaking after chief EU negotiator Michel Barnier briefed ministers from the remaining 27 member states at the general affairs council in Brussels.

Barnier said "no significant progress has been made on the three pillars that we are working on - withdrawal, future framework and Ireland" since March, Zaharieva said. She explained:

The council was confirmed that not much progress has been made since the European Council in March.

We look forward to a more intensive engagement by the UK Government in the coming weeks. October is only five months from now and still some key issues related to the withdrawal agreement need to be settled.

In June we need to see substantive progress on Ireland, on governance and all remaining separation issues.

Our citizens and our businesses on both sides of the Channel need more security and predictability for the future. As soon as possible they need clarity about what will happen when Brexit takes place.

Time is running... There is still 25% of open questions, and as you can imagine those 25% are the most difficult ones to be achieved.

Michel Barnier with and Ekaterina Zaharieva, the Bulgarian foreign minister, at the general affairs council in Brussels.Photograph: Stephanie Lecocq/EPA

6.06pm BST

Lord Stevenson of Balmacara, a Labour whip who is winding up for the ***opposition***, says the arguments against a second Leveson inquiry are very thin. He says having an inquiry would reassure victims of press intrusion that their concerns were being addressed.

6.01pm BST

Here are some more quotes from the debate, from the Press Association wires.

Leading crossbench peer Lord Pannick said:

There have been a large number of civil actions brought by phone hacking victims of cases against the press. And those victims have not gone without remedy. They have received very, very substantial financial compensation, and rightly so.

It is simply not the case that victims of phone hacking lack and have lacked legal remedies. Newspapers have rightly been ordered to pay very substantial sums by way of compensation.

Tory peer Lord Cormack said peers would be "over emphasising our constitutional legitimacy" if the Lords rejected the vote by MPs. He added:

The other place [the Commons] has thought again. This is not the moment to introduce new amendments, to protract ping pong by bringing in a new ball.

Baroness Cavendish of Little Venice, a journalist and Downing Street policy adviser under David Cameron, opposed the Leveson two amendment, warned about the impact on investigative journalism and cautioned peers against exacting "revenge". She said a great deal had changed over controls of the press and the "landscape" was now very different with a tougher regulator. Yet another public inquiry would reopen the door to "people who are very keen indeed to impose enormous costs on the major newspaper groups" to pay "malicious damages" for groundless claims, she said.

Tory Lord Black of Brentwood, deputy chairman of the Telegraph Media Group, also spoke out strongly against the move, insisting there had been wholesale change in press regulation since Leveson reported. He said all publishers were under "huge and sustained commercial pressure," adding:

It is a struggle for survival on a day-to-day basis which will be made all the more complicated by having to wind the clock back 10 to 15 years to rake over a world which no longer exists.

Leading lawyer and Labour peer Baroness Kennedy of the Shaws backed calls for a further inquiry, arguing the police had "got off rather lightly" in relation to inquiries into "media misbehaviour". She was aware of leaking by the police to the media in exchange for "bungs". She added:

I am concerned that the police still haven't been looked at adequately for the role that they played in some of this particularly iniquitous conduct.

Liberal Democrat peer Lord Paddick, a former senior police officer and a victim of phone hacking, said:

We need to consider the enormous burdens placed on innocent victims of the media.

5.53pm BST

Lord McNally is winding up now for the Lib Dems. He says he objects to the claim from peers opposed to a Leveson two inquiry that it is only people on their side who care about press freedom. He says peers who want to see a press that is respected and trusted are the ones who respect press freedom.

5.47pm BST

Lord Hunt of Wirral, the former Conservative cabinet minister and former chair of the Press Complaints Commission, says the new regulator, Ipso, has become more and more compliant with the Leveson requirements.

He says the media is facing a series of challenges. He does not think a new Leveson inquiry would address these problems.

A new inquiry would be "an analogue inquiry in a digital age".

And it would be seen as a fresh attempt to muzzle the press, he says.

5.33pm BST

Lord Grade of Yarmouth, a former chairman of both the BBC and ITV, is speaking in the Lords debate now. He says the call for a Leveson phase two inquiry takes no account of how much better Ipso (the Independent Press Standards Organisation) is as a regulator than the Press Complaints Commission, the body it replaced. He says there would be no public interest in having a new inquiry.

5.30pm BST

Media treatment of victims after Manchester Arena 'completely unacceptable', peers told

Lord Kerslake, the crossbencher and former head of the civil service, also spoke in favour of a fresh inquiry into press conduct in the House of Lords debate. Kerslake said he was influence by what he learnt when chairing [*an inquiry into the Manchester Arena terror attack (pdf).*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Kerslake said most of the participants who commented on their experiences of the media in the aftermath of the attack were negative.

People talked about being hounded and bombarded, and having to force their way through scrums of reporters at hospitals who wouldn't take no for an answer. Specific mention was made of photos being sneakily taken through the glass windows at the stadium when the families were being given the news of their bereavement. Several people told of the physical presence of crews outside their homes. One mentioned the forceful attempt by a reporter to gain entrance through their front door by ramming a foot in the door. There were at least two examples of impersonation.

Kerslake said some families spoke in praise of sympathetic reporting by the Manchester Evening News and other local papers.

But overall the panel was shocked and dismayed by these accounts. To have experienced such intrusive and overbearing behaviour at a time of such enormous vulnerability seemed to us to be completely unacceptable. By any measure these actions fell well below the standards set out in the editors' code.

Lord KerslakePhotograph: Parliament TV

5.16pm BST

Prescott attacks Sunday Times in Lords debate on press standards

In the Lords debate Lord Prescott, the Labour former deputy prime minister, said he had to go to court to establish that his phone was hacked.

Prescott said that, since then, [*new evidence had come to light about the Sunday Times using a private investigator to hack bank accounts.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Everybody now tells me, things have changed, you don't have to worry, we can now just get on with the business and not have a second inquiry. But then comes along the Sunday Times, Mr Witherow, the editor, who in fact now we know - the announcement is only quite recent, and court cases are going on - that [*a man called John Ford*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) was hired to commit criminal acts against individuals, including me and including the prime minister, at that time Gordon Brown. It is quite clear by his statements, his bank accounts, his personal effects, the solicitors were all hacked and intervened in criminal acts by this Mr John Ford who's made it absolutely clear everywhere he was employed by Mr Witherow. Now, of course you might play around with the word "employed", but he was paying him for 20 years. He might have been a separate investigator, but he was committing criminal acts, breaching the human rights of everyone involved.

Prescott claimed that the Sunday Times had denied these claims when asked about them at the Leveson inquiry. He went on:

Hello Mr Witherow, you appear to be a liar. I know there are strong words here, but you didn't tell the truth, and you did pay the money and you did commit criminal acts against people, breaching their human rights. That surely, in any democracy, is wrong.

Prescott was echoing an allegation against Witherow made by Brown when the new Ford allegations came out in March and [*Brown called for a police investigation*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw). At the time the Sunday Times said   [*these matters had been dealt with in the Leveson inquiry in 2012 and that it had nothing further to add.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

John PrescottPhotograph: Parliament TV

4.46pm BST

Scully says the petitioners are worried that, if the new panel members only join for phase two of the Grenfell Tower inquiry, they might not be able to reach conclusions because they were not involved for part one.

He also says some petitioners think the policy inquiry will be the most important one.

4.42pm BST

MPs debate Grenfell Tower inquiry

In Westminster Hall, the mini chamber set aside for general debates, MPs have just started debating the Grenfell Tower inquiry.

The debate was triggered by [*this e-petition*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) urging Theresa May to appoint additional panel members to the inquiry "to ensure those affected have confidence in and are willing to fully participate in the inquiry". The petition has received 156,660 signatories.

The Conservative MP Paul Scully, who represents Sutton and Cheam and who is a Conservative party vice chair for London, says [*Theresa May's announcement on Friday that extra panel members would be appointed*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) was welcome.

But he says the minister will have to clarify whether only two extra panel members are being appointed, or whether there could be more.

You can watch the hearing [*here.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Updated at 4.46pm BST

4.36pm BST

In the Lords peers have just started debating amendment 62A to the data protection bill, the one that would effectively order a Leveson phase two inquiry to go ahead. It was moved by Lady Hollins, a crossbencher. Earl Attlee, a Conservative peer and grandson of the great postwar Labour prime minister is speaking now and he says he will be backing the amendment if it gets put to a vote.

4.29pm BST

Jeremy Hunt, the health secretary, is winding up.

He says some people will wonder why a Conservative government is so keen to mark the legacy of a Labour cabinet minister. But those how knew Jowell will know the answer. It is because she had an incredible gift for bringing people together.

He says she achieved this with the Olympics.

And she did it again when, in her last few months, she persuaded the government to tear up its brain cancer strategy and start again. The government is doing that, he says. It is another example of the "Tessa magic".

And that's it. The tributes to Jowell are over.

4.24pm BST

Labour's Liam Byrne says Jowell was one of the greatest entrepreneurs we have seen in public life for decades. She was interested in ideas, but she wanted to turn them into achievements.

She had one of the best political sat navs in the business, he says. She thought, if you hit a problem, you had to find a way around it, he says.

He says he was told there are two sorts of politicians; those who divide and those who unite. Bringing the Olympics to London she brought the world together. He says people on the Labour benches often wonder how change happens; Jowell showed them how, he says.

4.21pm BST

Labour's Seema Malhotra says Jowell was "funny, kind, strong, warm, generous and brilliant". She was particularly helpful to people like Malhotra when they first became MPs.

4.19pm BST

Labour's Pat McFadden says there were many people who found Tessa Jowell was there for them when they were at a low ebb.

He says, at a time when there is so much that divides the country, we should remember that Jowell represented the ***opposite***.

4.16pm BST

Labour's Mary Creagh says, in an era of fast media and fast food and fast politics, Tessa Jowell was a slow politician. She means that in the best possible sense, Creagh says. Every word was measured for its kindness.

4.09pm BST

Labour's Barry Sheerman says Jowell was one of those special MPs who could lighten spirits. Mo Mowlam was one, Jowell was another. She brought joy into the Commons, he says.

4.08pm BST

Picking up on Cooper's story (see [*4.06pm)*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw), Labour's Caroline Flint says: "Once a public health minister, always a public health minister." (Flint was a public health minister too.)

4.06pm BST

Dame Margaret Hodge, the Labour MP, says Jowell was a feminist, but she was also feminine. She was always a good source of style advice, and her home was filled with flowers.

Labour's Yvette Cooper says Jowell was the mother of Sure Start. She did some amazing things, Cooper says.

She says, when people talk about Jowell and the Olympics, they think of her determination to ensure they happened. But Cooper says she remembers a briefing where Jowell spoke about ensure there were plenty of condoms available because she knew that, after the Games, all these super-fit athletes would be wanting to have sex. She says that was typical of Jowell - very down-to-earth, and practical.

4.02pm BST

The Labour MP Sarah Jones, who secured [*a debate on cancer treatment in Jowell's honour last month*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw), says that as a friend of Jowell's she got to recognise the velvet and the steel. She says when the debate was held last month Jowell insisted it was not about her. So, in that spirit, Jones says she wants to welcome   [*the new funding announced for brain cancer research.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

3.58pm BST

The Lib Dem MP Alistair Carmichael says Tessa Jowell was not just kind and generous to fellow MPs; she was like that with all staff in the House of Commons, and with civil servants, he says.

Carmichael says Jowell was brought up and educated in the north east of Scotland. She studied at the University of Aberdeen. Aberdeen graduates have never been over-represented in the Commons. But, as a fellow graduate, he likes to think they have made up in quality what they lack in quantity, and Jowell exemplifies that, he says.

He says death is the last taboo in our society. But, thanks to Jowell's example, that taboo is weaker than it was.

3.54pm BST

Helen Hayes, Jowell's success as Labour MP for Dulwich and West Norwood, says Jowell has left a legacy locally and nationally. Sure Start centres have transformed the lives of many families, she says.

And Jowell was determined to ensure the Olympics helped to transform London.

Her family will take consolation from the knowledge that Jowell leaves the world "a far better place than she found it," Hayes says.

3.51pm BST

Harriet Harman, the former Labour deputy leader, says Jowell was the embodiment of the women's movement phrase that the personal is political. Her commitment to Sure Start came out of her experience as a mother and a step-mother.

Harman says Jowell was always courteous. But she was tough and steely too, and if she felt people were letting down her constituents, she could be as tough as anyone, Harman says.

She says people who knew her will be intensely proud of that fact.

3.48pm BST

The SNP's Pete Wishart pays tribute to the way Tessa Jowell went around the country trying to ensure that all parts of the country backed the Olympics bid. She even managed to persuade people in Scotland who were originally sceptical, he says.

3.47pm BST

Sir Hugo Swire, a Conservative, says as an MP he has learnt to tell the difference between when MPs pay tribute to a late colleague because they feel they have to, and when they do it because they feel they want to. He says in this case it is the latter.

He says what was special about her was that she was unpartisan. He says, as a shadow minister, it was his job to oppose her over the Olympics bid and other matter. But she never held it against him.

3.44pm BST

Jeremy Corbyn thanks Bercow for arranging the Commons tribute.

He says people were devasted to hear of her death. The media coverage of Jowell's death goes far what is normal for a politician.

He says he first met Jowell when he was a union organiser in the 1970s, and Jowell was a councillor. He says he campaigned in her byelection.

In government she was determined to bring about Sure Start, he says.

He says her pivotal moment was helping to ***win*** the Olympics for London.

He says her family can be very proud of the legacy she left behind.

Her children and family are obviously totally devastated but I think they can be very proud of the legacy she left behind, and I think it's wonderful we now have the Tessa Jowell Brain Cancer Research Fund.

I hope we will all support that fund so that others don't suffer in the awful way that she suffered.

She taught us how to live and I think she also taught us how to die.

Updated at 4.13pm BST

3.40pm BST

Theresa May says Jowell was defined by her devotion to public service.

In parliament she would always reach out to any MP who was going through a tough time, May says. She says Jowell was always a person first, and a politician second.

Jowell was someone who refused to take no for an answer. She persuaded Tony Blair, the government and the country to back the Olympic bid. May says the summer of 2012 would never have happened without Jowell.

Her advocacy was so compelling because Dame Tessa was never one to take no for an answer, something I believe she put down to her Scottish roots.

And she certainly refused to take no for an answer when many said London should not even bid for the 2012 Olympics and Paralympic Games.

As secretary of state at the Department for Culture, Media and Sport, she persuaded Tony Blair and the Cabinet, the civil service and ultimately the whole country to get behind the bid.

And that historic summer of 2012, which brought us together so powerfully as a nation, simply would not have happened without her.

May says there will be an annual Tessa Jowell symposium to bring together the best research on brain cancer.

May says the way Jowell approached her death was typical of her life. She inspired everyone, and her legacy will live on, she says.

Updated at 4.15pm BST

3.36pm BST

MPs pay tribute to Tessa Jowell

Theresa May has arrived in the Commons chamber where MPs are now paying tribute to Tessa Jowell, [*the former Labour minister who died at the weekend.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

May probably expected to lead the tributes herself. But John Bercow, the speaker, goes first. He describes Jowell as the "embodiment of empathy, a stellar progressive changemaker and a well of practical compassion without rivalry".

The embodiment of empathy, a stellar progressive changemaker and a well of practical compassion without rival: Tessa Jowell was the best of us.

I rue her tragic and untimely passing which leaves all of us in this place - and countless others beyond it - infinitely and permanently poorer.

May Tessa rest in peace.

Updated at 3.53pm BST

3.14pm BST

In the House of Lords peers have just started debating the data protection bill, and specifically the amendments passed in the Commons. At some point we are expecting a vote on an amendment calling for a new Leveson-style inquiry into the press - seen as the Leveson phase two inquiry that was originally promised by David Cameron's government but dropped by Theresa May's government.

2.52pm BST

Sir Jeremy Heywood, cabinet secretary and head of the civil service, has posted a link to the full text of today's speech on security from MI5 boss Andrew Parker.

"In today's uncertain world we need that shared strength more than ever". Director General MI5, in first public speech outside the UK, praises the international response to Salisbury & says European intelligence partnerships have never been more crucial [*https://t.co/sdYBwpJu5M*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Sir Jeremy Heywood (@HeadUKCivServ) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

2.31pm BST

The Labour frontbencher Preet Gill has "clarified" what she meant when she posted a tweet saying she backed a "people's vote" on the final Brexit deal. (See [*1.35pm.)*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) She is using "clarify" in its political sense where a more appropriate word might be - "retract".

Just to clarify my position - a meaningful vote on the deal by Parliament is a must which will be informed by the people we represent. [*https://t.co/X6qrkSlqoD*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Preet Kaur Gill MP (@PreetKGillMP) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

2.21pm BST

Lunchtime summary

* A leader Conservative Brexiter, the MEP Daniel Hannan, has said that if MPs vote to keep the UK in the customs union, he would back a second Brexit referendum or a general election, to allow the public to have the final say. (See 1.16pm.) Generally Brexiters oppose a second referendum, and pressure for one is coming almost entirely from the remain camp, but Hannan's words could be a sign that this may be starting to change.

1. David Miliband, the Labour former foreign secretary, has said Jeremy Corbyn will be the "midwife of hard Brexit" unless Labour backs staying in the single market. (See 9.10am.) He was speaking before he joined Nick Clegg, the Lib Dem former deputy prime minister, and Nicky Morgan, the Conservative former education secretary, at an event where they urged MPs to back staying in the single market and the customs union after Brexit. At the event Morgan revealed that she will give evidence in a court case in June after she received an alleged death threat over her position on Brexit. As Sky's Faisal Islam reports, Miliband was also fiercely critical of the government.

David Miliband gives his take on the Government's position: "We have no negotiating position on customs. We have no negotiations position on regulatory oversight We have no negotiating position on nuclear safeguards" & 2 contradictory positions on Ireland [*pic.twitter.com/ts5Lo7N5G2*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Faisal Islam (@faisalislam) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

* Jeremy Hunt, the health secretary, has told Boris Johnson to keep his disagreements over Brexit private, warning that open expressions of dissent could mean a worse deal for the UK.

1. Tessa Jowell's family have hailed a government decision to double funding for brain cancer research and roll out better diagnostic tests to all NHS hospitals in tribute to the former Labour cabinet minister, saying they hoped it could help other people survive the illness.
2. The Russian government is the "chief protagonist" in a campaign aimed at undermining western democracies, the head of the UK intelligence agency MI5, Andrew Parker, has said.
3. Nicola Sturgeon has been urged to allow all Scottish prison inmates to vote in the country's elections by a majority of MSPs on Holyrood's equalities committee.
4. The new president of the Board of Deputies of British Jews has demanded the expulsion of Ken Livingstone and Jackie Walker from the Labour party by the end of July.
5. The High Court in Belfast has ruled that a senior civil servant had no power to approve a huge new incinerator project in a ruling that could hinder the ability of officials to administer government in Northern Ireland in the absence of a power-sharing executive.Sam McBride, political editor of the Belfast News Letter, has more in a Twitter thread starting here.

Hugely significant decision: Belfast High Court has ruled senior civil servant Peter May had no power to approve ARC21's planning application for huge incinerator at Hightown in Mallusk. The courts are putting a stop to officials taking big policy decisions in a democratic vacuum

- Sam McBride (@SJAMcBride) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

* One of the country's top property developers has described the UK's system of funding social housing as "nuts" and called for higher taxes to speed up building.

1.58pm BST

Sturgeon says 'obvious democratic compromise' is for UK to stay in single market and customs union

Nicola Sturgeon, Scotland's first minister, has said that the cabinet argument about post-Brexit customs models is absurd. Speaking News UK's Scotland Means Business event in London, she said:

I deeply regret the UK's decision to leave the EU and I believe the absurdity - and I believe that is the appropriate word - of the ongoing UK cabinet discussions and disputes over the post-Brexit customs arrangements strengthens one of the basic arguments that the Scottish government together with many businesses has been making. That argument is that in our view the approach if the UK is determined to leave the EU is to remain within the single market and within a customs union.

It is the obvious democratic compromise in a UK where 48% of voters and indeed two out of the four nations in the UK chose to remain in the EU. It is also the least damaging solution economically.

Nicola SturgeonPhotograph: Jeff J Mitchell/Getty Images

1.50pm BST

In the comments this morning [*Fishgirl23*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) suggested we should allow readers to post tributes to Tessa Jowell on a special page. Good idea. And that's what we're doing.

You can post them on the form here.

Related: [*Share your tributes and memories of Tessa Jowell*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

1.35pm BST

Labour frontbencher backs second Brexit referendum

While we're on the subject of a second referendum, PoliticsHome has revealed that Preet Gill, a shadow international development minister, backed a second Brexit referendum in a tweet - only to ***delete*** it when PoliticsHome publicised what she said. Labour does not back a second referendum, and Owen Smith got sacked from the shadow cabinet for proposing one.

These are from PoliticsHome's Kevin Schofield.

Wow. Labour frontbencher Preet Gill comes out in support of a fresh Brexit referendum. Owen Smith got sacked for saying the same thing. Great scoop by [*@wizbates*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*https://t.co/NnJcfXBHq9*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Kevin Schofield (@PolhomeEditor) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Within seconds of our scoop, Preet Gill has ***deleted*** her tweet backing a fresh EU referendum. But thanks to the wonder of computers, it is captured for posterity. [*https://t.co/NnJcfXTiOJ*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*pic.twitter.com/GCQJx23Xlt*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Kevin Schofield (@PolhomeEditor) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

In November last year the Guardian revealed that Diane Abbott, the shadow home secretary, had written to two constituents saying [*she favoured giving the public a vote on the final Brexit deal,*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) although Abbott subsequently claimed that backed party policy and that her letters had just been poorly worded.

1.16pm BST

Daniel Hannan says he would back 2nd Brexit referendum if MPs voted to stay in customs union

On the BBC's Daily Politics Daniel Hannan, the Conservative MEP and one of the leading leave campaigners in the EU referendum, said that if MPs voted to keep the UK in the customs union, he would back a second Brexit referendum or a general election, to allow the public to have the final say. He told the programme.

Ultimately, if parliament insists on staying in the customs union, then we are plainly worse off than we are now - leaving the EU, but staying in the customs union, in other words putting Brussels in charge of 100% of our trade policy, with 0% input. That would be worse than we are now. In that situation, I think you would need to have a new mandate, either in the form of a general election or another referendum.

This is significant because, until now, almost all the pressure for a second referendum has come from people who were in the remain camp at the referendum.

Last week, [*in an article for ConservativeHome*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw), Hannan admitted that Brexit was not working out quite as he expected - although he subsequently claimed that reports of what he had said glossed over who he thought was to blame.

Six newspapers have reported this piece as "Daniel Hannan says Brexit isn't working out". Unsurprisingly, not one has added "because of the behaviour of the peers and MPs who are mischievously trying to keep us in the customs union".

- Daniel Hannan (@DanielJHannan) [*May 12, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)Daniel HannanPhotograph: Finbarr Webster/REX/Shutterstock

12.46pm BST

Downing Street lobby briefing - Summary

Here are the main points from the Number 10 lobby briefing.

* Theresa May hopes to speak in the Commons this afternoon in a session being set aside for tributes to Tessa Jowell, the prime minister' spokesman said.

1. The spokesman declined to endorse the language used by Jeremy Hunt, the health secretary, to implicitly criticise Boris Johnson, the foreign secretary, for describing one of the government's post-Brexit customs options as "crazy". On the Today programme this morning Hunt said: "I do think that it's important that we have these debates in private, not just because of collective responsibility - which is what democracy depends on - but also because this is a negotiation." Asked if the prime minister agreed with Hunt's words, the prime minister's spokesman said Hunt had said it was important for the government to work together as a team, but - in line with the approach he took last week - he declined to endorse the specifics of what Hunt said.
2. The spokesman refused to say whether Theresa May had a preference between the "customs partnership" proposal and the "maximum facilitation" proposal. It has been widely reported that the partnership model is the one she likes best, but Downing Street has never confirmed this.
3. The spokesman said there was no timeframe for when the two cabinet working groups set up to look at the two customs options are due to present their findings.
4. The spokesman said there were "no plans" to extend the Brexit transition. Asked about this, the spokesman said:

The implementation period, both ourselves and the European Union are clear, ends in December 2020. There are no plans for an extension to that.

The government has repeatedly ruled out extending the transition, even though many commentators think an extension will prove necessary because new customs arrangements are very unlikely to be ready in time. But "no plans" is not the same as a denial, and this could be a hint that No 10 is starting to finesse its language ahead of an eventual climbdown. (I haven't heard Downing Street use "no plans" in this context before, but I don't attend all the briefings and so I may have missed it. But in the past the spokesman has just said the transition will end in December 2020, [*as he did last week.)*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

The question was prompted by Damian Green, the former first secretary of state, telling the Westminster Hour last night that he thought an extension - [*or a transition period after the transition, as he put it*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) - would prove necessary. Michael Gove, the environment secretary, said yesterday that   [*he was supposed to extending the transition*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) - although people forget that,   [*on the subject of farming subsidies, Gove wants the transition to last potentially up to 2024.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

* The spokesman was unable to explain what Theresa May meant when she asked for the "help" of the public in delivering Brexit in a Sunday Times article yesterday (paywall). In her article May said:

The path I am setting out is the path to deliver the Brexit people voted for. Of course, the details are incredibly complex and, as in any negotiation, there will have to be compromises. But if we stick to the task we will seize this once-in-a-generation opportunity to build a stronger, fairer Britain that is respected around the world and confident and united at home.

I will need your help and support to get there. And in return, my pledge to you is simple: I will not let you down.

Asked what she meant by saying she needed people's "help", the spokesman just said that she wrote the article to set out her commitment to delivering Brexit. He brushed aside a suggestion that she could have been asking people to send it viable ideas for a post-Brexit customs model. But he did dismiss one idea. Nigel Farage, the former Ukip leader, said May might be hinting at the need for another election in her article.

Theresa May is hinting at another election. Would you support her? [*#FarageOnLBC*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*https://t.co/uAHrE7feFo*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Nigel Farage (@Nigel\_Farage) [*May 13, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Asked whether May was floating the need for another election, the spokesman said:

I don't believe that's the case.

10 Downing StreetPhotograph: Adrian Dennis/AFP/Getty Images

Updated at 12.57pm BST

11.55am BST

Sir Nick Clegg (left), Nicky Morgan and David Miliband speaking at a crossparty event on Brexit at Tilda Rice Mill in Rainham, Essex.Photograph: Stefan Rousseau/PA

My colleague Lisa O'Carroll has been tweeting from the Miliband/Clegg/Morgan event in Essex. Here are some of her posts.

At Tilda Rice in Rainham. Huge plant that is at risk because of Brexit. Nicky Morgan, Nick Clegg, and David Milliband will be here shortly. Milliband earlier said Brexiteers were holding country to ransom. [*pic.twitter.com/tAxjO9N9mP*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- lisa o'carroll (@lisaocarroll) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Ahead of Nicky Morgan speech, Alex Waugh, head of Rice Association says £1bn flour and rice exports to EU under threat could lead to business moving out of UK and job loses.

- lisa o'carroll (@lisaocarroll) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Nicky Morgan: "the UK has been asked to experiment on other peoples whims with a new trade policy when they have no idea what the cost will be for business and people in this country. "

- lisa o'carroll (@lisaocarroll) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

David Miliband warns Brexit will "impoverish" Britain if it leaves the customs union and single market. No reason why UK cannot leave EU and stay in these arrangements.

- lisa o'carroll (@lisaocarroll) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

ITV to Milband: Is this the beginning of a return to British politics? Miliband: "It's not the beginning middle or end of anything, it's a contribution to the debate that I think is important".

- lisa o'carroll (@lisaocarroll) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Clegg, Morgan, say the answer to Brexiters is not a new political party. "right that politicians should work on a cross party basis to make those points more clearly," says Morgan

- lisa o'carroll (@lisaocarroll) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Miliband says he is "baffled" by Labour's ***opposition*** to EEA. "I am absolutely baffled why the Labour leadership is so worried about supporting the EEA I fear the position makes Jeremy Corbyn the midwife of a hard Brexit"

- lisa o'carroll (@lisaocarroll) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Tilda Rice deserve some sort of award for best product placement at a political event.

Clegg, Morgan and Miliband at the Tilda Rice Mill event.Photograph: Stefan Rousseau/PA

At least Labour's Tom Hamilton finds it funny.

More evidence that the Leave vote was motivated by ricism. [*pic.twitter.com/X0Wlj6okXw*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Tom Hamilton (@thhamilton) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

While the Times's Patrick Kidd reckons the notional leader of the remain-voting liberal metropolitan elite doesn't know his classics...

Some mixed classical messaging in Rainham this morning. Nicky Morgan says "we will not give in to Siren voices" but David Miliband criticises May for "lashing herself to the mast". But surely lashing self to a mast is how you beat the Sirens. Did none of them read The Odyssey?

- Patrick Kidd (@patrick\_kidd) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

11.41am BST

We did, however, find out at the lobby briefing that Theresa May has a series of meetings in the diary today with Conservative MPs - but only because a colleague raised the topic in a question.

The BBC's Norman Smith has more details.

Around ten senior pro Brexit and pro Remain backbench Tories called to see PM this morning re customs deadlock.

- norman smith (@BBCNormanS) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Tory MPs told at meeting with PM on customs options - "both models won't work in the current form."

- norman smith (@BBCNormanS) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

It's understood no breakthrough on customs options expected at Brexit sub committee tomorrow

- norman smith (@BBCNormanS) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

11.38am BST

I'm just back from the Number 10 lobby briefing and, on Brexit at least, it was a Groundhog Day experience. The prime minister's spokesman succeeded triumphantly at managing to avoid saying anything much new. For what it's worth, I'll post a summary shortly.

11.32am BST

Labour's national executive committee is interviewing candidates today for the Lewisham East by-election. However, local activists who are angry about the speed of the shortlisting process met overnight to draw up their own final shortlist - to try and steal a march on the NEC's decision.

The constituency Labour party chair Ian McKenzie told the Guardian that local party members wanted there to be a shortlist of four candidates - former Bexley Labour councillor Abena Appong-Asare, Lewisham deputy mayor Janet Daby, and councillors Brenda Dacres, and Rachel Onikosi. All four candidates are understood to have interviews with the NEC today.

The Labour leadership and the left-wing grassroots group Momentum were widely reported to have preferred three different candidates - Claudia Webbe, Sakina Sheikh and Phyll Opoku-Gyimah, who unexpectedly dropped out of the race on Sunday. Sheikh and Webbe are also being interviewed by the NEC panel today.

Left-wing figures in the party are also thought to be cautious about selecting Webbe, the former chair of Operation Trident, because she is a member of Labour's NEC. Were she to resign from the finely balanced committee, her place would go to a more Corbyn-sceptic replacement, Johanna Baxter.

After careful deliberation, Lewisham East CLP Executive decided, if asked, our shortlist for our MP candidate would have been: [*@abenaopp*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*@brenda\_dacres*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*@JanetDaby*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*@rachelonikosi*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) We hope   [*@Yasmine\_Dar*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*@kateosamor*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) and   [*@SarahOwen\_*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) listens to local members.   [*#memberleddemocracy*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- (((Ian McKenzie))) (@iMcKenzied) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Updated at 11.33am BST

10.58am BST

The EU is threatening to exclude the UK from the military aspects of Galileo, its new satellite navigation system, after Brexit. In an interview with the Today programme this morning Sam Gyimah, the science minister, accused the EU of "playing hard ball" and said that, if the UK were excluded, EU countries could end up paying billions more for it. He said:

The EU is playing hard ball with us.

We have helped to develop the Galileo system. We want to be part of the secure elements of the system and we want UK industry to be able to bid for contracts on a fair basis. It is only on those terms that it makes sense for the UK to be involved in the project.

This is a project that is of mutual benefit to the UK and the EU and if the UK is not part of the programme, it would cost EU members billions of pounds more to develop.

Gyimah also confirmed that, if the UK were excluded from the programme for military purposes, it would consider developing its own alternative.

Because of the implications for us in terms of defence and our national security, were we not to participate in Galileo we would look at alternative options and we will leave nothing off the table. That includes developing a British satellite navigation system.

In [*a Times story (paywall)*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) at the weekend Oliver Moody explained why Galileo is so important to the UK. Here's an extract.

Since January ministers have been fighting to prevent the UK from being frozen out of the heavily encrypted Public Regulated Service (PRS) arm of the EU's Galileo project, expected to be the world's most secure and precise global positioning technology...

Cracks are already appearing in the "M-code", the [American] GPS system Britain's armed forces depend on at present, as Russia, China and other ***strategic*** rivals develop increasingly sophisticated electronic warfare devices. Russia is thought to have been jamming American drones over Syria since March. In 2014 a similar technology is thought to have grounded UN surveillance drones in Ukraine. Some experts believe GPS spoofing was used to bring down a US drone in Iranian airspace in 2011...

Unlike the GPS M-code, the EU's PRS system is said to be highly resistant to interference. "PRS is on two frequencies, has a wider band signal and the signals are encrypted," John Pottle,of the Royal Institute of Navigation, said. "You need a much more sophisticated jammer to deny positioning and it ensures that spoofing is practically impossible."

Britain faces two headaches. One is winning permission to use the PRS signal at all, the other is getting a seat at the table to determine how it is used in future. Without an active role in the talks over PRS, the UK would struggle to make it compatible with its military hardware and might be kept in the dark over the technology's vulnerabilities.

In a UK paper on the security partnership with the EU after Brexit [*published last week (pdf),*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) the government said: "PRS access limited only to user status would not meet UK ***strategic*** security requirements and would not provide the basis for continued UK collaboration in Galileo."

I'm off to the lobby briefing now. I will post again after 11.30am.

10.20am BST

In his LBC phone-in Jacob Rees-Mogg, the Conservative Brexiter, claimed that Brexit offered particularly good opportunities for young people. He said:

I think in terms of the Brexit debate that the great opportunities for everybody, but particularly the younger generation, are in leaving and looking to the broader horizon of the rest of the world rather than the narrow closed protectionist European field. For younger people, leaving is the best opportunity that they could have.

Of course, younger people don't seem to see it quite that way. As [*this YouGov analysis*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) of how people voted in the EU referendum shows, under-50s voted remain, and under-25s did so by a massive margin.

How people voted in EU referendumPhotograph: YouGov

10.11am BST

On the Today programme Theresa Villiers, the leave-voting former Northern Ireland secretary, accused David Miliband of wanting to frustrate Brexit. She said:

He wants to frustrate the result of the referendum and stop it being implemented because he wants us to say stay in a Norway-style arrangement that leaves us accepting unfettered and unreformed free movement, all the rules of the single market without the chance to vote on them, and that is just not respecting the result of the referendum.

She also said that the amendment to the EU withdrawal bill passed by the Lords, and likely to be backed by pro-Europeans in the Commons, [*intended to strengthen parliament's hand when it gets to vote on the final withdrawal deal*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) could be "Brexit-wrecking amendment". She explained:

Attempts by MPs to constrain the government's negotiating discretion is potentially a Brexit-wrecking amendment, because it cuts the prime minister off at the knees.

Theresa Villiers during the EU referendum campaign in 2016.Photograph: Ian Forsyth/Getty Images

9.50am BST

Reaction to David Miliband's interview is highly polarised. The Labour MP Wes Streeting, who is in the centrist, pro-European camp in the party, liked it.

Excellent interview with [*@DMiliband*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) about the risks of a Hard Brexit and the responsibility of Parliament to act.   [*#BBCR4Today*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Wes Streeting MP (@wesstreeting) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

As did the former Labour Europe minister Denis MacShane.

on [*@BBCr4today*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*@davidmiliband*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) really good and clear. In contrast to other previous PMs, party leaders with so much baggage he brings new clarity of expression. Like concept of "safe harbour" where UK can moor post-Brexit. Wish he was back   [*@emmarossthomas*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*@GeorgeWParker*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Denis MacShane (@DenisMacShane) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

But Steve Howell, who was Jeremy Corbyn's deputy director of communications until the general election, says it will have been counter-productive.

Hard to imagine anything LESS likely to ***win*** over Brexit supporters than someone perceived as epitomising the metropolitan liberal elite flying in from New York to tell them the error of their ways. David Miliband's lack of self awareness is staggering. [*https://t.co/aqxuukfS9G*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Steve Howell (@FromSteveHowell) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

And the commentator Ian Birrell agrees.

I agree with much of what David Miliband says on Brexit. But sadly his ego & ambition stops him seeing that he symbolises so many of the things that drove people to back withdrawal & still corrode politics

- Ian Birrell (@ianbirrell) [*May 14, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

9.37am BST

Norwegian PM backs UK staying in EEA after Brexit

In his Today interview David Miliband, who confirmed that he was still a member of the Labour party, dismissed claims that, if MPs were to vote for the UK staying in the EEA, that would undermine Theresa May's position in the Brexit negotiations. The ***opposite*** was true, he claimed. He said:

There will be an enormous sigh of relief in Europe if the prime minister goes to the negotiations and says there are 400 plus members of parliament who believe [in a soft Brexit]... They don't want a weak Britain, because they think that will weaken Europe. They know there's trade both ways. And, at the moment, they are sitting there, strumming their fingers on the table, waiting for the government to come with a negotiating position.

Miliband also said it was "significant" that Erna Soldberg, the Norwegian prime minister, has told [*the Financial Times in an interview (paywall)*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) that Norway would be open to the UK remaining in the EEA after Brexit - joining Norway, Iceland and Lichtenstein as the only countries in the EEA but not in the EU. Soldberg told the FT:

I think we will cope very well if the Brits come in. It will give bargaining power on our side too. And it would ease Norway's access to the UK.

In the past Norway has been quite negative about the prospect of the UK staying in the EEA after Brexit because of its disruptive impact. Explaining the potential problem, the FT quotes the unnamed boss of a Norwegian company as saying: "We would go from being a big fish in a small pond to a small fish in still a pretty small pond."

9.23am BST

In the Lords vote last week Labour peers were ordered to abstain on the motion saying the UK should remain in the EEA after Brexit. For reference, this is what Jeremy Corbyn's spokesman said about the party's stance on this at a briefing on Wednesday last week. This is from the Telegraph's Jack Maidment.

Here's the key exchange with Jeremy Corbyn's spokesman on the EEA membership amendment. Seems pretty clear that Labour MPs will be told to abstain if Govt tries to overturn it. What do you make of this [*@OwenSmith\_MP*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)   [*@ChrisLeslieMP*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) ?   [*pic.twitter.com/GIwLTTwpMS*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

- Jack Maidment (@jrmaidment) [*May 9, 2018*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

9.10am BST

Corbyn will be 'midwife of hard Brexit' unless Labour backs staying in EEA, says David Miliband

There has been quite a lot of chatter at Westminster in recent months about the possibility of a new centrist party being set up. The consensus is that it will probably never happen - first past the post has a crippling impact on new entrants into the political party marketplace (in commerce, the competition authorities would probably ban it as a restraint on trade) - but this morning we are going to get a glimpse of what such a creature might look like when David Miliband, the Labour former foreign secretary, Nick Clegg, the Lib Dem former deputy prime minister, and Nicky Morgan, the Conservative former education secretary, take the stage together to urge MPs to reject a hard Brexit.

The involvement of Miliband is particularly intriguing because, in a classic kite-flying operation, some journalists have been talking up the prospect of Miliband returning from America, where he runs an aid organisation, to take charge of this putative new venture. Judging by the reaction I read, [*the kite swiftly crashed into the ground*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw), but that does not seem to have deterred Miliband and this morning he was on the Today programme with a warning for Jeremy Corbyn. If Labour does not back staying in the European Economic Area (ie, the "Norway option" - staying in the single market), Corbyn will be "the midwife of hard Brexit", he said. Miliband was so keen on the phrase he repeated it. He told the programme:

[Corbyn] has also made clear that he doesn't believe that we should remain in the single market. And I think there is a warning for Jeremy Corbyn here. Because Jeremy Corbyn has got to be very careful not to be the midwife of hard Brexit.

Remember, last week in the House of Lords, [*a very significant amendment was passed.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) It was passed with cross-party support, 80 Labour peers supported it, and that was that Britain should remain a member of the European Economic Area, in other words keeping the negotiated single market links that countries like Norway have.

Now, the Labour position was not to support that. And the warning for Jeremy Corbyn, he will be the midwife of a hard Brexit that threatens the living standards of the very people that he says he wants to stand up to represent.

I will post more from his interview, and reaction, shortly.

Here is the agenda for the day.

9am: Jacob Rees-Mogg, the Conservative backbenchers, hosts his LBC phone-in.

10.30am: David Miliband, Nick Clegg, and Nicky Morgan, the Conservative former education secretary, hold a joint Open Reason event at the Tilda Rice plant in Essex urging MPs to reject a hard Brexit.

11am: Downing Street lobby briefing

2.30pm: Damian Hinds, the education secretary, takes questions in the Commons.

After 3pm: Peers debate the date protection bill. As Jim Waterson reports, [*they are expected to defy the Commons and vote for what would effectively phase two of the Leveson inquiry into the press to go ahead.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

And at some point today in Brussels Michel Barnier, the EU's chief Brexit negotiator, will give a speech on security policy after Brexit.

As usual, I will be covering breaking political news as it happens, as well as bringing you the best reaction, comment and analysis from the web. I plan to post a summary at lunchtime and another in the afternoon.

You can read all today's Guardian politics stories [*here.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

Here is [*the Politico Europe round-up of this morning's political news from Jack Blanchard.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw) And here is the   [*PoliticsHome list of today' top 10 must reads.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

If you want to follow me or contact me on Twitter, I'm on [*@AndrewSparrow.*](https://twitter.com/hashtag/Grenfell?src=hash&ref_src=twsrc%5Etfw)

I try to monitor the comments BTL but normally I find it impossible to read them all. If you have a direct question, do include "Andrew" in it somewhere and I'm more likely to find it. I do try to answer direct questions, although sometimes I miss them or don't have time.

If you want to attract my attention quickly, it is probably better to use Twitter.

Updated at 9.52am BST

90382018-05-17T08:15:00Ztrue2018-05-14T08:10:52Zfalsefalse2018-05-14T18:55:37ZtrueUKtheguardian.com[*https://gu.com/p/8tpvkfalsetruehttps://media.guim.co.uk/325104b3de8d376ec2ef10eaaed92124875685f3/20\_0\_668\_401/500.pngfalseenOn*](https://gu.com/p/8tpvkfalsetruehttps://media.guim.co.uk/325104b3de8d376ec2ef10eaaed92124875685f3/20_0_668_401/500.pngfalseenOn) the Grenfell silent walk in west London, there are moving scenes as marchers embrace some of the firefighters who fought June's blaze and have lined Cambridge Gardens for the occasion. Paul Scully, the Conservative party vice chair for London, is now winding down this evening's proceedings. He pays tribute to the campaigners and notes how the contributions of four Cabinet ministers demonstrates the importance that the government has placed on solving the situation and bringing justice to the people most affected. The debate ends upon his remarks as he stresses that "action is needed". The timetable for the inquiry MPs are now discussing the sheer scale of the task at hand for the inquiry, which includes 547 core participants, including 519 individuals from the Grenfell community. On 27 April, the inquiry published a timetable for its first hearings which will focus on the factual narratives of events on 14 June 2017. Before then, evidentiary hearings begin on the 4 June and there will be two weeks of hearings beginning on 21 May, commemorating all those who lost their lives. The counsel to the inquiry has said that: "By starting the public hearings in this way, we can ensure that however technical and scientific the issues may become, and they will. However dry, however legal, we will never lose sight of who our work is for and why we are doing it." The hearings will hear evidence from the inquiry's expert witnesses and London fire brigade personnel, scheduled to last until the end of July. There will be no hearings in August as the inquiry prepares to hear evidence from the bereaved, survivors and local residents, which will run throughout September before further expert evidence will be heard ahead of closing statements in late October. An interim report will then be drawn up before the second phase of the inquiry. This morning, our front page bore the names of a number of the victims of the Grenfell Tower fire. The Guardian has been finding out about the lives of these Londoners. We have talked to as many families as were willing to speak, and asked friends and colleagues for anecdotes and their favourite memories. Here are some of their stories. Emma Dent-Coad has posted a video of her formidable speech from earlier this evening in case you missed it. Richard Burgon, the Labour MP for Leeds East, has made made a powerful intervention to the debate in Westminster Hall, where he warned against mistakes of the past repeating themselves. Far too often in this country politics seems to act as a dam, actually holding back justice rather than helping justice to flow. Hillsborough, Stephen Lawrence, Bloody Sunday - examples of when the state did not use its great powers to deliver truth and justice but instead blocked truth and justice for years and years. In all of these instances, the state was accused of cover up by those affected, in all of these instances, distrust was sowed. We can't allow Grenfell to join that list. Race and class and power is at the heart of this. Justice delayed is justice denied, so it's essential that this enquiry gets it right first time. Grenfell silent walk begins Hundreds of people gathered for tonight's silent walk for Grenfell which left from Notting Hill methodist church in Lancaster Road at 7pm. There was also a sister protest in Oxford earlier, in solidarity with protesters on Parliament Square in Westminster. Another march is planned for 16 June on the first anniversary of the Grenfell Tower tragedy. The Grenfell rally is continuing on Parliament Square where survivors demanded the urgent removal of flammable cladding from hundreds of tower blocks across the country. Rob Booth has the full story. Earlier, Labour MP Richard Burgon said solicitors acting for bereaved families and survivors were "concerned that they have only had access to 0.5% of relevant documentation". That raises concerns about what they're not seeing." Among the crowd was actor Michael Sheen, who said he wanted to see that "pressure is kept on" authorities and that "voices of residents are heard". The shadow home secretary, Diane Abbott, welcomed the expanded panel to include two experts in an effort to improve its diversity, but said it was "not enough". We need to know who they're going to be. If they just have puppets on the panel that is not going to help anybody." Good evening all, we're heading back to the debate on the Grenfell Tower inquiry in Westminster Hall. Earlier, Emma Dent-Coad, the MP for Kensington, gave an impassioned speech which detailed the litany of undelivered reassurances that the government offered in the wake of the Grenfell Tower fire. The former housing minister guaranteed that every household would be rehoused within the area - not delivered," she said. "The PM promised three 3 weeks for everyone affected to be rehoused - commitment not delivered." Seventy-two households remain in hotels, 11 months on from the tragedy, despite various promises to the contrary. David Lammy associated himself with her remarks and dedicated his speech to Khadija Saye and her mother, Mary Mendy, who died in the fire. He explained how the state must regain the trust of Grenfell Tower survivors, given their dependence on the public sector to survive. If you live on the 22nd floor of a tower block, the state literally has your life in their hands. It's the state that has told you to stay put. It is the state who has failed to ensure there are working fire alarms." Other MPs, from across the house, have said how far too little has been done for those living in blocks like Grenfell. Andy Slaughter called for action to ensure justice for Grenfell and to ensure the safety of people living in the dozens of cladded tower buildings across the country. Is it unreasonable that we only use non-combustible cladding? We need buildings with more than one means of escape. We need sprinkler systems and we need to stop this farce of desktop studies." The debate then moved towards identifying who was to blame for the tragedy. Bill Grant, the Conservative MP for Ayr, Carrick and Cumnock, said: It's quite clear that a series of failings led to the needless deaths of 72 individuals last year. In November 2016, I understand the Grenfell Action Group raised concerns of poor fire safety standards at Grenfell and they predicted a catastrophe. It's quite clear that no-one listened when they predicted catastrophe, and the question is, who didn't listen." Peers have inflicted a fresh defeat on the government by voting to legislate for a new Leveson-style press inquiry by a majority of 39. This majority is 10 higher than the majority for a Leveson two inquiry in the Lords when peers first defeated the government on this in January, suggesting there is no evidence peers are minded to back down. If anything, they may have been encouraged by the fact that the government majority on this topic in the Commons when MPs debated it last week was just nine. Theresa May and Jeremy Corbyn have led heartfelt tributes in the House of Commons to the former cabinet minister Tessa Jowell, who died of brain cancer at the weekend. EU ministers have been told by Michel Barnier, the EU's chief Brexit negotiator, that "no significant progress" has been made in the Brexit talks since March. (See 6.18pm.) That's all from me for tonight. My colleague Mattha Busby is taking over now. The government has lost the vote by 252 votes to 213 - a majority of 39. That means have voted in favour a new Leveson-style press inquiry. But the bill has to go back to the Commons, where the government is almost certain to try to take the amendment out. Last week in the Commons the government won a vote on this topic by a majority of nine. My colleague Jennifer Rankin has more from what Michel Barnier, the EU's chief Brexit negotiator, has been saying this afternoon. You can read the text of the amendment here (pdf). It is amendment 62A (which would trigger amendment 62B). And here is an extract. Insert the following new Clause- "Data protection breaches by national news publishers (1) The Secretary of State must, within the period of three months beginning with the day on which this Act is passed, establish an inquiry under the Inquiries Act 2005 into allegations of data protection breaches committed by or on behalf of national news publishers and other media organisations... (3) The terms of reference for the inquiry must include requirements- (a) to inquire into the extent of unlawful or improper conduct by or on behalf of national news publishers and other media organisations in respect of personal data; (b) to inquire into the extent of corporate governance and management failures and the role, if any, of politicians, public servants and others in relation to failures to investigate wrongdoing at media organisations within the scope of the inquiry; (c) to review the protections and provisions around media coverage of individuals subject to police inquiries, including the policy and practice of naming suspects of crime prior to any relevant charge or conviction; (d) to investigate the dissemination of information and news, including false news stories, by social media organisations using personal data; (e) to consider the adequacy of the current regulatory arrangements and the resources, powers and approach of the Information Commissioner and any other relevant authorities in relation to- (i) the news publishing industry (except in relation to entities regulated by Ofcom) across all platforms and in the light of experience since 2012; (ii) social media companies; (f) to make such recommendations as appear to the inquiry to be appropriate for the purpose of ensuring that the privacy rights of individuals are balanced with the right to freedom of expression, while supporting the integrity and freedom of the press, and its independence (including independence from Government) Lady Hollins, the crossbencher who has tabled the amendment calling for a new Leveson-style inquiry into the press, has just moved her amendment. She said she did not think the press had learnt enough lessons from what went wrong in the past. Peers are voting now. Lord Keen of Elie, the advocate general for Scotland and a Ministry of Justice spokesman in the Lords, wound up for the government in the Lords debate. He said the government ruled out a Leveson part two inquiry in the Conservative election manifesto. And he said the data protection bill was all about looking forward. An inquiry would be about looking to the past, he said. Turning to Brexit for a moment, EU ministers were told today that "no significant progress" had been made in the Brexit talks since March. The comment came from Ekaterina Zaharieva, the foreign minister of Bulgaria (current holder of the EU's six-month presidency) who was speaking after chief EU negotiator Michel Barnier briefed ministers from the remaining 27 member states at the general affairs council in Brussels. Barnier said "no significant progress has been made on the three pillars that we are working on - withdrawal, future framework and Ireland" since March, Zaharieva said. She explained: The council was confirmed that not much progress has been made since the European Council in March. We look forward to a more intensive engagement by the UK Government in the coming weeks. October is only five months from now and still some key issues related to the withdrawal agreement need to be settled. In June we need to see substantive progress on Ireland, on governance and all remaining separation issues. Our citizens and our businesses on both sides of the Channel need more security and predictability for the future. As soon as possible they need clarity about what will happen when Brexit takes place. Time is running... There is still 25% of open questions, and as you can imagine those 25% are the most difficult ones to be achieved. Lord Stevenson of Balmacara, a Labour whip who is winding up for the ***opposition***, says the arguments against a second Leveson inquiry are very thin. He says having an inquiry would reassure victims of press intrusion that their concerns were being addressed. Here are some more quotes from the debate, from the Press Association wires. Leading crossbench peer Lord Pannick said: There have been a large number of civil actions brought by phone hacking victims of cases against the press. And those victims have not gone without remedy. They have received very, very substantial financial compensation, and rightly so. It is simply not the case that victims of phone hacking lack and have lacked legal remedies. Newspapers have rightly been ordered to pay very substantial sums by way of compensation. Tory peer Lord Cormack said peers would be "over emphasising our constitutional legitimacy" if the Lords rejected the vote by MPs. He added: The other place [the Commons] has thought again. This is not the moment to introduce new amendments, to protract ping pong by bringing in a new ball. Baroness Cavendish of Little Venice, a journalist and Downing Street policy adviser under David Cameron, opposed the Leveson two amendment, warned about the impact on investigative journalism and cautioned peers against exacting "revenge". She said a great deal had changed over controls of the press and the "landscape" was now very different with a tougher regulator. Yet another public inquiry would reopen the door to "people who are very keen indeed to impose enormous costs on the major newspaper groups" to pay "malicious damages" for groundless claims, she said. Tory Lord Black of Brentwood, deputy chairman of the Telegraph Media Group, also spoke out strongly against the move, insisting there had been wholesale change in press regulation since Leveson reported. He said all publishers were under "huge and sustained commercial pressure," adding: It is a struggle for survival on a day-to-day basis which will be made all the more complicated by having to wind the clock back 10 to 15 years to rake over a world which no longer exists. Leading lawyer and Labour peer Baroness Kennedy of the Shaws backed calls for a further inquiry, arguing the police had "got off rather lightly" in relation to inquiries into "media misbehaviour". She was aware of leaking by the police to the media in exchange for "bungs". She added: I am concerned that the police still haven't been looked at adequately for the role that they played in some of this particularly iniquitous conduct. Liberal Democrat peer Lord Paddick, a former senior police officer and a victim of phone hacking, said: We need to consider the enormous burdens placed on innocent victims of the media. Lord McNally is winding up now for the Lib Dems. He says he objects to the claim from peers opposed to a Leveson two inquiry that it is only people on their side who care about press freedom. He says peers who want to see a press that is respected and trusted are the ones who respect press freedom. Lord Hunt of Wirral, the former Conservative cabinet minister and former chair of the Press Complaints Commission, says the new regulator, Ipso, has become more and more compliant with the Leveson requirements. He says the media is facing a series of challenges. He does not think a new Leveson inquiry would address these problems. A new inquiry would be "an analogue inquiry in a digital age". And it would be seen as a fresh attempt to muzzle the press, he says. Lord Grade of Yarmouth, a former chairman of both the BBC and ITV, is speaking in the Lords debate now. He says the call for a Leveson phase two inquiry takes no account of how much better Ipso (the Independent Press Standards Organisation) is as a regulator than the Press Complaints Commission, the body it replaced. He says there would be no public interest in having a new inquiry. Lord Kerslake, the crossbencher and former head of the civil service, also spoke in favour of a fresh inquiry into press conduct in the House of Lords debate. Kerslake said he was influence by what he learnt when chairing an inquiry into the Manchester Arena terror attack (pdf). Kerslake said most of the participants who commented on their experiences of the media in the aftermath of the attack were negative. People talked about being hounded and bombarded, and having to force their way through scrums of reporters at hospitals who wouldn't take no for an answer. Specific mention was made of photos being sneakily taken through the glass windows at the stadium when the families were being given the news of their bereavement. Several people told of the physical presence of crews outside their homes. One mentioned the forceful attempt by a reporter to gain entrance through their front door by ramming a foot in the door. There were at least two examples of impersonation. Kerslake said some families spoke in praise of sympathetic reporting by the Manchester Evening News and other local papers. But overall the panel was shocked and dismayed by these accounts. To have experienced such intrusive and overbearing behaviour at a time of such enormous vulnerability seemed to us to be completely unacceptable. By any measure these actions fell well below the standards set out in the editors' code. In the Lords debate Lord Prescott, the Labour former deputy prime minister, said he had to go to court to establish that his phone was hacked. Prescott said that, since then, new evidence had come to light about the Sunday Times using a private investigator to hack bank accounts. Everybody now tells me, things have changed, you don't have to worry, we can now just get on with the business and not have a second inquiry. But then comes along the Sunday Times, Mr Witherow, the editor, who in fact now we know - the announcement is only quite recent, and court cases are going on - that a man called John Ford was hired to commit criminal acts against individuals, including me and including the prime minister, at that time Gordon Brown. It is quite clear by his statements, his bank accounts, his personal effects, the solicitors were all hacked and intervened in criminal acts by this Mr John Ford who's made it absolutely clear everywhere he was employed by Mr Witherow. Now, of course you might play around with the word "employed", but he was paying him for 20 years. He might have been a separate investigator, but he was committing criminal acts, breaching the human rights of everyone involved. Prescott claimed that the Sunday Times had denied these claims when asked about them at the Leveson inquiry. He went on: Hello Mr Witherow, you appear to be a liar. I know there are strong words here, but you didn't tell the truth, and you did pay the money and you did commit criminal acts against people, breaching their human rights. That surely, in any democracy, is wrong. Prescott was echoing an allegation against Witherow made by Brown when the new Ford allegations came out in March and Brown called for a police investigation. At the time the Sunday Times said these matters had been dealt with in the Leveson inquiry in 2012 and that it had nothing further to add. Scully says the petitioners are worried that, if the new panel members only join for phase two of the Grenfell Tower inquiry, they might not be able to reach conclusions because they were not involved for part one. He also says some petitioners think the policy inquiry will be the most important one. In Westminster Hall, the mini chamber set aside for general debates, MPs have just started debating the Grenfell Tower inquiry. The debate was triggered by this e-petition urging Theresa May to appoint additional panel members to the inquiry "to ensure those affected have confidence in and are willing to fully participate in the inquiry". The petition has received 156,660 signatories. The Conservative MP Paul Scully, who represents Sutton and Cheam and who is a Conservative party vice chair for London, says Theresa May's announcement on Friday that extra panel members would be appointed was welcome. But he says the minister will have to clarify whether only two extra panel members are being appointed, or whether there could be more. You can watch the hearing here. In the Lords peers have just started debating amendment 62A to the data protection bill, the one that would effectively order a Leveson phase two inquiry to go ahead. It was moved by Lady Hollins, a crossbencher. Earl Attlee, a Conservative peer and grandson of the great postwar Labour prime minister is speaking now and he says he will be backing the amendment if it gets put to a vote. Jeremy Hunt, the health secretary, is winding up. He says some people will wonder why a Conservative government is so keen to mark the legacy of a Labour cabinet minister. But those how knew Jowell will know the answer. It is because she had an incredible gift for bringing people together. He says she achieved this with the Olympics. And she did it again when, in her last few months, she persuaded the government to tear up its brain cancer strategy and start again. The government is doing that, he says. It is another example of the "Tessa magic". And that's it. The tributes to Jowell are over. Labour's Liam Byrne says Jowell was one of the greatest entrepreneurs we have seen in public life for decades. She was interested in ideas, but she wanted to turn them into achievements. She had one of the best political sat navs in the business, he says. She thought, if you hit a problem, you had to find a way around it, he says. He says he was told there are two sorts of politicians; those who divide and those who unite. Bringing the Olympics to London she brought the world together. He says people on the Labour benches often wonder how change happens; Jowell showed them how, he says. Labour's Seema Malhotra says Jowell was "funny, kind, strong, warm, generous and brilliant". She was particularly helpful to people like Malhotra when they first became MPs. Labour's Pat McFadden says there were many people who found Tessa Jowell was there for them when they were at a low ebb. He says, at a time when there is so much that divides the country, we should remember that Jowell represented the ***opposite***. Labour's Mary Creagh says, in an era of fast media and fast food and fast politics, Tessa Jowell was a slow politician. She means that in the best possible sense, Creagh says. Every word was measured for its kindness. Labour's Barry Sheerman says Jowell was one of those special MPs who could lighten spirits. Mo Mowlam was one, Jowell was another. She brought joy into the Commons, he says. Picking up on Cooper's story (see 4.06pm), Labour's Caroline Flint says: "Once a public health minister, always a public health minister." (Flint was a public health minister too.) Dame Margaret Hodge, the Labour MP, says Jowell was a feminist, but she was also feminine. She was always a good source of style advice, and her home was filled with flowers. Labour's Yvette Cooper says Jowell was the mother of Sure Start. She did some amazing things, Cooper says. She says, when people talk about Jowell and the Olympics, they think of her determination to ensure they happened. But Cooper says she remembers a briefing where Jowell spoke about ensure there were plenty of condoms available because she knew that, after the Games, all these super-fit athletes would be wanting to have sex. She says that was typical of Jowell - very down-to-earth, and practical. The Labour MP Sarah Jones, who secured a debate on cancer treatment in Jowell's honour last month, says that as a friend of Jowell's she got to recognise the velvet and the steel. She says when the debate was held last month Jowell insisted it was not about her. So, in that spirit, Jones says she wants to welcome the new funding announced for brain cancer research. The Lib Dem MP Alistair Carmichael says Tessa Jowell was not just kind and generous to fellow MPs; she was like that with all staff in the House of Commons, and with civil servants, he says. Carmichael says Jowell was brought up and educated in the north east of Scotland. She studied at the University of Aberdeen. Aberdeen graduates have never been over-represented in the Commons. But, as a fellow graduate, he likes to think they have made up in quality what they lack in quantity, and Jowell exemplifies that, he says. He says death is the last taboo in our society. But, thanks to Jowell's example, that taboo is weaker than it was. Helen Hayes, Jowell's success as Labour MP for Dulwich and West Norwood, says Jowell has left a legacy locally and nationally. Sure Start centres have transformed the lives of many families, she says. And Jowell was determined to ensure the Olympics helped to transform London. Her family will take consolation from the knowledge that Jowell leaves the world "a far better place than she found it," Hayes says. Harriet Harman, the former Labour deputy leader, says Jowell was the embodiment of the women's movement phrase that the personal is political. Her commitment to Sure Start came out of her experience as a mother and a step-mother. Harman says Jowell was always courteous. But she was tough and steely too, and if she felt people were letting down her constituents, she could be as tough as anyone, Harman says. She says people who knew her will be intensely proud of that fact. The SNP's Pete Wishart pays tribute to the way Tessa Jowell went around the country trying to ensure that all parts of the country backed the Olympics bid. She even managed to persuade people in Scotland who were originally sceptical, he says. Sir Hugo Swire, a Conservative, says as an MP he has learnt to tell the difference between when MPs pay tribute to a late colleague because they feel they have to, and when they do it because they feel they want to. He says in this case it is the latter. He says what was special about her was that she was unpartisan. He says, as a shadow minister, it was his job to oppose her over the Olympics bid and other matter. But she never held it against him. Jeremy Corbyn thanks Bercow for arranging the Commons tribute. He says people were devasted to hear of her death. The media coverage of Jowell's death goes far what is normal for a politician. He says he first met Jowell when he was a union organiser in the 1970s, and Jowell was a councillor. He says he campaigned in her byelection. In government she was determined to bring about Sure Start, he says. He says her pivotal moment was helping to ***win*** the Olympics for London. He says her family can be very proud of the legacy she left behind. Her children and family are obviously totally devastated but I think they can be very proud of the legacy she left behind, and I think it's wonderful we now have the Tessa Jowell Brain Cancer Research Fund. I hope we will all support that fund so that others don't suffer in the awful way that she suffered. She taught us how to live and I think she also taught us how to die. Theresa May says Jowell was defined by her devotion to public service. In parliament she would always reach out to any MP who was going through a tough time, May says. She says Jowell was always a person first, and a politician second. Jowell was someone who refused to take no for an answer. She persuaded Tony Blair, the government and the country to back the Olympic bid. May says the summer of 2012 would never have happened without Jowell. Her advocacy was so compelling because Dame Tessa was never one to take no for an answer, something I believe she put down to her Scottish roots. And she certainly refused to take no for an answer when many said London should not even bid for the 2012 Olympics and Paralympic Games. As secretary of state at the Department for Culture, Media and Sport, she persuaded Tony Blair and the Cabinet, the civil service and ultimately the whole country to get behind the bid. And that historic summer of 2012, which brought us together so powerfully as a nation, simply would not have happened without her. May says there will be an annual Tessa Jowell symposium to bring together the best research on brain cancer. May says the way Jowell approached her death was typical of her life. She inspired everyone, and her legacy will live on, she says. Theresa May has arrived in the Commons chamber where MPs are now paying tribute to Tessa Jowell, the former Labour minister who died at the weekend. May probably expected to lead the tributes herself. But John Bercow, the speaker, goes first. He describes Jowell as the "embodiment of empathy, a stellar progressive changemaker and a well of practical compassion without rivalry". The embodiment of empathy, a stellar progressive changemaker and a well of practical compassion without rival: Tessa Jowell was the best of us. I rue her tragic and untimely passing which leaves all of us in this place - and countless others beyond it - infinitely and permanently poorer. May Tessa rest in peace. In the House of Lords peers have just started debating the data protection bill, and specifically the amendments passed in the Commons. At some point we are expecting a vote on an amendment calling for a new Leveson-style inquiry into the press - seen as the Leveson phase two inquiry that was originally promised by David Cameron's government but dropped by Theresa May's government. Sir Jeremy Heywood, cabinet secretary and head of the civil service, has posted a link to the full text of today's speech on security from MI5 boss Andrew Parker. The Labour frontbencher Preet Gill has "clarified" what she meant when she posted a tweet saying she backed a "people's vote" on the final Brexit deal. (See 1.35pm.) She is using "clarify" in its political sense where a more appropriate word might be - "retract". A leader Conservative Brexiter, the MEP Daniel Hannan, has said that if MPs vote to keep the UK in the customs union, he would back a second Brexit referendum or a general election, to allow the public to have the final say. (See 1.16pm.) Generally Brexiters oppose a second referendum, and pressure for one is coming almost entirely from the remain camp, but Hannan's words could be a sign that this may be starting to change. David Miliband, the Labour former foreign secretary, has said Jeremy Corbyn will be the "midwife of hard Brexit" unless Labour backs staying in the single market. (See 9.10am.) He was speaking before he joined Nick Clegg, the Lib Dem former deputy prime minister, and Nicky Morgan, the Conservative former education secretary, at an event where they urged MPs to back staying in the single market and the customs union after Brexit. At the event Morgan revealed that she will give evidence in a court case in June after she received an alleged death threat over her position on Brexit. As Sky's Faisal Islam reports, Miliband was also fiercely critical of the government. Jeremy Hunt, the health secretary, has told Boris Johnson to keep his disagreements over Brexit private, warning that open expressions of dissent could mean a worse deal for the UK. Tessa Jowell's family have hailed a government decision to double funding for brain cancer research and roll out better diagnostic tests to all NHS hospitals in tribute to the former Labour cabinet minister, saying they hoped it could help other people survive the illness. The Russian government is the "chief protagonist" in a campaign aimed at undermining western democracies, the head of the UK intelligence agency MI5, Andrew Parker, has said. Nicola Sturgeon has been urged to allow all Scottish prison inmates to vote in the country's elections by a majority of MSPs on Holyrood's equalities committee. The new president of the Board of Deputies of British Jews has demanded the expulsion of Ken Livingstone and Jackie Walker from the Labour party by the end of July. The High Court in Belfast has ruled that a senior civil servant had no power to approve a huge new incinerator project in a ruling that could hinder the ability of officials to administer government in Northern Ireland in the absence of a power-sharing executive. Sam McBride, political editor of the Belfast News Letter, has more in a Twitter thread starting here. One of the country's top property developers has described the UK's system of funding social housing as "nuts" and called for higher taxes to speed up building. Nicola Sturgeon, Scotland's first minister, has said that the cabinet argument about post-Brexit customs models is absurd. Speaking News UK's Scotland Means Business event in London, she said: I deeply regret the UK's decision to leave the EU and I believe the absurdity - and I believe that is the appropriate word - of the ongoing UK cabinet discussions and disputes over the post-Brexit customs arrangements strengthens one of the basic arguments that the Scottish government together with many businesses has been making. That argument is that in our view the approach if the UK is determined to leave the EU is to remain within the single market and within a customs union. It is the obvious democratic compromise in a UK where 48% of voters and indeed two out of the four nations in the UK chose to remain in the EU. It is also the least damaging solution economically. In the comments this morning Fishgirl23 suggested we should allow readers to post tributes to Tessa Jowell on a special page. Good idea. And that's what we're doing. You can post them on the form here. While we're on the subject of a second referendum, PoliticsHome has revealed that Preet Gill, a shadow international development minister, backed a second Brexit referendum in a tweet - only to ***delete*** it when PoliticsHome publicised what she said. Labour does not back a second referendum, and Owen Smith got sacked from the shadow cabinet for proposing one. These are from PoliticsHome's Kevin Schofield. In November last year the Guardian revealed that Diane Abbott, the shadow home secretary, had written to two constituents saying she favoured giving the public a vote on the final Brexit deal, although Abbott subsequently claimed that backed party policy and that her letters had just been poorly worded. On the BBC's Daily Politics Daniel Hannan, the Conservative MEP and one of the leading leave campaigners in the EU referendum, said that if MPs voted to keep the UK in the customs union, he would back a second Brexit referendum or a general election, to allow the public to have the final say. He told the programme. Ultimately, if parliament insists on staying in the customs union, then we are plainly worse off than we are now - leaving the EU, but staying in the customs union, in other words putting Brussels in charge of 100% of our trade policy, with 0% input. That would be worse than we are now. In that situation, I think you would need to have a new mandate, either in the form of a general election or another referendum. This is significant because, until now, almost all the pressure for a second referendum has come from people who were in the remain camp at the referendum. Last week, in an article for ConservativeHome, Hannan admitted that Brexit was not working out quite as he expected - although he subsequently claimed that reports of what he had said glossed over who he thought was to blame. Here are the main points from the Number 10 lobby briefing. Theresa May hopes to speak in the Commons this afternoon in a session being set aside for tributes to Tessa Jowell, the prime minister' spokesman said. The spokesman declined to endorse the language used by Jeremy Hunt, the health secretary, to implicitly criticise Boris Johnson, the foreign secretary, for describing one of the government's post-Brexit customs options as "crazy". On the Today programme this morning Hunt said: "I do think that it's important that we have these debates in private, not just because of collective responsibility - which is what democracy depends on - but also because this is a negotiation." Asked if the prime minister agreed with Hunt's words, the prime minister's spokesman said Hunt had said it was important for the government to work together as a team, but - in line with the approach he took last week - he declined to endorse the specifics of what Hunt said. The spokesman refused to say whether Theresa May had a preference between the "customs partnership" proposal and the "maximum facilitation" proposal. It has been widely reported that the partnership model is the one she likes best, but Downing Street has never confirmed this. The spokesman said there was no timeframe for when the two cabinet working groups set up to look at the two customs options are due to present their findings. The spokesman said there were "no plans" to extend the Brexit transition. Asked about this, the spokesman said: The implementation period, both ourselves and the European Union are clear, ends in December 2020. There are no plans for an extension to that. The government has repeatedly ruled out extending the transition, even though many commentators think an extension will prove necessary because new customs arrangements are very unlikely to be ready in time. But "no plans" is not the same as a denial, and this could be a hint that No 10 is starting to finesse its language ahead of an eventual climbdown. (I haven't heard Downing Street use "no plans" in this context before, but I don't attend all the briefings and so I may have missed it. But in the past the spokesman has just said the transition will end in December 2020, as he did last week.) The question was prompted by Damian Green, the former first secretary of state, telling the Westminster Hour last night that he thought an extension - or a transition period after the transition, as he put it - would prove necessary. Michael Gove, the environment secretary, said yesterday that he was supposed to extending the transition - although people forget that, on the subject of farming subsidies, Gove wants the transition to last potentially up to 2024. The spokesman was unable to explain what Theresa May meant when she asked for the "help" of the public in delivering Brexit in a Sunday Times article yesterday (paywall). In her article May said: The path I am setting out is the path to deliver the Brexit people voted for. Of course, the details are incredibly complex and, as in any negotiation, there will have to be compromises. But if we stick to the task we will seize this once-in-a-generation opportunity to build a stronger, fairer Britain that is respected around the world and confident and united at home. I will need your help and support to get there. And in return, my pledge to you is simple: I will not let you down. Asked what she meant by saying she needed people's "help", the spokesman just said that she wrote the article to set out her commitment to delivering Brexit. He brushed aside a suggestion that she could have been asking people to send it viable ideas for a post-Brexit customs model. But he did dismiss one idea. Nigel Farage, the former Ukip leader, said May might be hinting at the need for another election in her article. Asked whether May was floating the need for another election, the spokesman said: I don't believe that's the case. My colleague Lisa O'Carroll has been tweeting from the Miliband/Clegg/Morgan event in Essex. Here are some of her posts. Tilda Rice deserve some sort of award for best product placement at a political event. At least Labour's Tom Hamilton finds it funny. While the Times's Patrick Kidd reckons the notional leader of the remain-voting liberal metropolitan elite doesn't know his classics... We did, however, find out at the lobby briefing that Theresa May has a series of meetings in the diary today with Conservative MPs - but only because a colleague raised the topic in a question. The BBC's Norman Smith has more details. I'm just back from the Number 10 lobby briefing and, on Brexit at least, it was a Groundhog Day experience. The prime minister's spokesman succeeded triumphantly at managing to avoid saying anything much new. For what it's worth, I'll post a summary shortly. Labour's national executive committee is interviewing candidates today for the Lewisham East by-election. However, local activists who are angry about the speed of the shortlisting process met overnight to draw up their own final shortlist - to try and steal a march on the NEC's decision. The constituency Labour party chair Ian McKenzie told the Guardian that local party members wanted there to be a shortlist of four candidates - former Bexley Labour councillor Abena Appong-Asare, Lewisham deputy mayor Janet Daby, and councillors Brenda Dacres, and Rachel Onikosi. All four candidates are understood to have interviews with the NEC today. The Labour leadership and the left-wing grassroots group Momentum were widely reported to have preferred three different candidates - Claudia Webbe, Sakina Sheikh and Phyll Opoku-Gyimah, who unexpectedly dropped out of the race on Sunday. Sheikh and Webbe are also being interviewed by the NEC panel today. Left-wing figures in the party are also thought to be cautious about selecting Webbe, the former chair of Operation Trident, because she is a member of Labour's NEC. Were she to resign from the finely balanced committee, her place would go to a more Corbyn-sceptic replacement, Johanna Baxter. The EU is threatening to exclude the UK from the military aspects of Galileo, its new satellite navigation system, after Brexit. In an interview with the Today programme this morning Sam Gyimah, the science minister, accused the EU of "playing hard ball" and said that, if the UK were excluded, EU countries could end up paying billions more for it. He said: The EU is playing hard ball with us. We have helped to develop the Galileo system. We want to be part of the secure elements of the system and we want UK industry to be able to bid for contracts on a fair basis. It is only on those terms that it makes sense for the UK to be involved in the project. This is a project that is of mutual benefit to the UK and the EU and if the UK is not part of the programme, it would cost EU members billions of pounds more to develop. Gyimah also confirmed that, if the UK were excluded from the programme for military purposes, it would consider developing its own alternative. Because of the implications for us in terms of defence and our national security, were we not to participate in Galileo we would look at alternative options and we will leave nothing off the table. That includes developing a British satellite navigation system. In a Times story (paywall) at the weekend Oliver Moody explained why Galileo is so important to the UK. Here's an extract. Since January ministers have been fighting to prevent the UK from being frozen out of the heavily encrypted Public Regulated Service (PRS) arm of the EU's Galileo project, expected to be the world's most secure and precise global positioning technology... Cracks are already appearing in the "M-code", the [American] GPS system Britain's armed forces depend on at present, as Russia, China and other ***strategic*** rivals develop increasingly sophisticated electronic warfare devices. Russia is thought to have been jamming American drones over Syria since March. In 2014 a similar technology is thought to have grounded UN surveillance drones in Ukraine. Some experts believe GPS spoofing was used to bring down a US drone in Iranian airspace in 2011... Unlike the GPS M-code, the EU's PRS system is said to be highly resistant to interference. "PRS is on two frequencies, has a wider band signal and the signals are encrypted," John Pottle,of the Royal Institute of Navigation, said. "You need a much more sophisticated jammer to deny positioning and it ensures that spoofing is practically impossible." Britain faces two headaches. One is winning permission to use the PRS signal at all, the other is getting a seat at the table to determine how it is used in future. Without an active role in the talks over PRS, the UK would struggle to make it compatible with its military hardware and might be kept in the dark over the technology's vulnerabilities. In a UK paper on the security partnership with the EU after Brexit published last week (pdf), the government said: "PRS access limited only to user status would not meet UK ***strategic*** security requirements and would not provide the basis for continued UK collaboration in Galileo." I'm off to the lobby briefing now. I will post again after 11.30am. In his LBC phone-in Jacob Rees-Mogg, the Conservative Brexiter, claimed that Brexit offered particularly good opportunities for young people. He said: I think in terms of the Brexit debate that the great opportunities for everybody, but particularly the younger generation, are in leaving and looking to the broader horizon of the rest of the world rather than the narrow closed protectionist European field. For younger people, leaving is the best opportunity that they could have. Of course, younger people don't seem to see it quite that way. As this YouGov analysis of how people voted in the EU referendum shows, under-50s voted remain, and under-25s did so by a massive margin. On the Today programme Theresa Villiers, the leave-voting former Northern Ireland secretary, accused David Miliband of wanting to frustrate Brexit. She said: He wants to frustrate the result of the referendum and stop it being implemented because he wants us to say stay in a Norway-style arrangement that leaves us accepting unfettered and unreformed free movement, all the rules of the single market without the chance to vote on them, and that is just not respecting the result of the referendum. She also said that the amendment to the EU withdrawal bill passed by the Lords, and likely to be backed by pro-Europeans in the Commons, intended to strengthen parliament's hand when it gets to vote on the final withdrawal deal could be "Brexit-wrecking amendment". She explained: Attempts by MPs to constrain the government's negotiating discretion is potentially a Brexit-wrecking amendment, because it cuts the prime minister off at the knees. Reaction to David Miliband's interview is highly polarised. The Labour MP Wes Streeting, who is in the centrist, pro-European camp in the party, liked it. As did the former Labour Europe minister Denis MacShane. But Steve Howell, who was Jeremy Corbyn's deputy director of communications until the general election, says it will have been counter-productive. And the commentator Ian Birrell agrees. In his Today interview David Miliband, who confirmed that he was still a member of the Labour party, dismissed claims that, if MPs were to vote for the UK staying in the EEA, that would undermine Theresa May's position in the Brexit negotiations. The ***opposite*** was true, he claimed. He said: There will be an enormous sigh of relief in Europe if the prime minister goes to the negotiations and says there are 400 plus members of parliament who believe [in a soft Brexit]... They don't want a weak Britain, because they think that will weaken Europe. They know there's trade both ways. And, at the moment, they are sitting there, strumming their fingers on the table, waiting for the government to come with a negotiating position. Miliband also said it was "significant" that Erna Soldberg, the Norwegian prime minister, has told the Financial Times in an interview (paywall) that Norway would be open to the UK remaining in the EEA after Brexit - joining Norway, Iceland and Lichtenstein as the only countries in the EEA but not in the EU. Soldberg told the FT: I think we will cope very well if the Brits come in. It will give bargaining power on our side too. And it would ease Norway's access to the UK. In the past Norway has been quite negative about the prospect of the UK staying in the EEA after Brexit because of its disruptive impact. Explaining the potential problem, the FT quotes the unnamed boss of a Norwegian company as saying: "We would go from being a big fish in a small pond to a small fish in still a pretty small pond." In the Lords vote last week Labour peers were ordered to abstain on the motion saying the UK should remain in the EEA after Brexit. For reference, this is what Jeremy Corbyn's spokesman said about the party's stance on this at a briefing on Wednesday last week. This is from the Telegraph's Jack Maidment. There has been quite a lot of chatter at Westminster in recent months about the possibility of a new centrist party being set up. The consensus is that it will probably never happen - first past the post has a crippling impact on new entrants into the political party marketplace (in commerce, the competition authorities would probably ban it as a restraint on trade) - but this morning we are going to get a glimpse of what such a creature might look like when David Miliband, the Labour former foreign secretary, Nick Clegg, the Lib Dem former deputy prime minister, and Nicky Morgan, the Conservative former education secretary, take the stage together to urge MPs to reject a hard Brexit. The involvement of Miliband is particularly intriguing because, in a classic kite-flying operation, some journalists have been talking up the prospect of Miliband returning from America, where he runs an aid organisation, to take charge of this putative new venture. Judging by the reaction I read, the kite swiftly crashed into the ground, but that does not seem to have deterred Miliband and this morning he was on the Today programme with a warning for Jeremy Corbyn. If Labour does not back staying in the European Economic Area (ie, the "Norway option" - staying in the single market), Corbyn will be "the midwife of hard Brexit", he said. Miliband was so keen on the phrase he repeated it. He told the programme: [Corbyn] has also made clear that he doesn't believe that we should remain in the single market. And I think there is a warning for Jeremy Corbyn here. Because Jeremy Corbyn has got to be very careful not to be the midwife of hard Brexit. Remember, last week in the House of Lords, a very significant amendment was passed. It was passed with cross-party support, 80 Labour peers supported it, and that was that Britain should remain a member of the European Economic Area, in other words keeping the negotiated single market links that countries like Norway have. Now, the Labour position was not to support that. And the warning for Jeremy Corbyn, he will be the midwife of a hard Brexit that threatens the living standards of the very people that he says he wants to stand up to represent. I will post more from his interview, and reaction, shortly. Here is the agenda for the day. 9am: Jacob Rees-Mogg, the Conservative backbenchers, hosts his LBC phone-in. 10.30am: David Miliband, Nick Clegg, and Nicky Morgan, the Conservative former education secretary, hold a joint Open Reason event at the Tilda Rice plant in Essex urging MPs to reject a hard Brexit. 11am: Downing Street lobby briefing 2.30pm: Damian Hinds, the education secretary, takes questions in the Commons. After 3pm: Peers debate the date protection bill. As Jim Waterson reports, they are expected to defy the Commons and vote for what would effectively phase two of the Leveson inquiry into the press to go ahead. And at some point today in Brussels Michel Barnier, the EU's chief Brexit negotiator, will give a speech on security policy after Brexit. As usual, I will be covering breaking political news as it happens, as well as bringing you the best reaction, comment and analysis from the web. I plan to post a summary at lunchtime and another in the afternoon. You can read all today's Guardian politics stories here. Here is the Politico Europe round-up of this morning's political news from Jack Blanchard. And here is the PoliticsHome list of today' top 10 must reads. If you want to follow me or contact me on Twitter, I'm on @AndrewSparrow. I try to monitor the comments BTL but normally I find it impossible to read them all. If you have a direct question, do include "Andrew" in it somewhere and I'm more likely to find it. I do try to answer direct questions, although sometimes I miss them or don't have time. If you want to attract my attention quickly, it is probably better to use Twitter.52242falseLord Falconer speaking in the Lords debate on a new Leveson inquiryMichel Barnier with and Ekaterina Zaharieva, the Bulgarian foreign minister, at the general affairs council in Brussels.Lord KerslakeJohn PrescottNicola SturgeonDaniel Hannan10 Downing StreetSir Nick Clegg (left), Nicky Morgan and David Miliband speaking at a crossparty event on Brexit at Tilda Rice Mill in Rainham, Essex.Clegg, Morgan and Miliband at the Tilda Rice Mill event.How people voted in EU referendumTheresa Villiers during the EU referendum campaign in 2016.

**Load-Date:** August 3, 2018

**End of Document**



[***Australia legalises same-sex marriage - politics live; MPs agree to legalise same-sex marriage after marathon campaign. Follow here for all the day's events***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5R44-XW11-JCJY-G4WP-00000-00&context=1516831)

The Guardian(London)

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**Body**

block-time published-time 8.30am GMT

OK, we are just about done for the day (and the year) but here is what your parliamentary chamber looked like, Australia.

The ayes. Photograph: Mike Bowers for the Guardian The nos. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 8.39am GMT

block-time published-time 8.23am GMT

Just need to correct an earlier post:

I said Scott Morrison voted yes but I was wrong - I am now being told he abstained.

My apologies.

So the abstain list (at this stage) includes:

Tony Abbott

Kevin Andrews

Scott Morrison

Barnaby Joyce.

I don't think I saw Andrew Hastie in the chamber either but am happy to be corrected.

block-time updated-timeUpdated at 8.40am GMT

block-time published-time 8.06am GMT

A few more photos from the moment history was made, because Mike Bowers is amazing:

Cathy McGowan, Adam Bandt and Andrew Wilkie celebrate. Photograph: Mike Bowers for the Guardian Celebrations after the bill to amend the marriage act passes through the House of Representatives. Photograph: Mike Bowers for the Guardian Penny Wong celebrates. Photograph: Mike Bowers for the Guardian As the bill passed... Photograph: Mike Bowers for the Guardian And the party goes on. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 8.14am GMT

block-time published-time 7.59am GMT

enltrAustralia, you had our backs, thankyou @[*MagdaSzubanski#marriageequality@AmyRemeikis@Paul\_Karppic.twitter.com*](mailto:MagdaSzubanski#marriageequality@AmyRemeikis@Paul_Karppic.twitter.com)/O26Ef3Arha

- Katharine Murphy (@murpharoo) December 7, 2017

enltrWe got it done, thankyou, says Ian Thorpe. Parliament did what it said what it would do, I'm surprised, he says [*#marriageequality@AmyRemeikis@Paul\_Karppic.twitter.com*](mailto:#marriageequality@AmyRemeikis@Paul_Karppic.twitter.com)/v22BFuOYJR

- Katharine Murphy (@murpharoo) December 7, 2017

block-time published-time 7.54am GMT

Louise Pratt:

I am incredibly proud today it to be part of the Australian parliament and to have, to have been part of delivering marriage equality in this nation. I have been an out MP in this country since 2001 and we have had many struggles inside Labor party.

There is my girlfriend, come over here, come here, honey.

I could not be prouder today. We have had to campaign for all of our life, for all of our rights in our relationship and finally that task is complete and we could not be happier, and I just want to say thank you to all of my comrades in the Labor party, particularly Rainbow Labor, who have given their heart and soul to make this happen. Absolutely. Thank you, Australia.

And they fall out of shot hugging. It's a wonderful image to end the press conference on.

block-time updated-timeUpdated at 8.01am GMT

block-time published-time 7.52am GMT

Rodney Croome:

In the course of all those years, I met many couples were no longer with us and who would say to me, they were grabbing by the arm and they would say please make this happen before it is too late. But, for them, it is too late.

This day is for them. We heard the word gift used and, for me, this reform is a gift that we're all here give to the next generation, a gift of the quality and inclusion, for them to build a better Australia from.

block-time updated-timeUpdated at 7.54am GMT

block-time published-time 7.49am GMT

Ian Thorpe:

Like the other people who have spoken today, today really is a momentous day for Australia and today I am proud to call myself an Australian, as much as I have any other day of my life.

I realise what this means for young LGBTQI people, right across the country, for them to know that the person that they love, the way that they feel, is equal to that of anyone else and the change that that will mean for future generations is significant.

So I would like to thank the parliament today, I would like to thank both sides of politics for really getting on with the day and doing what they said they would do. I am surprised, frankly.

But it was amazing to see and it shows what can happen here, and that is what I am pleased to know, but I am really also very thankful for our straight brothers and sisters, who quite literally, without them and their voting for us, this would never have happened.

And it means that we have created an Australia that is more equitable, more fair and more just, and it is the kind of place that more Australians want to see, so thank you everyone for what they have contributed to this and we got it done.

block-time updated-timeUpdated at 7.52am GMT

block-time published-time 7.46am GMT

Magda Szubanski :

When I watched all of those people move to the yes side of the House, I thought Canberra was going to tip over. And for someone who grew up feeling on the brink of suicide, seriously, as so many of us have because we have felt unwanted, unliked, we fell below, to feel so loved now and to see that Parliament nearly tip over in support for us was an amazing feeling. And it was the people of Australia and all of us, I am sure, feel incredibly indebted and grateful to you that, when it was put to you, you had our backs. Thank you forever for that. Thank you so much. Thank you.

block-time updated-timeUpdated at 8.05am GMT

block-time published-time 7.44am GMT

enltrThe marriage equality group of MPs, declaring victory in the Mural Hall @[*AmyRemeikis@Paul\_Karp#marriageequalitypic.twitter.com*](mailto:AmyRemeikis@Paul_Karp#marriageequalitypic.twitter.com)/llnOi5IJzb

- Katharine Murphy (@murpharoo) December 7, 2017

block-time published-time 7.43am GMT

Tim Wilson:

Today, this is a strong message to every kid that is questioning their sexual orientation or gender identity, that you do not need to be afraid, that when you look to the nation's parliament, to our sporting heroes, and to the values that underpin this country, that you can be what you see. You see a country that is forward-looking, modern and embracing the idea that everybody has a place at our nation's table.

Terri Butler :

I am proud today to be an Australian, I am proud today that we have, as a parliament, acted to remove discrimination, and they certainly look forward to many, many weddings to come.

Janet Rice:

I am overwhelmed. It has been such a long time coming, from 2004 and well before that, the campaigning that has been done and what is so special about having achieved this today has been achieving it with the support of people from right across the political spectrum, with the support of people from right across Australia.

block-time updated-timeUpdated at 7.49am GMT

block-time published-time 7.39am GMT

Dean Smith, who just made history as one of only 30 (I think) private members' bills to pass the Australian parliament:

People can be proud that over the last few weeks they have seen the best of their parliament, the best of their parliamentarians.

He dedicates the day to young LGBTIQ Australians.

You are OK, it will all be OK and this is a great country to grow up and be an LGBTI Australian.

block-time updated-timeUpdated at 7.49am GMT

block-time published-time 7.36am GMT

Alex Greenwich of the Equality Campaign:

We came, we saw and love finally conquered... Marriage equality is finally the law of the land.

block-time updated-timeUpdated at 7.49am GMT

block-time published-time 7.33am GMT

From Mike Bowers to you:

The final division. Photograph: Mike Bowers for the Guardian Celebrations after the bill to amend the marriage act passed. Photograph: Mike Bowers for the Guardian As the public gallery sang... Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 7.44am GMT

block-time published-time 7.27am GMT

Reforms to commence from Saturday.

George Brandis has sent out a statement.

He says that as of Saturday December 9 same-sex couples will be able "to lodge a notice of intended marriage to commence the one-month minimum notice period required before the solemnisation of marriages under the Marriage Act".

That means the first marriages under this change can happen just a month later.

Oh, and as for those religious freedoms?

"Under the new laws, ministers of religion and religious marriage celebrants will be able to act in accordance with their religious beliefs about marriage.

"Religious bodies will be able to act in accordance with their doctrines, tenets and beliefs in providing facilities goods and services in connection with marriage."

block-time updated-timeUpdated at 7.50am GMT

block-time published-time 7.22am GMT

Barnaby Joyce abstained.

block-time updated-timeUpdated at 7.45am GMT

block-time published-time 7.22am GMT

Peter Dutton and Julie Bishop voted yes, for those who were asking.

\*correction: an earlier version of this post said Scott Morrison voted yes. He abstained

block-time updated-timeUpdated at 8.22am GMT

block-time published-time 7.20am GMT

I'm being told Andrew Broad was one of the voices who called for the division.

But it led to this moment:

enltrHere's the moment the #MarriageEquality bill passed the Australian Parliament #auspolpic.twitter.com/MUoBTgBIhk

- Political Alert (@political\_alert) December 7, 2017

block-time published-time 7.16am GMT

The Liberal MP Warren Entsch lifts up Labor MP Linda Burney as they celebrate the passing of the marriage amendment bill. Photograph: Lukas Coch/AAP

block-time updated-timeUpdated at 7.45am GMT

block-time published-time 7.13am GMT

Labor staff formed a guard of honour behind the Speaker's chair and gave an ovation to all the MPs leaving the chamber.

block-time published-time 7.13am GMT

Christine Forster said she will be getting a few bottles of champagne popped and few glasses drunk.

She then remembers that her brother Tony Abbott offered to buy the drinks. She says she'll take him up on that offer.

block-time updated-timeUpdated at 7.46am GMT

block-time published-time 7.12am GMT

We are still working on the list of people who abstained.

We couldn't see Tony Abbott or Kevin Andrews in the chamber.

block-time published-time 7.08am GMT

I can report the earth has continued to turn.

There is a feeling of jubilation in this building. But I do have to acknowledge the mixed emotions that come with this. It has been a very long process and a very painful process for a lot of people. And this vote, while a long time coming, is not going to make all of those knots suddenly release, or all the pain disappear.

But it's a start.

block-time updated-timeUpdated at 7.14am GMT

block-time published-time 7.05am GMT

Outside in the mural hall, the celebrations are on-going.

block-time updated-timeUpdated at 7.07am GMT

block-time published-time 7.04am GMT

Australia's parliamentarians are applauding the people in the gallery.

Tony Smith moves the parliament on to other business but, really, who cares?

block-time updated-timeUpdated at 7.05am GMT

block-time published-time 7.02am GMT

OK. I'm crying.

The gallery is singing "We are Australian".

The chamber pauses in its applause to watch and sing with them.

block-time updated-timeUpdated at 7.03am GMT

block-time published-time 6.59am GMT

MARRIAGE EQUALITY PASSES

"That's it" is the final word from the floor.

And the chamber erupts. The gallery erupts.

I'm not crying, you're crying.

block-time published-time 6.58am GMT

Tony Smith is just letting the public gallery know that at the end of the division there are a couple of procedures to be done [so hold off on the celebrations].

For all my grousing over the division, it is wonderful to see the parliament divide. The no side is almost empty. Bob Katter is there, so is Russell Broadbent, David Littleproud and Keith Pitt.

block-time updated-timeUpdated at 6.58am GMT

block-time published-time 6.56am GMT

And because TWO voices said a division was required, the House divides.

Because, sure. Let's drag out this moment for as long as possible. It is not as if we have waited decades, put people through a survey, a terrible debate, then another terrible debate on a bunch of stuff that had nothing to do with marriage equality to get to this point. We definitely need to spend these next eight minutes making the parliament divide for something that Australia was already forced to decide.

block-time updated-timeUpdated at 6.57am GMT

block-time published-time 6.54am GMT

Adam Bandt agrees the bill should be read a third time.

"Love has won and it is time to pop the bubbly."

He says he is going to keep it short because it is time for the bells to ring and the public gallery is doing all it can to not yell DUH.

block-time updated-timeUpdated at 6.54am GMT

block-time published-time 6.52am GMT

"When this bill is passed we should declare we are no longer a nation who voted no or yes, we are simply Australians all," Bill Shorten says. "Equality is never a gift to be given."

block-time updated-timeUpdated at 6.53am GMT

block-time published-time 6.51am GMT

Malcolm Turnbull is reminded to formally move the bill a third time. He does.

Bill Shorten :

Australia we are going to make marriage equality a reality in minutes.

block-time updated-timeUpdated at 6.53am GMT

block-time published-time 6.49am GMT

'This is Australia' - bill read for a third time.

This time the public gallery is allowed to applaud, and they do, standing up and waving rainbow flags, their hands in the air.

The chamber is also on their feet. Malcolm Turnbull is clapping. The gallery is singing.

"I am, you are, we are Australian."

Tony Smith reminds them that there is still the third reading to go.

"What a day, what a day for love, for equality for respect," says Malcolm Turnbull. "It is time for more marriages, more equality, more love."

block-time updated-timeUpdated at 6.51am GMT

block-time published-time 6.47am GMT

The question now is this bill be agreed to.

And it IS!

block-time published-time 6.47am GMT

Final amendment voted down

We are talking lunchtime on free dress levels of chatter in the chamber right now.

There is manic laughter coming from the floor.

The final pointless amendment in this pointless debate is lost.

Malcolm Turnbull spent the final division (on the yes to amendment side) telling a story that required a lot of arm-waving to Tanya Plibersek.

This was the closest of the votes but it is won with Trent Zimmerman, Trevor Evans, Tim Wilson, Warren Entsch and Julia Banks (I know I'm missing some but they are the ones I can see) and most of the crossbench on the Labor side.

Ayes: 63

Noes: 79

We are less than 30 minutes away from history, my friends.

In other news, I can no longer feel my fingers. Or my face.

block-time updated-timeUpdated at 6.52am GMT

block-time published-time 6.39am GMT

It is the last division. We have spent about 55 hours getting to this point (in the parliament these last two weeks. My math is not good enough to add up all the years we have waited for this. This is why I am a journalist and make with the words and not the numbers).

block-time updated-timeUpdated at 6.42am GMT

block-time published-time 6.37am GMT

I have a conscientious objection to hearing that Labor was not allowed a conscience vote on these amendments, which have nothing to do with the marriage equality bill, and are yet to be shown to be needed.

block-time published-time 6.36am GMT

Sarah Henderson does not receive leave. WE ARE CLOSE PEOPLE

Penny Wong blows a kiss to the gallery. Photograph: Mike Bowers for the Guardian Mwah Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 6.42am GMT

block-time published-time 6.33am GMT

Sarah Henderson seeks leave to put the question on the two amendments separately.

NO NO NO can be heard from the Guardian office. And also the chamber.

block-time published-time 6.32am GMT

Speaking of people with a lot of fondness for their cycling mates, even if he doesn't want to marry them, Kevin Andrews gives, if there really is a higher power, his last speech today before the vote.

(Not on this topic mind you. Because as I am sure you have heard me screaming from my desk, this is not the last time we will have this debate. It is not even the real debate. That is coming next year)

He says if he is proven right and religious freedoms are torn to pieces in this nation when this bill receives its royal assent, and baby Jesus just won't stop crying, he hopes we have the courage and humility to admit we were wrong.

I assume that goes both ways.

block-time published-time 6.28am GMT

Andrew Wilkie then says to all of those pushing the amendments in the name of religious freedoms and opponents of same-sex marriage:

"You have had your day."

"The time has come to give the LGBTI community freedom from religion," he says.

block-time published-time 6.27am GMT

Tim Wilson gives his final address on the debate.

And brings it back to what this debate is actually supposed to be about.

Not Jesus

Not crocodiles

Not the word G A Y

Not safe schools

Not electric guitars

Not charities being stripped of tax free status

Not boys in dresses

Not procreation

Not the fondness you feel for your cycling mates

Not any of the other frankly ridiculous arguments we have heard in this nonsensical debate.

We are removing the barrier and the boundaries which stop being enabling themselves to get married."

block-time published-time 6.21am GMT

We are coming to the end people. Tanya Plibersek makes the point that we are all going to remember where we were this vote happened.

For me, that may be running screaming through the corridors.

The member for Indi Cathy McGowan passes senator Jordan Steele-John Photograph: Mike Bowers for the Guardian The prime minister Malcolm Turnbull as the debate on amendments to the marriage amendment bill continues Photograph: Mike Bowers for the Guardian

block-time published-time 6.16am GMT

You know what the really great thing about all of this is?

It's that we get to do it all again, when the actual debate on religious freedoms occurs next year, after the Philip Ruddock review is handed down.

Isn't that just amazing? We get to do it all again. AND THEN SOME, because when it happens again, it will be for realsies, and not for the grandstanding ridiculousness it is today.

Yet another reason to await 1 January 2018 with gleeful eagerness.

block-time published-time 6.13am GMT

Craig Kelly, who has upgraded his speech performance delivery from 'interrupting you and your mate debating at the pub', to 'yelling at you from his car window for cutting him off in traffic', has a problem with all the marriage celebrants who don't want to marry same-sex couples only having 90 days to register that wish.

But, in a wonderful stroke of irony, he runs out of time to make his point.

block-time published-time 6.10am GMT

"Please excuse me, because we are a little paranoid we Christians, we have a history of being picked on, in a big way," says Bob Katter without irony or any sort of self-awareness that his contributions to this debate have done nothing but "pick on" the LGBTIQ community.

"And we get a little bit paranoid, so please excuse me for getting a little bit paranoid today."

A timeless statement from Bob Katter.

block-time updated-timeUpdated at 6.12am GMT

block-time published-time 6.08am GMT

I wish you could see Adam Bandt's face right now. He is listening to Bob Katter talk about boys being forced to wear dresses and is throwing Michelle Obama level side-eye.

block-time updated-timeUpdated at 6.12am GMT

block-time published-time 6.05am GMT

And, because this day has not had enough punishment, Bob Katter is back.

block-time updated-timeUpdated at 6.08am GMT

block-time published-time 6.04am GMT

We may have just heard Tony Abbott' s last contribution on this debate:

"We have heard contributor after contributor to these debates say that 'nothing in this bill will impinge on freedom of religion'."

And if he had just stopped there, we could move on. But, of course, he does not.

"Well, supporting this amendment is an opportunity to demonstrate the absolute fair-dinkumness (not a word) when it comes to those statements."

Sigh.

He then suggests passing this amendment, before sending the bill back to the Senate for agreement, and, in the meantime, everyone can go have a drink and then come back and "do it the right way".

I very much want a drink. But I know a faustian bargain when I see one.

Trent Zimmerman gets to his feet for the last time in this amendment debate to point out that this amendment actually extends discrimination.

Which it does.

Christopher Pyne then points out that the amendment is "based on a false premise" as the marriage equality change doesn't actually inhibit religious freedoms.

"There has never been [any suggestion] that marriage equality somehow inhibits religious freedoms of either ministers of religion or religious organisations."

You know where that is made clear? THE CONSTITUTION.

I know the parliament is obsessed with section 44 but there are other sections to that document, including section 116.

The commonwealth shall not make any law for establishing any religion, or for imposing any religious observance, or for prohibiting the free exercise of any religion, and no religious test shall be required as a qualification for any office or public trust under the commonwealth.

Or, THE SEPARATION BETWEEN CHURCH AND STATE.

block-time updated-timeUpdated at 6.07am GMT

block-time published-time 5.53am GMT

Henderson says the amendment is to make clear that religious freedoms are prevented and the marriage equality change won't alter, interfere or prevent people from practising their religion.

The second half of the amendment is to protect the civil celebrants who want to be able to object to marrying a same-sex couple, because of their beliefs, any beliefs, without the religious protections.

How many marriage celebrants out there are happy to conduct weddings outside of a church but have massive issues with marrying a same-sex couple?

We're all fine with Marriage at First Sight and Britney Spears getting married for 55 hours (never forget) but apparently we have a whole slab of marriage celebrants who have a massive problem with marrying same-sex couples?

block-time updated-timeUpdated at 5.58am GMT

block-time published-time 5.46am GMT

Final amendment moved

Sarah Henderson is on her feet, talking about this "historic day for this nation and this parliament".

She then moves on to freedom of speech and freedom of religion.

One more time for the people at the back - this has nothing to do with marriage equality.

block-time published-time 5.44am GMT

Malcolm Turnbull arrived to vote for that second part of the Andrew Broad amendment.

block-time published-time 5.43am GMT

Andrew Broad's second amendments are voted down

The MPs have trudged back into the chamber to vote this latest amendment down

Ayes: 60

Noes: 85

We now move on to the last-minute addition of Sarah Henderson's amendments, which are basically the amendments George Brandis attempted to get up in the Senate and lost.

Because none of these amendments are getting up. We already know this. We have been told this. The people moving the amendments and speaking in support of them know this. That debate is to be had once the Ruddock review is handed down. Am I just typing into an abyss? Why is this still happening?

block-time published-time 5.37am GMT

As the latest division bells are called (thankfully without a contribution from Bob Katter or anything about electric guitar wielding home invaders) question time Emma Husar is all of us.

The member for Lindsay Emma Husar and the member for Longman Susan Lamb during question time Photograph: Mike Bowers for the Guardian

Bill Shorten and Penny Wong just made a trip to the public gallery to shake hands. Everyone needs a bit of respite after some of the ridiculousness we have just heard

block-time published-time 5.32am GMT

Luke Howarth is using his time talking about an amendment that has nothing to do with marriage equality by again attacking Labor for not holding a conscience vote.

Which, again, has nothing to do with marriage equality.

Howarth says he is standing up for the 70% of Australians who said in the census they had a religion. Perhaps they received a different marriage survey form to me and everyone else I know, because none of this was on the ABS form I received.

I am also pretty sure that changing the marriage act doesn't actually change the charities act or taxation legislation.

You know what this vote, if we ever get to it, will do though? CHANGE THE DEFINITION OF MARRIAGE TO THE ONE AUSTRALIA VOTED FOR.

block-time updated-timeUpdated at 5.37am GMT

block-time published-time 5.28am GMT

His next amendments are to allow religious and faith-based organisations to be able to express their views, and not have their tax status threatened.

"I haven't seen too many people on the LGBTI community ... become great social advocates like I have the religious community."

This will be news to all of the LGBTIQ advocates and allies who have stood up for minorities, the vulnerable and just generally been a decent human FOR DECADES despite the amount of discrimination they have been subjected to. Including when homosexuality was illegal in states across the nation and police were raiding private homes to catch couples in the "illegal act" of being in love.

Warren Entsch also has no time for this.

"This is a marriage bill, this is not the time to be changing the charities act."

The public gallery applauds and are told, again, to be quiet.

block-time updated-timeUpdated at 5.32am GMT

block-time published-time 5.22am GMT

Andrew Broad is now moving his second lot of amendments.

He has moved on from electric guitars to Jesus. Parliament just became Bible class, but apparently we still need to talk about religious protections

block-time updated-timeUpdated at 5.31am GMT

block-time published-time 5.20am GMT

Andrew Broad's first amendments are voted down

There is a lot of chatter as this division occurs.

No Malcolm Turnbull for those keeping count.

Ayes: 52

Noes: 86

Bob Katter managed to work out which side of the chamber he wanted to sit on, so that's something.

Tony Smith just gave another warning to the public gallery.

"It is very important that members of parliament ... are able to make their contributions without noise coming from the public gallery, it really is, on behalf of their electorates."

To be fair, they have refrained from running from the place screaming, so I think they have shown some restraint.

block-time updated-timeUpdated at 5.23am GMT

block-time published-time 5.13am GMT

Andrew Broad is making his last ditch appeal for support for his amendment by talking about his daughter who is learning the electric guitar, and unfortunately, right now, she is not very good.

He then relates his amendment to allowing his daughter to walk into any house she wants and play her electric guitar very loudly and very badly for as long as she wants "and you wouldn't be able to do anything about it". Because that apparently, is what freedom is. (I would think that trespass, breaking and entering and public nuisance laws would probably protect you from this apparent consequence of marriage equality, but it's been a while since someone burst into my house to play the electric guitar)

"If you wouldn't give that freedom away in your own home, don't take it away from the churches and religious organisations of Australia," he says.

The division bells are called.

block-time published-time 5.07am GMT

For some reason Bob Katter is now talking about how they couldn't afford to run candidates in every electorate in the Queensland election and how he only saw one ad for the no campaign.

He wants to know where the money for that came from.

I want to know why he is still talking, so we all have questions.

block-time published-time 5.04am GMT

Oh for goodness sakes.

The "honourable" member for Kennedy may have just broken me.

" I think you have a damn hide and an inflated opinion of yourself as well. The rest of the world would agree with me.

"They took the word gay off us and now they are taking the word marriage of us."

block-time updated-timeUpdated at 5.08am GMT

block-time published-time 5.00am GMT

Bob Katter is now talking about how the marriage equality debate "makes no difference as far as I can see to anything" and then talks about the Queensland election, where he saw the primary vote for both the major parties drop to the 30s.

"You've been talking about this all year... so congratulations."

He doesn't mention that the survey was won with a yes vote of 61.6%.

"I refuse to say the word G A Y," Katter says after saying he can't understand why people in relationships would want to call those relationships marriage.

He then reads out the definition of gay, including beautiful, light, happy and ethereal. The gallery breaks into applause.

"They are proud of it. I would be embarrassed to go around calling myself all these wonderful adjectives."

I'm sure we'll hear about crocodiles any moment now but I really cannot spend any more time on his contribution. There are limits. I have found mine.

block-time updated-timeUpdated at 5.04am GMT

block-time published-time 4.55am GMT

Oh great. Bob Katter is up. This is just what this day needed.

block-time published-time 4.53am GMT

George Christensen begins his speech in support of the latest amendment that has nothing to do with the issue at hand, by criticising Labor for not having its conscience vote.

Then he turns to the public gallery.

"We have seen cheers from the gallery, cheering for the erosion of religious liberty."

The public gallery breaks into applause.

block-time updated-timeUpdated at 4.58am GMT

block-time published-time 4.50am GMT

Warren Entsch points out that there are already protections in place for religious organisations and this amendment would extend discrimination.

Mark Dreyfus makes a similar point.

block-time published-time 4.48am GMT

Barnaby Joyce just gave a very half-hearted speech in support of Andrew Broad's amendment.

Where he commented on his marital status:

"I don't come to this debate pretending to be a saint... I acknowledge that I'm currently separated, that's on the public record."

block-time updated-timeUpdated at 4.50am GMT

block-time published-time 4.44am GMT

Andrew Broad wants religious organisations to be able to keep "the vibe" of their beliefs within their own facilities.

"What you believe is your own business and, if you pay for it, you should have the final say."

Basically he wants churches and religious organisations to be able to turn down events they have objections to. So a church hall would not have to host a Safe Schools education night is the example Broad gives.

Once again, in what is becoming a timeless statement in relation to this debate: this has nothing to do with marriage equality.

The public gallery is getting antsy. They have just been asked to quiet down their conversations so the very important debate which has nothing to do with marriage equality (you know, the reason they are all here) can be heard.

Just on this particular amendment, the Gold Coast Bulletin ran a story today about how the Queensland government was legally unable to do anything about a Milo Yiannopoulos event booked in a state-owned venue.

block-time updated-timeUpdated at 4.51am GMT

block-time published-time 4.36am GMT

The public gallery bursts into applause again before we move on to what I think are he second last amendments to be made, although Andrew Broad tells us he is going to be moving his amendments in two parts.

Yay.

block-time updated-timeUpdated at 4.51am GMT

block-time published-time 4.34am GMT

Scott Morrison amendments are voted down

The division ends with

Ayes: 59

Noes: 82

I don't see Malcolm Turnbull or Julie Bishop in the chamber, so it looks like they are abstaining again.

block-time published-time 4.26am GMT

Scott Morrison is making his last stand on an amendment he knows will be voted down, by listing the faith leaders who have asked for the protection, which already appears to exist, on an amendment which has nothing to do with marriage equality.

He then states his disappointment in there not being a conscience vote in the Labor party.

Which just seems to be an even bigger waste of time, because a) this debate will be happening for real after the Ruddock review is handed down and b) EVERYONE ALREADY KNOWS THIS.

The division bells are ringing.

block-time updated-timeUpdated at 4.33am GMT

block-time published-time 4.17am GMT

Trevor Evans is back and is very respectfully pointing out why his colleagues voting for this amendment are wrong.

He reads from the letter from the charities commissioner on the issue: "In short, not legally necessary but could remove any legal debate."

The Brisbane MP again, very respectfully, points out that the Ruddock review is the place for all of these discussions and he will be happy to revisit the conversation then.

block-time updated-timeUpdated at 4.19am GMT

block-time published-time 4.07am GMT

Kevin Andrews is so excited he can't help but wave around his hands and keeps hitting his microphone.

This has as much to do with marriage equality as his current contribution to this debate.

block-time published-time 4.06am GMT

Marriage equality legislation debate resumes

Kevin Andrews begins by pointing out that those who have said the amendment ( Scott Morrison's amendment to protect faith based charities, which already appear to have protections) are wrong.

Again, this amendment will fail. Because everyone knows that these things will be debated after Philip Ruddock hands down his review early next year, on religious freedoms in Australia.

Also, the legislation in question is about changing the marriage act. Not changing the charities act.

To be clear, this has nothing to do with marriage equality.

block-time published-time 4.03am GMT

Mood:

Labor's Stephen Jones, Claire O' Neil, Ed Husic and Tim Hammond during question time. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 4.11am GMT

block-time published-time 4.01am GMT

We are just dealing with some administration stuff and then we'll be back to the amendment debate.

Rainbow socks belonging to the feet of Mark Dreyfus and Jenny Macklin during question time. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 4.11am GMT

block-time published-time 3.59am GMT

Question time ends

Bill Shorten is called to the despatch box for the final question... but Malcolm Turnbull cuts him off by asking the rest of the questions be placed on notice.

Shorten points to the clock (it is 2.57) but it is done.

block-time updated-timeUpdated at 3.59am GMT

block-time published-time 3.57am GMT

Craig Kelly has the final Dixer.

He delivers it in his usual style of looking like he can't help but interrupt the debate you and your mate are having in the pub.

It's on citizenship and, honestly, we spent enough time on this yesterday.

block-time updated-timeUpdated at 3.59am GMT

block-time published-time 3.56am GMT

Anthony Albanese is next to give Tony Abbott a chuckle:

(Given how the amendment debate is going, I guess Labor figures he needs the cheering up)

The member for Warringah once famously ordered the now prime minister to demolish the NBN. Given the prime minister's second rate NBN is plagued by cost blowouts, problems with speed and reliability and is subject to a record number of complaints from Australians, can the prime minister now proudly declare "mission accomplished"?

Paul Fletcher takes this one:

It is worth reminding the house that carriage of the NBN in the disastrous final days of the Rudd government, the downfall phase of the Rudd government briefly passed from the land of Conrovia, to the land of Albonia and the record that the shadow minister has to offer when it comes to NBN is atrocious, it's a clear comparison.

We're delivering, getting on with the job, we're on track to getting this done by 2020. This lot has a hopeless record. You can't believe them, you can't trust them.

(It is amazing how knowing when question time is actually going to end tends to speed up the answers)

block-time updated-timeUpdated at 4.01am GMT

block-time published-time 3.52am GMT

Christian Porter is next on the Bennelong election campaign shuffle.

block-time published-time 3.51am GMT

Tanya Plibersek is next with a question on the NBN:

The prime minister promised every Australian would have access to the NBN by 2016. He also promised he would deliver it for $29.5bn. When will every Australian have access to the NBN like the prime minister promised and what will it cost?

Malcolm Turnbull says the Labor party keeps "verballing" him on this.

Let me read to you what was said in our policy document. "Our goal is for every household and business to have access to broadband with the download data rate of between 25 and100 megabits per second by late 2016."

The timetable for the completion of the NBN and our policy was stated at p7, I recall, as 2019. The proposition that it was our policy and our promise to complete the NBN by 2016 is simply not consistent with the policy document we produced.

block-time updated-timeUpdated at 4.03am GMT

block-time published-time 3.45am GMT

Peter Dutton is asked a question about border security.

Answer: Sam Dastyari and Kristina Keneally

block-time updated-timeUpdated at 3.45am GMT

block-time published-time 3.44am GMT

I forgot to update the Queensland count but Labor has held on to the seat of Townsville. That brings Annastacia Palaszczuk to 48 seats, giving her a small buffer if one of her MPs (like, I don't know, Jo-Ann Miller ) decides to jump to the crossbench.

The seat count is still not official but that should come soon. Under convention, the leader of the defeated party needs to concede before the government can claim victory. Tim Nicholls hasn't done that just yet.

block-time updated-timeUpdated at 3.47am GMT

block-time published-time 3.40am GMT

Christopher Pyne explains why both Sam Dastyari and Kristina Keneally are terrible and then we move on to the NBN again.

Paul Fletcher reads from the usual statistics.

block-time published-time 3.38am GMT

Bill Shorten to Malcolm Turnbull :

The prime minister promised every Australian would have access to internet speeds between 25-100 mega bits per second by the end of 2016. It's now the end of 2017 and 2 million Australian households have been told to wait even longer. Why has the prime minister failed to deliver the NBN like he promised?"

Turnbull:

The policy document was very clear and it said our objective was to get everyone to have access to 25 megabits per second by 2016. We did not say we would complete the NBN by 2016, in fact the policy document forecast a completion date by 2019 and will be completed, so the company says, the following year. After we came into government, we obviously had the first time to see what had happened at the NBN. It was our first time to examine the circumstances and we conducted a ***strategic*** audit, the results of which were published at the end of 2013.

Armed with that information, it was clear that our objectives could not be achieved and we said so and we said why. The company was set on a new, more practical business-like course and it is getting on with the job and it will have three-quarters of Australian premises covered by June next year and it will be completed according to the company's forecast by 2020.

We inherited a colossal wreck from the Labor party, hopelessly mismanaged, and what we have done is made the best with that. There's a lot of money that has been wasted by Labor we cannot recover but we're getting on and completing the project.

block-time updated-timeUpdated at 3.44am GMT

block-time published-time 3.33am GMT

Barnaby Joyce gets the next "vote 1 John Alexander " election ad dressed up as a Dixer.

He doesn't seem very in to it and can barely work up enough of a yell for any more of his cheeks to flush.

block-time updated-timeUpdated at 3.44am GMT

block-time published-time 3.31am GMT

Michelle Rowland gives Tony Abbott a laugh with this question:

I refer to the former prime minister, the member for Warringah, and his letter to Australia the day after the 2013 election: "I want our NBN rolled out within three years and Malcolm Turnbull is the right person to make this happen."

More than four years later, can the prime minister confirm he's failed to deliver on the government's promise?"

Malcolm Turnbull:

A not entirely unfamiliar question and the answer will be more familiar so I'll be brief. As of the last weekly report, the NBN Co has 6,518,096 premises ready to connect and 3,282,093 are active paying customers. There were just under 80,000 premises added to the network in the last week. This rollout is proceeding at an extraordinary pace, unprecedented. The honourable member knows very well that we inherited a train wreck, created by her predecessor, Senator Conroy. We put in a thorough ***strategic*** audit shortly after the election in 2013, we changed the board, we put in new management and, since that new management has been in place, all of their corporate plan objectives have been met so they're on track to get the project completed as they said they would and they will, as they said they will, by 2020. The honourable member has raised in the past issues around HFC which represents a little over 5% of the network. That deployment has been slow for six months to ensure our customer experience is improved but the company assures us the project will still be completed in time as forecast.

block-time updated-timeUpdated at 3.36am GMT

block-time published-time 3.28am GMT

Trent Zimmerman authorises the latest Bennelong by-election ad for John Alexander, in a dixer to Julie Bishop:

"Will the minister update the house on how the Government's economic diplomacy agenda is benefitting Australian businesses, including those in the electorate of Bennelong?"

Bishop: Kristina Keneally can not be trusted

block-time published-time 3.25am GMT

Andrew Wilkie has the cross bench question today:

"My question is to the Prime Minister. A backbencher gets a quarter of a million dollars in wages, superannuation and vehicle. Big business is still being promised a tax cut and now you're promising income tax cuts but at the same time, people relying on Government pensions and payments are struggling terribly.

"For example, it's not unusual for a single aged pensioner to go without meals and medicines in order to pay rent. Indeed, according to a recent survey, 61% of pensioners go without necessities, including fresh food. Do you really think this is OK, Prime Minister and when will you start talking about increasing Government pensions and payments to sensible levels?"

Malcolm Turnbull :

"I thank the member for his question. We all know that there are many Australians not just in Denison but across the nation that are doing it tough. We know how hard it can be for many of our pensioners and for those who rely on the social welfare safety net. "In the 2017 Budget, the honourable member will recall we introduced a one off energy assistance payment for around 3.8 million Australians. That payment was $75 for singles and $62.50 for each member of a couple."

He goes one and Wilkie interrupts to ask what is happening in the future:

"As a result of our changes, more than 90% of pensioners are either better off or have had no change to their position. The pensioner concession card was reinstated on 9 October to approximately 92,300 pensioners whose entitlement ceased on 1 January due to the rebalancing of the assets test measure and that included 453 pensioners in Denison. We're committed to ensure our social welfare safety net supports those most in need and we want to - I want to state again our respect and our thanks to all our senior Australians who have built our great nation and to whom we owe so much."

block-time published-time 3.15am GMT

From a little earlier, here's how the afternoon arrangements were worked out.

Leader of the house Christopher Pyne and the manager of ***opposition*** business Tony Burke talk to speaker Tony Smith Photograph: Mike Bowers for the Guardian

block-time published-time 3.13am GMT

Bill Shorten to Malcolm Turnbull :

This year the prime minister has lost three ministers, lost multiple votes in parliament, cancelled parliament, announced a tax hike for seven million Australians, cut penalty rates for 700,000 workers, ruled out a banking commission and then announced it and made two million premises wait longer for the NBN.

Given the prime minister has spent 2017 hostage to his backbench and to events, why should Australians believe 2018 will be any better?

Turnbull: Sam Dastyari

block-time updated-timeUpdated at 3.19am GMT

block-time published-time 3.11am GMT

Not content with a press conference which included slides, and the world's longest press statement, Scott Morrison has now taken a dixer on the national accounts.

block-time published-time 3.10am GMT

Bill Shorten to Malcolm Turnbull :

Next week the royal commission into institutional responses to child sexual abuse hands down its final report. Will the prime minister join me to acknowledge the survivors of child sexual abuse for their courage in giving evidence, thank the royal commissioners and their staff for their efforts to expose responses on child sexual abuse and in the nation's parliament? Will he join with me in committing to ensuring survivors get the justice and the real redress they deserve?

Turnbull:

We thank and we honour the courage of the survivors who bravely told their stories to the royal commission. We thank the royal commissioners and their staff for the long hours and the very hard hours, the very emotionally draining hours that they have spent listening to those stories, comforting the survivors. We honour them and we believe them. That is the most important thing you can say. I remember years ago when prime minister Rudd and I made a statement of apology to the survivors of institutional care, the forgotten Australians, often described. The words they wanted to hear most of all was that they, after a lifetime of being ignored and neglected and pushed away, they were believed and that the charities and churches and governments that had done them so much wrong were going to be held to account.

Justice, honesty, transparency, that's what the royal commission has been delivering. I want to thank the commissioners, I want to thank above all the survivors. We believe you, we love you, we will stand with you.

block-time updated-timeUpdated at 3.16am GMT

block-time published-time 3.08am GMT

I missed this earlier:

enltrThe Nationals' Deputy Leadership contest finished in this order: 1. Bridget McKenzie 2. Michael McCormack 3. Matt Canavan 4. Keith Pitt

- David Speers (@David\_Speers) December 7, 2017

block-time published-time 3.06am GMT

The first Dixer is an election ad for John Alexander Bennelong's by-election.

And we have had our first mention of Kristina Keneally. Although she has apparently become "she who will not be named" as she is referenced, but not identified.

block-time updated-timeUpdated at 3.08am GMT

block-time published-time 3.05am GMT

Question time begins

It's the last time we'll be doing this, this year.

Bill Shorten starts by asking Malcolm Turnbull to defer question time so the marriage equality vote can be brought forward.

Short answer - no.

Turnbull:

This must be the first time the leader of an ***opposition*** has asked that question time be abandoned.

It must be the first time. I wonder why. I'll say this, Mr Speaker: in the course of this week, many hours have been taken up with Labor party motions about citizenship and penalty rates, matters that could properly have been dealt with after marriage had been dealt with, but no, the Labor party rushed their motion in in the hope that they would get it voted on before the member for New England made his return.

That bit of fancy footwork slipped up. The government is accountable in question time and so is the ***opposition*** so we will all be accountable in question time today as we are every day that parliament sits.

I will say this to the leader of the ***opposition***: I'll ask further questions be placed on the notice paper at 3pm, which is when the broadcast finishes.

block-time updated-timeUpdated at 3.09am GMT

block-time published-time 2.40am GMT

Amedment debate breaks until after question time

The last speaker before the debate break is Tony Abbott.

He continues the pattern of talking about things with nothing to do with marriage equality legislation.

He can't imagine a world without the hospitals, charities, schools and other great works of our faith-based organisations.

"It is their faith that drives them, they do it because of their faith motivation and part of that faith is that marriage is between a man and a woman, preferably for life and usually dedicated to kids.

"Once same-sex marriage is enshrined in law, on public policy grounds, organisations don't recognise same-sex marriage could indeed be subject to some kind of official sanction.

"Overseas this has happened. Catholic adoption agencies have been forced to withdraw their services. Orthodox Jewish schools have had their funding threatened. American Christian colleges have registration refused to their law graduates because of their teaching on marriage..."

(Note from Amy: I just have to insert in here that one of the reasons these cases have popped up in America is because they have a bill of rights, enshrined in their constitution. Many of these cases have been examined in the light of how they meet those constitutional rights. Australia does not have a bill of rights. It is not apples and apples.)

"Don't think that it can't happen in this country. It already has. I recall, as employment minister in 2003, finding a human rights commissioner threatening faith-based employment agencies because of their own employment practices. And if that threat had been acted upon, they would have had to withdraw their services. So these amendments are important and, I stress, they are not against same-sex marriage, they are simply in favour of the rights of religious organisations to keep doing what they have always done in the great interests of the Australian people."

And we are on break from one of the most ridiculous last stands ever, until at least 3.15.

block-time updated-timeUpdated at 2.48am GMT

block-time published-time 2.30am GMT

Christopher Pyne is explaining this afternoon's proceedings.

The debate will end at 1.30. People book in for question time, so the public gallery will have to be emptied, so those people can take their seats.

Pyne says the debate will resume after the matter of public interest debate.

That debate today is from the ***opposition*** on the topic of the need to bring the government down. Tony Burke jumps up to say that Labor will delay speaking about the need to bring the government down until February to ensure that the debate can continue straight after question time at 3.15pm.

We won't get through this amendment then. Then there is the last couple to go. Don't expect a vote until later this afternoon.

block-time published-time 2.26am GMT

Mark Dreyfus is now explaining why the amendments aren't needed, as the current charities legislation already includes these protections.

I feel compelled to add that this amendment has NOTHING TO DO WITH THE LEGISLATION UNDER DEBATE.

block-time published-time 2.21am GMT

We may get through this unnecessary and doomed-to-fail amendment before question time. But then we still have a couple to go before we get to the vote.

block-time updated-timeUpdated at 2.36am GMT

block-time published-time 2.21am GMT

Warren Entsch is explaining that the amendments aren't needed. He also points out the bill has been out for four months for consultation and the amendments should not be rushed into.

What is clear is these amendments are they are completely unnecessary, they certainly carry risks and they should be opposed.

Nicole Flint is speaking in support and repeats the now common line that while the change to the Marriage Act is the will of the Australian people, we "must remember" to protect the views of all Australians.

Again, I don't remember voting on anything other than marriage equality in the survey. If someone has a different form, which included a question on religious and conscientious freedoms, please send it to me so I can take it up with the ABS.

block-time updated-timeUpdated at 2.48am GMT

block-time published-time 2.17am GMT

While Scott Morrison talks about the great faith works, let's look at some Mike Bowers magic from inside the chamber

Mark Dreyfus and his rainbow socks during a division on amendments. Photograph: Mike Bowers for the Guardian The leader of the House, Christopher Pyne, with Anthony Albanese during a division. Photograph: Mike Bowers for the Guardian Votes are counted on amendments to the bill to amend the marriage act. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 2.49am GMT

block-time published-time 2.09am GMT

Scott Morrison is next to watch his amendments fail.

He wants to make sure that faith-based charities can continue to object to marriage equality without fear of losing their charitable status.

block-time updated-timeUpdated at 2.49am GMT

block-time published-time 2.05am GMT

Alex Hawke amendment voted down

The Alex Hawke amendment goes down:

Ayes: 59

Noes: 87

Still more laughter and good times coming from the no-to-amendment camp.

block-time updated-timeUpdated at 2.24am GMT

block-time published-time 2.00am GMT

The division has been called and Malcolm Turnbull has walked in. He is sitting with the yes to amendment camp.

enltrPM Malcolm Turnbull is voting in favour of Alex Hawke's amendment, aimed at exempting Defence chaplains #marriageequality#auspol

- Roje Adaimy (@rojeadaimy) December 7, 2017

block-time published-time 1.57am GMT

As the latest division voting down the latest unnecessary amendment goes on, I am loathe to report that Sarah Henderson has just added another amendment to the list.

Henderson is voting in favour of marriage equality, but has added ANOTHER amendment doomed to fail, to protect all those civil celebrants who love marrying people outside a church but have conscientious objections to same-sex marriage.

This means we won't be getting to a vote until late this afternoon now. Probably a couple of hours after question time.

block-time updated-timeUpdated at 2.08am GMT

block-time published-time 1.53am GMT

Lo and behold, this debate has me agreeing with Andrew Laming again.

"As far as I am concerned the armed forces are an apparatus of the state. The state has agreed to a broadened definition of marriage. If you are a seconded religious chaplain from the church, an exemption exists for you. But if you are not, you are part of the state's apparatus, that is the armed forces, you follow a chain of command.

"This is a matter for the Chief of the Defence Force. If they are marrying, they are receiving a state salary and they adhere to the law of the land. I am not in favour of these exemptions trickling through the armed forces and you would know very well, as I did, I did not go to Afghanistan with a body armour, a pay packet and the will of the Australian people, I went as a volunteer, but I know when I got there, there wasn't a lot of conscience thinking when you are serving in the armed forces.

"If you are chaplain, you have the possibility of religious exemption, if you are seconded from a church. You are taking a state salary, from a nation that allows marriage in all its forms, between two adults and that is what you can do as part of your service, otherwise you can leave the military."

Look, I am not saying the world didn't actually end in 2012, but I am not, not saying it either. This is the second time Laming has been one of the MPs to make the most sense in talking down these amendments today.

block-time published-time 1.37am GMT

Wait, Alex Hawke surprises, by not only moving his amendment that will be voted down, and is probably not actually needed, but by then spending time attacking the ***opposition*** for not having a true conscience vote.

He wants military chaplains to be able to refuse to carry out same-sex marriages on religious and conscientious belief.

Because even though he disagrees with his colleagues, he respects that they can debate it and "have a genuine disagreement" on some issues. And he is most upset that Labor is not having that same genuine disagreement.

"This is your chance, this your moment, this is where the leader of the ***opposition*** can step up and show some leadership."

We are hearing again about the no voters and why their views need to be protected. Again, I would have enjoyed hearing how passionate Hawke would have been in arguing to protect the rights and views of yes voters, if this had gone the other way.

Terri Butler again argues against the amendment, saying she doesn't want to be here any longer than she wants to, but "more importantly" the people of Australia don't want it to take any longer. The public gallery applauds. They are told to be quiet.

Butler then points out the bill has also already addressed this issue, by creating a secular position of 'marriage officer' and she can't understand why someone with religious or conscientious beliefs against marriage equality, would sign up to be a secular marriage officer in the first place.

block-time published-time 1.26am GMT

Next amendments on the chopping block are those of Alex Hawke.

He is going to say that the amendments are straightforward and will improve the bill and are needed to protect the views of those who do not support same-sex marriage.

Then those who are against them (which right now is the majority of the parliament) will point out that now is not the time for these amendments and besides, the amendments are not needed as what they seek to protect is already protected and adding to those protections is legislating discrimination (essentially).

We'll spend more time than we need to on it, the divide will be called, the amendment will be voted down and we will move on.

block-time updated-timeUpdated at 1.35am GMT

block-time published-time 1.22am GMT

Andrew Hastie amendments voted down

The chamber has divided on Andrew Hastie's amendments:

One thing is clear, the no side certainly has a lot more colour. And chat.

Ayes - 56

Noes - 87

Looks like the prime minister is abstaining again.

block-time updated-timeUpdated at 2.24am GMT

block-time published-time 1.13am GMT

Meanwhile, outside in the "real world", where Australia voted in favour of marriage equality (and that was it) in the survey the government forced on everyone, among those waiting on the vote is 10-year-old Cully.

Those in favour of the amendments seem to think that along with ticking yes for marriage equality, supporters of same-sex marriage also ticked yes for "protecting religious freedoms'.

That particular question must have been missing from my form.

That is not to say that the debate shouldn't happen. It will, regardless of whether it should or not. It's set in stone as part of the Philip Ruddock review. But flagging it here, when most of the amendments have nothing to do with this legislation, is pointless.

Cully 10, from Rainbow Families ahead of the debate Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 1.17am GMT

block-time published-time 1.06am GMT

Trent Zimmerman makes the very obvious point that all these religious leaders who feel the need to speak out against marriage equality and hold on to their traditional views as tightly to their bosom as they possibly can, already have those protections.

Andrew Hastie says the spirit of his amendment is to protect the views of the 39% of Australians who voted no. I am very, very sorry we won't ever get to hear his impassioned defence of the Australians who voted yes, if the survey result went the other way.

block-time updated-timeUpdated at 1.08am GMT

block-time published-time 1.04am GMT

To be clear, it is just the House lighting that does this.

Tony Abbott speaks on amendments to the bill Photograph: Mike Bowers for the Guardian

block-time published-time 1.02am GMT

And for those asking, here are the MPs who voted for the amendments.

The yes amendment voters Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 1.06am GMT

block-time published-time 1.00am GMT

Here is what it looks like when the parliament (largely) works together.

The chamber divides on amendments to the bill to amend the marriage act Photograph: Mike Bowers for the Guardian

block-time published-time 12.59am GMT

Cathy McGowan stands up to ask for members to remember that regional Australia, which is constantly being pointed to as wanting to respect "traditional marriage" given that it is usually used as the example of "real Australia" by conservative politicians when making their points, "voted overwhelmingly in favour" of marriage equality.

block-time published-time 12.56am GMT

"The day you start to cherry-pick which human rights are important is a dangerous day," says Kevin Andrews, as he now cites the UN for not having a hierarchy of rights.

Yes, you read that correctly. Kevin Andrews just referred to the UN.

There was laughter from the gallery as he said it. Can't for the life of me understand why.

block-time updated-timeUpdated at 1.02am GMT

block-time published-time 12.52am GMT

Adam Bandt smacks down Tony Abbott's attack on safe schools and receives applause from the public gallery

Christopher Pyne stands up to say he doesn't want to be the "Christmas grinch" and he understands everyone is excited, but they need to settle down.

Kevin Andrews is now talking about protecting human rights. We have three more amendments to go after this.

block-time published-time 12.52am GMT

Sigh.

Tony Abbott has risen again to support the Hastie amendments.

He brings up Safe Schools. Which a) has nothing to do with this legislation; b) is deliberately misrepresented for political purposes; and c) was rolled out under his government; and d) HAS NOTHING TO DO WITH THIS LEGISLATION.

He has another go at Malcolm Turnbull for not putting religious freedoms in place before this vote. He then does the parliamentary equivalent of yelling at clouds, by wondering why the House is so concerned with what the Senate decided.

"What would Paul Keating say?" he says.

block-time published-time 12.44am GMT

Meanwhile in Queensland, the Greens are celebrating winning their first seat in the state parliament.

Michael Berkman took the seat of Maiwar from the LNP

enltrHow will the Greens celebrate winning Maiwar? "With a compost party," one jokes ?????? @[*mcberkman@tennewsqldpic.twitter.com*](mailto:mcberkman@tennewsqldpic.twitter.com)/fNdf1Hswuq

- Tegan George (@tegangeorge) December 7, 2017

block-time published-time 12.30am GMT

Lucy Wicks is standing to support Andrew Hastie's amendments.

Tim Wilson can be seen waving to the public gallery behind her.

You can guess which interaction those in the gallery are enjoying more.

Again, if you want to see the amendments being put forward, you can see them here.

They are very similar to the ones which were voted down in the Senate.

All of the amendments will be voted down. This is just a taste of what we are in for when the Philip Ruddock review comes down next year. Basically, everyone is putting their views on the record as a symbolic gesture now, and indicating where the battle lines will be drawn once that review is handed down.

Meanwhile, Tim Wilson, Trent Zimmerman and Craig Kelly are looking as though they are having best time ever behind Wicks.

block-time updated-timeUpdated at 12.40am GMT

block-time published-time 12.25am GMT

Terri Butler explains why Labor won't be supporting the amendments.

One - because it is delaying the vote and everyone has waited long enough

Two - because any big changes to Australian law should be properly considered and consulted on.

block-time published-time 12.19am GMT

That sound you hear is Malcolm Turnbull dusting off his leather jacket - the PM has been confirmed as the guest on Q&A next Monday.

block-time updated-timeUpdated at 12.26am GMT

block-time published-time 12.18am GMT

Andrew Hastie is moving his amendments now. He keeps talking about protecting "traditional marriage".

For a reminder, here is what he believes "traditional marriage" is for:

enltrAndrew Hastie: The 'normal' way marriage is conducted is with the 'purpose of procreation'. MORE: [*https://t.co/Ww4yA5TED7pic.twitter.com/LubEGUcyUZ*](https://t.co/Ww4yA5TED7pic.twitter.com/LubEGUcyUZ)

- Sky News Australia (@SkyNewsAust) September 1, 2017

Warning: what has been heard can never not be heard.

block-time updated-timeUpdated at 12.26am GMT

block-time published-time 12.14am GMT

Michael Sukkar amendments voted down

The division result is in:

Ayes - 43

Noes - 97

There is applause from the public gallery and from some of those in the chamber who voted against the amendments.

block-time updated-timeUpdated at 2.23am GMT

block-time published-time 12.11am GMT

Looking at the chamber, it is quite amazing to see so many Coalition and Labor MPs on the same side.

Given the laughter coming from that side of the chamber, they know it.

block-time published-time 12.10am GMT

From the chamber:

Josh Frydenberg talks with Michael Sukkar, Jason Wood and Craig Kelly as debate winds up on the bill to amend the Marriage Act. Photograph: Mike Bowers for the Guardian Tony Abbott leaves the house as debate winds up. Photograph: Mike Bowers for the Guardian Kate Ellis arrives with Charlie. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 12.15am GMT

block-time published-time 12.04am GMT

Just ducking out of the chamber to update you on other matters - Andrew Leigh has criticised the appointment of Gary Johns to the ACNC:

Mr Johns has been a foe of charities and he has been one of the strongest critics of charities in Australia. He has attacked Indigenous charities, he has attacked mental health charities and he has attacked charities that attempt to engage in advocacy. That's the thing about this government, they have a "charities should be seen and not heard" approach. They think that charities are OK so long as they're running soup kitchens, but once they start talking about poverty and inequality, they're overstepping their mark and they should go back to the kitchen. It's that sort of anti-advocacy approach in legal charities, in environmental charities, in social service charities that characterises the worst aspects of this government sand which characterises Gary Johns' views on charities throughout his career. A leopard doesn't change its spots. Gary Johns will not cease being a foe to charities in this new role.

Charities will be horrified by this appointment. This is somebody being appointed to head the charities commission who is a critic of theirs, not a supporter of theirs. This is like putting Dracula in charge of the bloodbank. It's like putting Ned Kelly in charge of bank security.

block-time updated-timeUpdated at 12.12am GMT

block-time published-time 12.02am GMT

The public gallery has been told to calm down the clapping. But the feeling, we are told, is electric.

It is absolutely packed in there.

Poor Michael Sukkar tried to defend his amendments (which are in the process of being voted down in a division) but all attention was on Kate Ellis's newborn baby Charlie, who is also in the chamber.

He looked almost disappointed to have his moment overtaken by a baby.

block-time updated-timeUpdated at 12.12am GMT

block-time published-time 12.00am GMT

Trevor Evans has also spoken out against the amendment to alter the definition of marriage to essentially two categories, marriage between a man and a woman and marriage between two people.

Evans asks his colleagues who are in support of the amendment whether those two categories are equal. And whether it is a legal change or a symbolic one.

If this is symbolic, then this is a pointless and unnecessary amendment with no legal effect and there is no justification to support it.

Pointless regulation is illiberal regulation. This government is philosphically opposed to pointless regulation.

Our statute books are not the place for symbolism and gestures; we have Sky News for that.

block-time updated-timeUpdated at 12.11am GMT

block-time published-time 11.56pm GMT

The Liberal MP Trevor Evans then summed up why the amendments were bupkis:

To best understand why these amendments are ill-considered, let's remember how this bill formed its current positions. Both with respect to the definition of marriage and on celebrants. This started as a government bill. An exposure draft prepared by our attorney general, it subsequently went through a Senate committee, a comprehensive process, with extensive consultation with many of Australia's religious organisations and other community leaders and organisations. Four hundred submissions. 40-something witnesses and significant scrutiny by all of those senators and that consultation led to a unanimous set of findings. That is unanimous agreement from senators across the political spectrum, including government senators.

So what is proposed in these amendments goes against the informed and unanimous findings of those senators from right across the political spectrum. And given these amendments are essentially the same as those defeated recently in the Senate, they should be rejected again here, for similar reasons ...

To be clear, the bill in front of us protects civil celebrants. The bill allows existing civil celebrants who have strong religious beliefs against same-sex marriage to identify as religious marriage celebrants, which then gives them the right to refuse to solemnise same-sex marriages.

What the amendments propose to do is create a carve-out which would be ongoing and would allow not just religious objections to same-sex marriage, but non-religious objections as well and, to be clear, that approach has been strongly rejected by the associations representing civil celebrants.

I have taken the time to meet with some of them to confirm this; the civil celebrants' organisations do not want this.

block-time updated-timeUpdated at 12.10am GMT

block-time published-time 11.43pm GMT

Tony Abbott has risen in support of Michael Sukkar's amendments. No surprise there.

These amendments are not designed to frustrate this bill, they are not designed to delay this bill, they are designed to improve this bill and make this bill a unifying occasion, as unifying as can be, under all the circumstances.

"Almost 8 million Australians voted yes, almost 5 million Australians voted no, all Australians, whichever way they voted, deserve to have their views respected and as far as is possible, accommodated in the legislation.

"I suspect that many of the 8 million who voted yes did not want to exclude traditional marriage, they simply wanted to embrace same-sex marriage too.

(Note from Amy: because Tony Abbott has obviously proven to have his finger is on the pulse on this, and so many other issues.)

Then Abbott had his dig at Malcolm Turnbull :

In the course of the campaign, when both the prime minister and the leader of the ***opposition*** pledged that before same-sex marriage became law there would be adequate freedoms of conscience, religion expression in place, that is simply what these amendments seek to do.

To make the words of the prime minister and the leader of the ***opposition*** become a reality.

block-time updated-timeUpdated at 11.57pm GMT

block-time published-time 11.28pm GMT

Adam Bandt's contributions are proving quite popular with the public gallery.

He and Anthony Albanese got into a little verbal skirmish earlier, when Albo, who explained that Labor would not be supporting the Greens amendments because "you can't always get what you want, but you can get what you need", said he was part of a major party because it supported things which were important to people.

He was criticising the Greens amendment to change the name of the bill to reflect marriage equality. Albanese said that what wasn't important to people, and it was taking up time. Bandt fired back that the only reason we were here was because Labor supported John Howard's change to the marriage laws, and he would not be lectured.

But we have moved on.

The public gallery is packed. There is a pretty big feeling of anticipation in this building today. Everyone is waiting on that final vote.

block-time updated-timeUpdated at 11.36pm GMT

block-time published-time 11.07pm GMT

Greens amendments voted down

The Greens amendments are voted down on the voices.

Now to the amendments from Michael Sukkar. These will also be defeated.

There are four other amendments after this - you can find them here.

All of them will be voted down. There is also a loose agreement to keep speeches against them short.

block-time updated-timeUpdated at 2.23am GMT

block-time published-time 11.05pm GMT

For those playing along at home, you can follow the bill's progress here.

At this stage, it looks like we will get a vote just before question time, or just after.

All the amendments are being quickly dealt with and dismissed by both major parties, who are very firmly of the mind that it is time to "just get it done".

As for the need for protections, Trevor Evans has made his views clear:

Australia is not America... the case for the homophobic baker in Australia remains unfulfilled.

Evans said he doubts a case like the US is now dealing with would be seen in Australia, because, basically, he doesn't think anyone would be bothered - they would just take their business elsewhere is the basic gist.

block-time updated-timeUpdated at 11.14pm GMT

block-time published-time 11.01pm GMT

The Labor MP Terri Butler moved to the other side of the chamber to support Warren Entsch and the other members of the Coalition's "rainbow rebels" who helped move the bill through the party room, while Senator Dean Smith watches.

Warren Entsch, surrounded by supporters from both sides of the house and watched by Senator Dean Smith, as debate winds up on the bill to amend the Marriage Act. Photograph: Mike Bowers for the Guardian

block-time updated-timeUpdated at 11.05pm GMT

block-time published-time 10.56pm GMT

The Greens have responded to the US decision to recognise Jerusalem as Israel's capital.

From the party statement:

The Greens condemn in the strongest possible terms US President Donald Trump's decision to recognise Jerusalem as the capital of Israel and relocate the US Embassy from Tel Aviv, said Leader of the Australian Greens Dr Richard Di Natale.

Australia now stands alone in its craven refusal to join those in Europe, Asia and the Middle East in standing against this move, which will devastate the peace process.

"This decision by President Trump is a body blow for the peace process and for the Palestinian people," Di Natale said.

"Trump's announcement has been universally condemned - by the United Nations, European and Middle Eastern leaders and religious leaders.

"Yet the Australian Government stands alone in maintaining that this is a matter only for the United States.

"It is shameful that Malcolm Turnbull cannot even display the leadership to stand with our allies in Europe and Asia to publicly urge Trump not to proceed with this deeply unfair and dangerous decision.

"If it wasn't enough to see Donald Trump's inflammatory tweets on North Korea, or his decision to pull out of the Paris Climate Agreement, surely this latest move is all the evidence needed to prove that we are shackled to an unhinged ally intent on making the world far more dangerous."

\*end statement\*

Julie Bishop has repeated her confirmation from yesterday that Australia would continue to keep its diplomatic presence in Tel Aviv. Labor has also given its support for Australia's position.

The Petrie MP Luke Howarth' s decision to retweet this, then, has raised a couple of eyebrows:

enltrThis is a historic day. Jerusalem has been the capital of Israel for nearly 70 years. Jerusalem has been the focus of our hopes, our dreams, our prayers for three millennia. Jerusalem has been the capital of the Jewish people for 3,000 years. Thank you, @realDonaldTrump ! ???????? pic.twitter.com/mWCUpUMpiC

- Benjamin Netanyahu (@netanyahu) December 6, 2017

block-time updated-timeUpdated at 11.05pm GMT

block-time published-time 10.52pm GMT

This week Labor announced it would not support the extension of the cashless welfare card to any other communities unless there were amendments.

Here's Alan Tudge reflecting on that on 6PR Perth radio:

I am so deeply disappointed, because Labor has people that have been there. They know the issues. They know the damage which alcohol does, paid for by the welfare dollar.

They know the impact which this cashless welfare card is having on the ground up in the east Kimberley, and yet they have clearly got too much pressure from their Melbourne and Sydney representatives who are scared about the Green votes in Melbourne and Sydney, and so they are willing to chase those votes and abandon the children in the Goldfields and abandon the women.

That's what they are doing. I am flabbergasted, I am disappointed, but we are not going to let them slow us down because the leaders there, including Rick Wilson, the federal member, have been so strong on wanting to give this a go there to address some of the issues there, and so we are going to press ahead.

We wanted bipartisan support for this. We are not going to get that now, but we will press ahead nevertheless and back those community leaders, back the children, and back the women.

block-time updated-timeUpdated at 11.03pm GMT

block-time published-time 10.50pm GMT

Here is what the man himself has to say about his amendments.

enltrOut of respect for the millions of Australians who take religious freedom seriously I moved my amendment; out of respect for the millions who want the SSM bill swiftly passed I chose not to divide on it

- Tony Abbott (@TonyAbbottMHR) December 6, 2017

block-time updated-timeUpdated at 11.02pm GMT

block-time published-time 10.45pm GMT

Amendment debate begins

Warren Entsch commends the bill to the house and there is a smattering of applause.

Tony Abbott's amendments, designed to protect "religious freedoms", which critics have called an attempt to "legalise discrimination" were moved and lost on the voices.

Abbott did not call for a division. So it looks as though the intervention to separate the amendments from this bill, and instead have them dealt with by the Ruddock review within the Coalition party room, worked.

The pious debate would have have delayed the marriage equality legislation vote considerably - and potentially have made the parliament sit longer to make sure the government could meet its promise to legislate by the end of the year, which is why there was an intervention in the first place.

The house has moved on to other amendments, including the Greens amendments to ensure civil celebrants can't reject same-sex marriage.

These will also fail.

The Dean Smith bill will go through unadulterated now.

block-time updated-timeUpdated at 2.22am GMT

block-time published-time 10.39pm GMT

Warren Entsch is calling out Bob Katter for his speech. Katter left the chamber as Entsch began. He can barely hold back his fury.

Here's Entsch:

This was parliament at its best, with so many people on their feet, standing up for what they believe is right and doing is in a dignified and a very, very respectful manner. However, there was one contribution - and I'm disappointed to see that he has left the chamber - that was the exception and it deserves special mention, and that was the contribution of the member for Kennedy, Bob Katter, who was the last speaker on the second reading last night. His pathetic attempts to humour, insensitivity and grossly misleading comments were devoid of any facts and were highly offensive, embarrassing and cringeworthy. They need to be called out for what they are. His speech exemplifies what the LGBTI community have had to endure for so long. I've got to say that member for Kennedy's speech needs to be taken in isolation and does not represent the views of the parliament and certainly does not represent the views of the overwhelming majority of Australians.

Entsch also says no amendments to the bill are necessary.

This bill gives so much and takes from no one.

block-time updated-timeUpdated at 10.46pm GMT

block-time published-time 10.35pm GMT

Warren Entsch delivers the final second reading speech on marriage equality

The Queensland MP has taken the floor to give the final speech on the marriage equality legislation.

He is wearing his rainbow tie again and holding back tears.

block-time published-time 10.34pm GMT

Oh boy.

Michael Sukkar has just confirmed that Dr Gary Johns will take over as the full-time commissioner of the Australian Charities and Not-for-profits Commission, and well, though he might be a former Keating government MP, his views haven't exactly endeared himself to the sector over the years.

Here he is referring to Indigenous women as "cash cows".

And here he is on LGBTI rates of depression.

Johns has made his opinions made on quite a few points over the years. Expect a lot of people to have a lot of opinions on this appointment.

block-time updated-timeUpdated at 10.42pm GMT

block-time published-time 10.25pm GMT

Bridget McKenzie's ***win*** also means she will be elevated to the cabinet. We'll let you know what portfolio she'll hold when we hear.

She gave a brief speech in front of the media and paid homage to Fiona Nash, who previously held the post, before she was found to be ineligible by the high court for being a dual citizen:

I would just like to briefly mention Fiona Nash, a great friend and a colleague, who yesterday [had her return] ruled out and I guess, um, Nashy, I love you.

And I can't wait to get on the golf course with you as soon as possible, and I know Fiona has a great future in public service in whatever field she chooses.

But I guess I would like to say thank you to my party room. Now it's about getting on with the job of delivering for regional Australia within the Coalition government."

McKenzie was referring to the high court handing down its reasons for finding Hollie Hughes ineligible to fill Nash's spot (short version, when George Brandis appointed her to the AAT, he ruined her chances under section 44 to fill the Senate spot) and that will most likely see Jim Molan fill the spot.

But don't rule Nash out. She might not fill that Senate spot, but most believe she'll be back - and sooner rather than later.

block-time updated-timeUpdated at 10.39pm GMT

block-time published-time 10.16pm GMT

And the winner of the Nationals deputy ballot is ...

Bridget McKenzie

( Entirely my fault that her name was left of the original post on this - when I went to bold her name, I accidentally ***deleted*** it and my tired brain didn't pick that up until right now.)

block-time updated-timeUpdated at 10.20pm GMT

block-time published-time 10.15pm GMT

Penny Wong is ready for the vote. Beyond ready I would say.

We will wait for the vote but judging by the people who have spoken we are in a good place. Obviously, if not all, then the overwhelming majority of Labor will be supporting and we will have enough Liberals and crossbench people to get it over the line. It will be the end of a very long journey. It's an outcome that will have been achieved because of the Australian people and in this, as I said in my third reading speech, we are their representatives but they have been our leaders. They have demonstrated grace and decency and I hope we demonstrate that today.

block-time updated-timeUpdated at 10.20pm GMT

block-time published-time 10.10pm GMT

Matt Canavan is 'unhinged' - Bill Shorten

The Queensland election race has not officially been called but Labor has its majority, with Annastacia Palaszczuk winning the 47 seats she needs for a majority government.

That has led the Queensland senator and federal resources minister, Matt Canavan, to lash out, again, about Palaszczuk's decision to veto the billion-dollar rail line loan.

Speaking to the Courier-Mail, Canavan accused Labor of "racism" and "xenophobia" in making the decision.

The Labor party has a long and colourful history of xenophobia and racism and this is just the latest chapter in that book. If it was a British company building this rail line, or the Australian government building the rail line, I don't think we would have the controversy it has attracted. It's down to that it is an Indian company.

A spokesman for Bill Shorten returned fire, telling AAP:

Matt is clearly unhinged and lashing out."

Adani is still waiting on funding for its Queensland mine. After saying it did not need the federal government loan to move ahead, it has since changed tack and said it does.

There were reports it was set to receive Chinese funding, but Bob Carr, who has been lobbying Chinese organisations on behalf of the Australian Conservation Foundation, said on Wednesday he had it confirmed from the Chinese embassy no funding commitments had been made.

Palaszczuk has confirmed the veto against the loan stands and said she will not facilitate any taxpayer funds being spent on the mine.

Adani was one of the biggest issues in the Queensland election campaign, with the veto dominating much of the first half of the campaign, before being judged as helping Labor ***win*** Brisbane seats, which in turn, helped it ***win*** the election.

block-time updated-timeUpdated at 10.18pm GMT

block-time published-time 9.58pm GMT

As I said, Bob Katter was the last speaker on the marriage equality bill overnight. It went places. And all of them were terrible. I'm only going to put a little of it here, and only for context, because I expect Warren Entsch, who is from a similar part of the world as Katter, will want to correct the many, many wrongs in this speech.

Here's a taste:

The people advocating this proposition tonight, the LGBTIs, have maybe 60 years on their side. I have 3.5m years of genetic programming on my side, because we human beings, they tell us, have been around for 3.5m years. One thing that is absolutely certain is that we've all developed from heterosexual couples. That is one thing we know absolutely - up until the last 40 years, anyway. So, genetically, we are programmed that way. If you want to make a young lad between the age of nine or 10 and 15 go to school wearing a dress, you'll seriously mess with his head. If you are looking for reasons why, there are distinguishing factors of the incredible race of people, as I call us in my book - and I think we are. We always get there in the end, but, jeez, we run off the rails badly at times. If you analyse why this country continuously has the highest male juvenile suicide rates in the world - why is that? - there is something going wrong here. We have an extraordinary incidence of homosexual behaviour in Australia compared with other nations, and I think the people who have been speaking for this bill would agree with me on that.

block-time updated-timeUpdated at 10.04pm GMT

block-time published-time 9.26pm GMT

enltr??today could be the day #marriageequality ????????????????????????????????????????????

- Alex Greenwich MP (@AlexGreenwich) December 6, 2017

The action started early this morning.

The Equality Campaign held an event at 7am with ambassadors Magda Szubanski, Ian Thorpe, Daniel Kowalski, Prof Kerryn Phelps and Christine Forster on the lawns outside parliament.

There was dancing but also a serious message - get the vote done.

Understandable, really.

block-time updated-timeUpdated at 9.32pm GMT

block-time published-time 9.16pm GMT

Barnaby Joyce is back and he's looking for a deputy.

Basically the entire Nationals party room has put up their hands. The ballot is at 9am, with a result at 9.30. Look out for the battle between Matt Canavan, Nigel Scullion and Michael McCormack.

block-time updated-timeUpdated at 9.30pm GMT

block-time published-time 9.13pm GMT

Donald Trump has confirmed diplomacy's worst-kept secret- he has decided, despite warnings from almost every Middle Eastern ally, to recognise Jerusalem as the capital of Israel. It took about 39 minutes into his speech to get there, but he says it is "the right thing to do".

Australia doesn't agree. Julie Bishop hasn't criticised Trump but she has made clear Australia will be sticking with Tel Aviv and, this morning, reiterated what she said yesterday.

The Australian government is committed to a two-state solution whereby the Israeli people and the Palestinian people can live in peace, side by side within internationally recognised boundaries. That remains our foreign-policy objective in relation to the issues in Israel with the Israeli state and the Palestinian authority. We will not be taking steps to move our embassy. It will continue to offer diplomatic representation in Tel Aviv.

block-time updated-timeUpdated at 9.29pm GMT

block-time published-time 9.09pm GMT

Good morning

Welcome to the last scheduled sitting day of the year.

And it looks set to be one for the history books.

After years, YEARS, of faffing around, disappointment, ridiculous arguments and just straight-up stupidity, the Australian parliament is ready to pass marriage equality.

Bob Katter became the second last speaker (there were 120 or so MPs who spoke on this debate) overnight, and well, the less said about what he had to say, the better.

Today Warren Entsch will close off the speeches and then we move on to the amendment debate, for which Peter Dutton yesterday all but confirmed Tony Abbott's amendments don't have the numbers.

That is because the conservatives have been appeased by the Philip Ruddock review into religious freedoms. It doesn't mean it's over, just delayed.

But today is a day about getting it done. Finally.

With that in mind, make sure you follow Mike Bowers as he makes sure I get across the line. You'll catch him @mpbowers and @mikepbowers. I'll be watching the comments, but you'll have better luck catching me at @amyremeikis. Political tragics and those interested in Queensland political news can also follow along with my story here.

So with the world's biggest coffee in hand, I'm ready to get started. Hope you are too!

block-time updated-timeUpdated at 9.29pm GMT

12982 2017-12-09T21:15:00Z true 2017-12-06T21:09:41Z false false 2017-12-07T08:40:13Z true AUS theguardian.com [*https://gu.com/p/7yapz*](https://gu.com/p/7yapz) false true   [*https://media.guim.co.uk/4a0f33a796ec78c2c4d4cff79eb96a1d371cfcc1/0\_0\_4500\_2700/500.jpg*](https://media.guim.co.uk/4a0f33a796ec78c2c4d4cff79eb96a1d371cfcc1/0_0_4500_2700/500.jpg) false en OK, we are just about done for the day (and the year) but here is what your parliamentary chamber looked like, Australia. Just need to correct an earlier post: I said Scott Morrison voted yes but I was wrong - I am now being told he abstained. My apologies. So the abstain list (at this stage) includes: Tony Abbott Kevin Andrews Scott Morrison Barnaby Joyce. I don't think I saw Andrew Hastie in the chamber either but am happy to be corrected. A few more photos from the moment history was made, because Mike Bowers is amazing: Louise Pratt: I am incredibly proud today it to be part of the Australian parliament and to have, to have been part of delivering marriage equality in this nation. I have been an out MP in this country since 2001 and we have had many struggles inside Labor party. There is my girlfriend, come over here, come here, honey. I could not be prouder today. We have had to campaign for all of our life, for all of our rights in our relationship and finally that task is complete and we could not be happier, and I just want to say thank you to all of my comrades in the Labor party, particularly Rainbow Labor, who have given their heart and soul to make this happen. Absolutely. Thank you, Australia. And they fall out of shot hugging. It's a wonderful image to end the press conference on. Rodney Croome: In the course of all those years, I met many couples were no longer with us and who would say to me, they were grabbing by the arm and they would say please make this happen before it is too late. But, for them, it is too late. This day is for them. We heard the word gift used and, for me, this reform is a gift that we're all here give to the next generation, a gift of the quality and inclusion, for them to build a better Australia from. Ian Thorpe: Like the other people who have spoken today, today really is a momentous day for Australia and today I am proud to call myself an Australian, as much as I have any other day of my life. I realise what this means for young LGBTQI people, right across the country, for them to know that the person that they love, the way that they feel, is equal to that of anyone else and the change that that will mean for future generations is significant. So I would like to thank the parliament today, I would like to thank both sides of politics for really getting on with the day and doing what they said they would do. I am surprised, frankly. But it was amazing to see and it shows what can happen here, and that is what I am pleased to know, but I am really also very thankful for our straight brothers and sisters, who quite literally, without them and their voting for us, this would never have happened. And it means that we have created an Australia that is more equitable, more fair and more just, and it is the kind of place that more Australians want to see, so thank you everyone for what they have contributed to this and we got it done. Magda Szubanski: When I watched all of those people move to the yes side of the House, I thought Canberra was going to tip over. And for someone who grew up feeling on the brink of suicide, seriously, as so many of us have because we have felt unwanted, unliked, we fell below, to feel so loved now and to see that Parliament nearly tip over in support for us was an amazing feeling. And it was the people of Australia and all of us, I am sure, feel incredibly indebted and grateful to you that, when it was put to you, you had our backs. Thank you forever for that. Thank you so much. Thank you. Tim Wilson: Today, this is a strong message to every kid that is questioning their sexual orientation or gender identity, that you do not need to be afraid, that when you look to the nation's parliament, to our sporting heroes, and to the values that underpin this country, that you can be what you see. You see a country that is forward-looking, modern and embracing the idea that everybody has a place at our nation's table. Terri Butler: I am proud today to be an Australian, I am proud today that we have, as a parliament, acted to remove discrimination, and they certainly look forward to many, many weddings to come. Janet Rice: I am overwhelmed. It has been such a long time coming, from 2004 and well before that, the campaigning that has been done and what is so special about having achieved this today has been achieving it with the support of people from right across the political spectrum, with the support of people from right across Australia. Dean Smith, who just made history as one of only 30 (I think) private members' bills to pass the Australian parliament: People can be proud that over the last few weeks they have seen the best of their parliament, the best of their parliamentarians. He dedicates the day to young LGBTIQ Australians. You are OK, it will all be OK and this is a great country to grow up and be an LGBTI Australian. Alex Greenwich of the Equality Campaign: We came, we saw and love finally conquered... Marriage equality is finally the law of the land. From Mike Bowers to you: George Brandis has sent out a statement. He says that as of Saturday December 9 same-sex couples will be able "to lodge a notice of intended marriage to commence the one-month minimum notice period required before the solemnisation of marriages under the Marriage Act". That means the first marriages under this change can happen just a month later. Oh, and as for those religious freedoms? "Under the new laws, ministers of religion and religious marriage celebrants will be able to act in accordance with their religious beliefs about marriage. "Religious bodies will be able to act in accordance with their doctrines, tenets and beliefs in providing facilities goods and services in connection with marriage." Barnaby Joyce abstained. Peter Dutton and Julie Bishop voted yes, for those who were asking. \*correction: an earlier version of this post said Scott Morrison voted yes. He abstained I'm being told Andrew Broad was one of the voices who called for the division. But it led to this moment: Labor staff formed a guard of honour behind the Speaker's chair and gave an ovation to all the MPs leaving the chamber. Christine Forster said she will be getting a few bottles of champagne popped and few glasses drunk. She then remembers that her brother Tony Abbott offered to buy the drinks. She says she'll take him up on that offer. We are still working on the list of people who abstained. We couldn't see Tony Abbott or Kevin Andrews in the chamber. I can report the earth has continued to turn. There is a feeling of jubilation in this building. But I do have to acknowledge the mixed emotions that come with this. It has been a very long process and a very painful process for a lot of people. And this vote, while a long time coming, is not going to make all of those knots suddenly release, or all the pain disappear. But it's a start. Outside in the mural hall, the celebrations are on-going. Australia's parliamentarians are applauding the people in the gallery. Tony Smith moves the parliament on to other business but, really, who cares? OK. I'm crying. The gallery is singing "We are Australian". The chamber pauses in its applause to watch and sing with them. "That's it" is the final word from the floor. And the chamber erupts. The gallery erupts. I'm not crying, you're crying. Tony Smith is just letting the public gallery know that at the end of the division there are a couple of procedures to be done [so hold off on the celebrations]. For all my grousing over the division, it is wonderful to see the parliament divide. The no side is almost empty. Bob Katter is there, so is Russell Broadbent, David Littleproud and Keith Pitt. And because TWO voices said a division was required, the House divides. Because, sure. Let's drag out this moment for as long as possible. It is not as if we have waited decades, put people through a survey, a terrible debate, then another terrible debate on a bunch of stuff that had nothing to do with marriage equality to get to this point. We definitely need to spend these next eight minutes making the parliament divide for something that Australia was already forced to decide. Adam Bandt agrees the bill should be read a third time. "Love has won and it is time to pop the bubbly." He says he is going to keep it short because it is time for the bells to ring and the public gallery is doing all it can to not yell DUH. "When this bill is passed we should declare we are no longer a nation who voted no or yes, we are simply Australians all," Bill Shorten says. "Equality is never a gift to be given." Malcolm Turnbull is reminded to formally move the bill a third time. He does. Bill Shorten: Australia we are going to make marriage equality a reality in minutes. This time the public gallery is allowed to applaud, and they do, standing up and waving rainbow flags, their hands in the air. The chamber is also on their feet. Malcolm Turnbull is clapping. The gallery is singing. "I am, you are, we are Australian." Tony Smith reminds them that there is still the third reading to go. "What a day, what a day for love, for equality for respect," says Malcolm Turnbull. "It is time for more marriages, more equality, more love." The question now is this bill be agreed to. And it IS! We are talking lunchtime on free dress levels of chatter in the chamber right now. There is manic laughter coming from the floor. The final pointless amendment in this pointless debate is lost. Malcolm Turnbull spent the final division (on the yes to amendment side) telling a story that required a lot of arm-waving to Tanya Plibersek. This was the closest of the votes but it is won with Trent Zimmerman, Trevor Evans, Tim Wilson, Warren Entsch and Julia Banks (I know I'm missing some but they are the ones I can see) and most of the crossbench on the Labor side. Ayes: 63 Noes: 79 We are less than 30 minutes away from history, my friends. In other news, I can no longer feel my fingers. Or my face. It is the last division. We have spent about 55 hours getting to this point (in the parliament these last two weeks. My math is not good enough to add up all the years we have waited for this. This is why I am a journalist and make with the words and not the numbers). I have a conscientious objection to hearing that Labor was not allowed a conscience vote on these amendments, which have nothing to do with the marriage equality bill, and are yet to be shown to be needed. Sarah Henderson does not receive leave. WE ARE CLOSE PEOPLE Sarah Henderson seeks leave to put the question on the two amendments separately. NO NO NO can be heard from the Guardian office. And also the chamber. Speaking of people with a lot of fondness for their cycling mates, even if he doesn't want to marry them, Kevin Andrews gives, if there really is a higher power, his last speech today before the vote. (Not on this topic mind you. Because as I am sure you have heard me screaming from my desk, this is not the last time we will have this debate. It is not even the real debate. That is coming next year) He says if he is proven right and religious freedoms are torn to pieces in this nation when this bill receives its royal assent, and baby Jesus just won't stop crying, he hopes we have the courage and humility to admit we were wrong. I assume that goes both ways. Andrew Wilkie then says to all of those pushing the amendments in the name of religious freedoms and opponents of same-sex marriage: "You have had your day." "The time has come to give the LGBTI community freedom from religion," he says. Tim Wilson gives his final address on the debate. And brings it back to what this debate is actually supposed to be about. Not Jesus Not crocodiles Not the word G A Y Not safe schools Not electric guitars Not charities being stripped of tax free status Not boys in dresses Not procreation Not the fondness you feel for your cycling mates Not any of the other frankly ridiculous arguments we have heard in this nonsensical debate. We are removing the barrier and the boundaries which stop being enabling themselves to get married." We are coming to the end people. Tanya Plibersek makes the point that we are all going to remember where we were this vote happened. For me, that may be running screaming through the corridors. You know what the really great thing about all of this is? It's that we get to do it all again, when the actual debate on religious freedoms occurs next year, after the Philip Ruddock review is handed down. Isn't that just amazing? We get to do it all again. AND THEN SOME, because when it happens again, it will be for realsies, and not for the grandstanding ridiculousness it is today. Yet another reason to await 1 January 2018 with gleeful eagerness. Craig Kelly, who has upgraded his speech performance delivery from 'interrupting you and your mate debating at the pub', to 'yelling at you from his car window for cutting him off in traffic', has a problem with all the marriage celebrants who don't want to marry same-sex couples only having 90 days to register that wish. But, in a wonderful stroke of irony, he runs out of time to make his point. "Please excuse me, because we are a little paranoid we Christians, we have a history of being picked on, in a big way," says Bob Katter without irony or any sort of self-awareness that his contributions to this debate have done nothing but "pick on" the LGBTIQ community. "And we get a little bit paranoid, so please excuse me for getting a little bit paranoid today." A timeless statement from Bob Katter. I wish you could see Adam Bandt's face right now. He is listening to Bob Katter talk about boys being forced to wear dresses and is throwing Michelle Obama level side-eye. And, because this day has not had enough punishment, Bob Katter is back. We may have just heard Tony Abbott's last contribution on this debate: "We have heard contributor after contributor to these debates say that 'nothing in this bill will impinge on freedom of religion'." And if he had just stopped there, we could move on. But, of course, he does not. "Well, supporting this amendment is an opportunity to demonstrate the absolute fair-dinkumness (not a word) when it comes to those statements." Sigh. He then suggests passing this amendment, before sending the bill back to the Senate for agreement, and, in the meantime, everyone can go have a drink and then come back and "do it the right way". I very much want a drink. But I know a faustian bargain when I see one. Trent Zimmerman gets to his feet for the last time in this amendment debate to point out that this amendment actually extends discrimination. Which it does. Christopher Pyne then points out that the amendment is "based on a false premise" as the marriage equality change doesn't actually inhibit religious freedoms. "There has never been [any suggestion] that marriage equality somehow inhibits religious freedoms of either ministers of religion or religious organisations." You know where that is made clear? THE CONSTITUTION. I know the parliament is obsessed with section 44 but there are other sections to that document, including section 116. The commonwealth shall not make any law for establishing any religion, or for imposing any religious observance, or for prohibiting the free exercise of any religion, and no religious test shall be required as a qualification for any office or public trust under the commonwealth. Or, THE SEPARATION BETWEEN CHURCH AND STATE. Henderson says the amendment is to make clear that religious freedoms are prevented and the marriage equality change won't alter, interfere or prevent people from practising their religion. The second half of the amendment is to protect the civil celebrants who want to be able to object to marrying a same-sex couple, because of their beliefs, any beliefs, without the religious protections. How many marriage celebrants out there are happy to conduct weddings outside of a church but have massive issues with marrying a same-sex couple? We're all fine with Marriage at First Sight and Britney Spears getting married for 55 hours (never forget) but apparently we have a whole slab of marriage celebrants who have a massive problem with marrying same-sex couples? Sarah Henderson is on her feet, talking about this "historic day for this nation and this parliament". She then moves on to freedom of speech and freedom of religion. One more time for the people at the back - this has nothing to do with marriage equality. Malcolm Turnbull arrived to vote for that second part of the Andrew Broad amendment. The MPs have trudged back into the chamber to vote this latest amendment down Ayes: 60 Noes: 85 We now move on to the last-minute addition of Sarah Henderson's amendments, which are basically the amendments George Brandis attempted to get up in the Senate and lost. Because none of these amendments are getting up. We already know this. We have been told this. The people moving the amendments and speaking in support of them know this. That debate is to be had once the Ruddock review is handed down. Am I just typing into an abyss? Why is this still happening? As the latest division bells are called (thankfully without a contribution from Bob Katter or anything about electric guitar wielding home invaders) question time Emma Husar is all of us. Bill Shorten and Penny Wong just made a trip to the public gallery to shake hands. Everyone needs a bit of respite after some of the ridiculousness we have just heard Luke Howarth is using his time talking about an amendment that has nothing to do with marriage equality by again attacking Labor for not holding a conscience vote. Which, again, has nothing to do with marriage equality. Howarth says he is standing up for the 70% of Australians who said in the census they had a religion. Perhaps they received a different marriage survey form to me and everyone else I know, because none of this was on the ABS form I received. I am also pretty sure that changing the marriage act doesn't actually change the charities act or taxation legislation. You know what this vote, if we ever get to it, will do though? CHANGE THE DEFINITION OF MARRIAGE TO THE ONE AUSTRALIA VOTED FOR. His next amendments are to allow religious and faith-based organisations to be able to express their views, and not have their tax status threatened. "I haven't seen too many people on the LGBTI community ... become great social advocates like I have the religious community." This will be news to all of the LGBTIQ advocates and allies who have stood up for minorities, the vulnerable and just generally been a decent human FOR DECADES despite the amount of discrimination they have been subjected to. Including when homosexuality was illegal in states across the nation and police were raiding private homes to catch couples in the "illegal act" of being in love. Warren Entsch also has no time for this. "This is a marriage bill, this is not the time to be changing the charities act." The public gallery applauds and are told, again, to be quiet. Andrew Broad is now moving his second lot of amendments. He has moved on from electric guitars to Jesus. Parliament just became Bible class, but apparently we still need to talk about religious protections There is a lot of chatter as this division occurs. No Malcolm Turnbull for those keeping count. Ayes: 52 Noes: 86 Bob Katter managed to work out which side of the chamber he wanted to sit on, so that's something. Tony Smith just gave another warning to the public gallery. "It is very important that members of parliament ... are able to make their contributions without noise coming from the public gallery, it really is, on behalf of their electorates." To be fair, they have refrained from running from the place screaming, so I think they have shown some restraint. Andrew Broad is making his last ditch appeal for support for his amendment by talking about his daughter who is learning the electric guitar, and unfortunately, right now, she is not very good. He then relates his amendment to allowing his daughter to walk into any house she wants and play her electric guitar very loudly and very badly for as long as she wants "and you wouldn't be able to do anything about it". Because that apparently, is what freedom is. (I would think that trespass, breaking and entering and public nuisance laws would probably protect you from this apparent consequence of marriage equality, but it's been a while since someone burst into my house to play the electric guitar) "If you wouldn't give that freedom away in your own home, don't take it away from the churches and religious organisations of Australia," he says. The division bells are called. For some reason Bob Katter is now talking about how they couldn't afford to run candidates in every electorate in the Queensland election and how he only saw one ad for the no campaign. He wants to know where the money for that came from. I want to know why he is still talking, so we all have questions. Oh for goodness sakes. The "honourable" member for Kennedy may have just broken me. " I think you have a damn hide and an inflated opinion of yourself as well. The rest of the world would agree with me. "They took the word gay off us and now they are taking the word marriage of us." Bob Katter is now talking about how the marriage equality debate "makes no difference as far as I can see to anything" and then talks about the Queensland election, where he saw the primary vote for both the major parties drop to the 30s. "You've been talking about this all year... so congratulations." He doesn't mention that the survey was won with a yes vote of 61.6%. "I refuse to say the word G A Y," Katter says after saying he can't understand why people in relationships would want to call those relationships marriage. He then reads out the definition of gay, including beautiful, light, happy and ethereal. The gallery breaks into applause. "They are proud of it. I would be embarrassed to go around calling myself all these wonderful adjectives." I'm sure we'll hear about crocodiles any moment now but I really cannot spend any more time on his contribution. There are limits. I have found mine. Oh great. Bob Katter is up. This is just what this day needed. George Christensen begins his speech in support of the latest amendment that has nothing to do with the issue at hand, by criticising Labor for not having its conscience vote. Then he turns to the public gallery. "We have seen cheers from the gallery, cheering for the erosion of religious liberty." The public gallery breaks into applause. Warren Entsch points out that there are already protections in place for religious organisations and this amendment would extend discrimination. Mark Dreyfus makes a similar point. Barnaby Joyce just gave a very half-hearted speech in support of Andrew Broad's amendment. Where he commented on his marital status: "I don't come to this debate pretending to be a saint... I acknowledge that I'm currently separated, that's on the public record." Andrew Broad wants religious organisations to be able to keep "the vibe" of their beliefs within their own facilities. "What you believe is your own business and, if you pay for it, you should have the final say." Basically he wants churches and religious organisations to be able to turn down events they have objections to. So a church hall would not have to host a Safe Schools education night is the example Broad gives. Once again, in what is becoming a timeless statement in relation to this debate: this has nothing to do with marriage equality. The public gallery is getting antsy. They have just been asked to quiet down their conversations so the very important debate which has nothing to do with marriage equality (you know, the reason they are all here) can be heard. Just on this particular amendment, the Gold Coast Bulletin ran a story today about how the Queensland government was legally unable to do anything about a Milo Yiannopoulos event booked in a state-owned venue. The public gallery bursts into applause again before we move on to what I think are he second last amendments to be made, although Andrew Broad tells us he is going to be moving his amendments in two parts. Yay. The division ends with Ayes: 59 Noes: 82 I don't see Malcolm Turnbull or Julie Bishop in the chamber, so it looks like they are abstaining again. Scott Morrison is making his last stand on an amendment he knows will be voted down, by listing the faith leaders who have asked for the protection, which already appears to exist, on an amendment which has nothing to do with marriage equality. He then states his disappointment in there not being a conscience vote in the Labor party. Which just seems to be an even bigger waste of time, because a) this debate will be happening for real after the Ruddock review is handed down and b) EVERYONE ALREADY KNOWS THIS. The division bells are ringing. Trevor Evans is back and is very respectfully pointing out why his colleagues voting for this amendment are wrong. He reads from the letter from the charities commissioner on the issue: "In short, not legally necessary but could remove any legal debate." The Brisbane MP again, very respectfully, points out that the Ruddock review is the place for all of these discussions and he will be happy to revisit the conversation then. Kevin Andrews is so excited he can't help but wave around his hands and keeps hitting his microphone. This has as much to do with marriage equality as his current contribution to this debate. Kevin Andrews begins by pointing out that those who have said the amendment (Scott Morrison's amendment to protect faith based charities, which already appear to have protections) are wrong. Again, this amendment will fail. Because everyone knows that these things will be debated after Philip Ruddock hands down his review early next year, on religious freedoms in Australia. Also, the legislation in question is about changing the marriage act. Not changing the charities act. To be clear, this has nothing to do with marriage equality. Mood: We are just dealing with some administration stuff and then we'll be back to the amendment debate. Bill Shorten is called to the despatch box for the final question... but Malcolm Turnbull cuts him off by asking the rest of the questions be placed on notice. Shorten points to the clock (it is 2.57) but it is done. Craig Kelly has the final Dixer. He delivers it in his usual style of looking like he can't help but interrupt the debate you and your mate are having in the pub. It's on citizenship and, honestly, we spent enough time on this yesterday. Anthony Albanese is next to give Tony Abbott a chuckle: (Given how the amendment debate is going, I guess Labor figures he needs the cheering up) The member for Warringah once famously ordered the now prime minister to demolish the NBN. Given the prime minister's second rate NBN is plagued by cost blowouts, problems with speed and reliability and is subject to a record number of complaints from Australians, can the prime minister now proudly declare "mission accomplished"? Paul Fletcher takes this one: It is worth reminding the house that carriage of the NBN in the disastrous final days of the Rudd government, the downfall phase of the Rudd government briefly passed from the land of Conrovia, to the land of Albonia and the record that the shadow minister has to offer when it comes to NBN is atrocious, it's a clear comparison. We're delivering, getting on with the job, we're on track to getting this done by 2020. This lot has a hopeless record. You can't believe them, you can't trust them. (It is amazing how knowing when question time is actually going to end tends to speed up the answers) Christian Porter is next on the Bennelong election campaign shuffle. Tanya Plibersek is next with a question on the NBN: The prime minister promised every Australian would have access to the NBN by 2016. He also promised he would deliver it for $29.5bn. When will every Australian have access to the NBN like the prime minister promised and what will it cost? Malcolm Turnbull says the Labor party keeps "verballing" him on this. Let me read to you what was said in our policy document. "Our goal is for every household and business to have access to broadband with the download data rate of between 25 and100 megabits per second by late 2016." The timetable for the completion of the NBN and our policy was stated at p7, I recall, as 2019. The proposition that it was our policy and our promise to complete the NBN by 2016 is simply not consistent with the policy document we produced. Peter Dutton is asked a question about border security. Answer: Sam Dastyari and Kristina Keneally I forgot to update the Queensland count but Labor has held on to the seat of Townsville. That brings Annastacia Palaszczuk to 48 seats, giving her a small buffer if one of her MPs (like, I don't know, Jo-Ann Miller) decides to jump to the crossbench. The seat count is still not official but that should come soon. Under convention, the leader of the defeated party needs to concede before the government can claim victory. Tim Nicholls hasn't done that just yet. Christopher Pyne explains why both Sam Dastyari and Kristina Keneally are terrible and then we move on to the NBN again. Paul Fletcher reads from the usual statistics. Bill Shorten to Malcolm Turnbull: The prime minister promised every Australian would have access to internet speeds between 25-100 mega bits per second by the end of 2016. It's now the end of 2017 and 2 million Australian households have been told to wait even longer. Why has the prime minister failed to deliver the NBN like he promised?" Turnbull: The policy document was very clear and it said our objective was to get everyone to have access to 25 megabits per second by 2016. We did not say we would complete the NBN by 2016, in fact the policy document forecast a completion date by 2019 and will be completed, so the company says, the following year. After we came into government, we obviously had the first time to see what had happened at the NBN. It was our first time to examine the circumstances and we conducted a ***strategic*** audit, the results of which were published at the end of 2013. Armed with that information, it was clear that our objectives could not be achieved and we said so and we said why. The company was set on a new, more practical business-like course and it is getting on with the job and it will have three-quarters of Australian premises covered by June next year and it will be completed according to the company's forecast by 2020. We inherited a colossal wreck from the Labor party, hopelessly mismanaged, and what we have done is made the best with that. There's a lot of money that has been wasted by Labor we cannot recover but we're getting on and completing the project. Barnaby Joyce gets the next "vote 1 John Alexander" election ad dressed up as a Dixer. He doesn't seem very in to it and can barely work up enough of a yell for any more of his cheeks to flush. Michelle Rowland gives Tony Abbott a laugh with this question: I refer to the former prime minister, the member for Warringah, and his letter to Australia the day after the 2013 election: "I want our NBN rolled out within three years and Malcolm Turnbull is the right person to make this happen." More than four years later, can the prime minister confirm he's failed to deliver on the government's promise?" Malcolm Turnbull: A not entirely unfamiliar question and the answer will be more familiar so I'll be brief. As of the last weekly report, the NBN Co has 6,518,096 premises ready to connect and 3,282,093 are active paying customers. There were just under 80,000 premises added to the network in the last week. This rollout is proceeding at an extraordinary pace, unprecedented. The honourable member knows very well that we inherited a train wreck, created by her predecessor, Senator Conroy. We put in a thorough ***strategic*** audit shortly after the election in 2013, we changed the board, we put in new management and, since that new management has been in place, all of their corporate plan objectives have been met so they're on track to get the project completed as they said they would and they will, as they said they will, by 2020. The honourable member has raised in the past issues around HFC which represents a little over 5% of the network. That deployment has been slow for six months to ensure our customer experience is improved but the company assures us the project will still be completed in time as forecast. Trent Zimmerman authorises the latest Bennelong by-election ad for John Alexander, in a dixer to Julie Bishop: "Will the minister update the house on how the Government's economic diplomacy agenda is benefitting Australian businesses, including those in the electorate of Bennelong?" Bishop: Kristina Keneally can not be trusted Andrew Wilkie has the cross bench question today: "My question is to the Prime Minister. A backbencher gets a quarter of a million dollars in wages, superannuation and vehicle. Big business is still being promised a tax cut and now you're promising income tax cuts but at the same time, people relying on Government pensions and payments are struggling terribly. "For example, it's not unusual for a single aged pensioner to go without meals and medicines in order to pay rent. Indeed, according to a recent survey, 61% of pensioners go without necessities, including fresh food. Do you really think this is OK, Prime Minister and when will you start talking about increasing Government pensions and payments to sensible levels?" Malcolm Turnbull: "I thank the member for his question. We all know that there are many Australians not just in Denison but across the nation that are doing it tough. We know how hard it can be for many of our pensioners and for those who rely on the social welfare safety net. "In the 2017 Budget, the honourable member will recall we introduced a one off energy assistance payment for around 3.8 million Australians. That payment was $75 for singles and $62.50 for each member of a couple." He goes one and Wilkie interrupts to ask what is happening in the future: "As a result of our changes, more than 90% of pensioners are either better off or have had no change to their position. The pensioner concession card was reinstated on 9 October to approximately 92,300 pensioners whose entitlement ceased on 1 January due to the rebalancing of the assets test measure and that included 453 pensioners in Denison. We're committed to ensure our social welfare safety net supports those most in need and we want to - I want to state again our respect and our thanks to all our senior Australians who have built our great nation and to whom we owe so much." From a little earlier, here's how the afternoon arrangements were worked out. Bill Shorten to Malcolm Turnbull: This year the prime minister has lost three ministers, lost multiple votes in parliament, cancelled parliament, announced a tax hike for seven million Australians, cut penalty rates for 700,000 workers, ruled out a banking commission and then announced it and made two million premises wait longer for the NBN. Given the prime minister has spent 2017 hostage to his backbench and to events, why should Australians believe 2018 will be any better? Turnbull: Sam Dastyari Not content with a press conference which included slides, and the world's longest press statement, Scott Morrison has now taken a dixer on the national accounts. Bill Shorten to Malcolm Turnbull: Next week the royal commission into institutional responses to child sexual abuse hands down its final report. Will the prime minister join me to acknowledge the survivors of child sexual abuse for their courage in giving evidence, thank the royal commissioners and their staff for their efforts to expose responses on child sexual abuse and in the nation's parliament? Will he join with me in committing to ensuring survivors get the justice and the real redress they deserve? Turnbull: We thank and we honour the courage of the survivors who bravely told their stories to the royal commission. We thank the royal commissioners and their staff for the long hours and the very hard hours, the very emotionally draining hours that they have spent listening to those stories, comforting the survivors. We honour them and we believe them. That is the most important thing you can say. I remember years ago when prime minister Rudd and I made a statement of apology to the survivors of institutional care, the forgotten Australians, often described. The words they wanted to hear most of all was that they, after a lifetime of being ignored and neglected and pushed away, they were believed and that the charities and churches and governments that had done them so much wrong were going to be held to account. Justice, honesty, transparency, that's what the royal commission has been delivering. I want to thank the commissioners, I want to thank above all the survivors. We believe you, we love you, we will stand with you. I missed this earlier: The first Dixer is an election ad for John Alexander Bennelong's by-election. And we have had our first mention of Kristina Keneally. Although she has apparently become "she who will not be named" as she is referenced, but not identified. It's the last time we'll be doing this, this year. Bill Shorten starts by asking Malcolm Turnbull to defer question time so the marriage equality vote can be brought forward. Short answer - no. Turnbull: This must be the first time the leader of an ***opposition*** has asked that question time be abandoned. It must be the first time. I wonder why. I'll say this, Mr Speaker: in the course of this week, many hours have been taken up with Labor party motions about citizenship and penalty rates, matters that could properly have been dealt with after marriage had been dealt with, but no, the Labor party rushed their motion in in the hope that they would get it voted on before the member for New England made his return. That bit of fancy footwork slipped up. The government is accountable in question time and so is the ***opposition*** so we will all be accountable in question time today as we are every day that parliament sits. I will say this to the leader of the ***opposition***: I'll ask further questions be placed on the notice paper at 3pm, which is when the broadcast finishes. The last speaker before the debate break is Tony Abbott. He continues the pattern of talking about things with nothing to do with marriage equality legislation. He can't imagine a world without the hospitals, charities, schools and other great works of our faith-based organisations. "It is their faith that drives them, they do it because of their faith motivation and part of that faith is that marriage is between a man and a woman, preferably for life and usually dedicated to kids. "Once same-sex marriage is enshrined in law, on public policy grounds, organisations don't recognise same-sex marriage could indeed be subject to some kind of official sanction. "Overseas this has happened. Catholic adoption agencies have been forced to withdraw their services. Orthodox Jewish schools have had their funding threatened. American Christian colleges have registration refused to their law graduates because of their teaching on marriage..." (Note from Amy: I just have to insert in here that one of the reasons these cases have popped up in America is because they have a bill of rights, enshrined in their constitution. Many of these cases have been examined in the light of how they meet those constitutional rights. Australia does not have a bill of rights. It is not apples and apples.) "Don't think that it can't happen in this country. It already has. I recall, as employment minister in 2003, finding a human rights commissioner threatening faith-based employment agencies because of their own employment practices. And if that threat had been acted upon, they would have had to withdraw their services. So these amendments are important and, I stress, they are not against same-sex marriage, they are simply in favour of the rights of religious organisations to keep doing what they have always done in the great interests of the Australian people." And we are on break from one of the most ridiculous last stands ever, until at least 3.15. Christopher Pyne is explaining this afternoon's proceedings. The debate will end at 1.30. People book in for question time, so the public gallery will have to be emptied, so those people can take their seats. Pyne says the debate will resume after the matter of public interest debate. That debate today is from the ***opposition*** on the topic of the need to bring the government down. Tony Burke jumps up to say that Labor will delay speaking about the need to bring the government down until February to ensure that the debate can continue straight after question time at 3.15pm. We won't get through this amendment then. Then there is the last couple to go. Don't expect a vote until later this afternoon. Mark Dreyfus is now explaining why the amendments aren't needed, as the current charities legislation already includes these protections. I feel compelled to add that this amendment has NOTHING TO DO WITH THE LEGISLATION UNDER DEBATE. We may get through this unnecessary and doomed-to-fail amendment before question time. But then we still have a couple to go before we get to the vote. Warren Entsch is explaining that the amendments aren't needed. He also points out the bill has been out for four months for consultation and the amendments should not be rushed into. What is clear is these amendments are they are completely unnecessary, they certainly carry risks and they should be opposed. Nicole Flint is speaking in support and repeats the now common line that while the change to the Marriage Act is the will of the Australian people, we "must remember" to protect the views of all Australians. Again, I don't remember voting on anything other than marriage equality in the survey. If someone has a different form, which included a question on religious and conscientious freedoms, please send it to me so I can take it up with the ABS. While Scott Morrison talks about the great faith works, let's look at some Mike Bowers magic from inside the chamber Scott Morrison is next to watch his amendments fail. He wants to make sure that faith-based charities can continue to object to marriage equality without fear of losing their charitable status. The Alex Hawke amendment goes down: Ayes: 59 Noes: 87 Still more laughter and good times coming from the no-to-amendment camp. The division has been called and Malcolm Turnbull has walked in. He is sitting with the yes to amendment camp. As the latest division voting down the latest unnecessary amendment goes on, I am loathe to report that Sarah Henderson has just added another amendment to the list. Henderson is voting in favour of marriage equality, but has added ANOTHER amendment doomed to fail, to protect all those civil celebrants who love marrying people outside a church but have conscientious objections to same-sex marriage. This means we won't be getting to a vote until late this afternoon now. Probably a couple of hours after question time. Lo and behold, this debate has me agreeing with Andrew Laming again. "As far as I am concerned the armed forces are an apparatus of the state. The state has agreed to a broadened definition of marriage. If you are a seconded religious chaplain from the church, an exemption exists for you. But if you are not, you are part of the state's apparatus, that is the armed forces, you follow a chain of command. "This is a matter for the Chief of the Defence Force. If they are marrying, they are receiving a state salary and they adhere to the law of the land. I am not in favour of these exemptions trickling through the armed forces and you would know very well, as I did, I did not go to Afghanistan with a body armour, a pay packet and the will of the Australian people, I went as a volunteer, but I know when I got there, there wasn't a lot of conscience thinking when you are serving in the armed forces. "If you are chaplain, you have the possibility of religious exemption, if you are seconded from a church. You are taking a state salary, from a nation that allows marriage in all its forms, between two adults and that is what you can do as part of your service, otherwise you can leave the military." Look, I am not saying the world didn't actually end in 2012, but I am not, not saying it either. This is the second time Laming has been one of the MPs to make the most sense in talking down these amendments today. Wait, Alex Hawke surprises, by not only moving his amendment that will be voted down, and is probably not actually needed, but by then spending time attacking the ***opposition*** for not having a true conscience vote. He wants military chaplains to be able to refuse to carry out same-sex marriages on religious and conscientious belief. Because even though he disagrees with his colleagues, he respects that they can debate it and "have a genuine disagreement" on some issues. And he is most upset that Labor is not having that same genuine disagreement. "This is your chance, this your moment, this is where the leader of the ***opposition*** can step up and show some leadership." We are hearing again about the no voters and why their views need to be protected. Again, I would have enjoyed hearing how passionate Hawke would have been in arguing to protect the rights and views of yes voters, if this had gone the other way. Terri Butler again argues against the amendment, saying she doesn't want to be here any longer than she wants to, but "more importantly" the people of Australia don't want it to take any longer. The public gallery applauds. They are told to be quiet. Butler then points out the bill has also already addressed this issue, by creating a secular position of 'marriage officer' and she can't understand why someone with religious or conscientious beliefs against marriage equality, would sign up to be a secular marriage officer in the first place. Next amendments on the chopping block are those of Alex Hawke. He is going to say that the amendments are straightforward and will improve the bill and are needed to protect the views of those who do not support same-sex marriage. Then those who are against them (which right now is the majority of the parliament) will point out that now is not the time for these amendments and besides, the amendments are not needed as what they seek to protect is already protected and adding to those protections is legislating discrimination (essentially). We'll spend more time than we need to on it, the divide will be called, the amendment will be voted down and we will move on. The chamber has divided on Andrew Hastie's amendments: One thing is clear, the no side certainly has a lot more colour. And chat. Ayes - 56 Noes - 87 Looks like the prime minister is abstaining again. Meanwhile, outside in the "real world", where Australia voted in favour of marriage equality (and that was it) in the survey the government forced on everyone, among those waiting on the vote is 10-year-old Cully. Those in favour of the amendments seem to think that along with ticking yes for marriage equality, supporters of same-sex marriage also ticked yes for "protecting religious freedoms'. That particular question must have been missing from my form. That is not to say that the debate shouldn't happen. It will, regardless of whether it should or not. It's set in stone as part of the Philip Ruddock review. But flagging it here, when most of the amendments have nothing to do with this legislation, is pointless. Trent Zimmerman makes the very obvious point that all these religious leaders who feel the need to speak out against marriage equality and hold on to their traditional views as tightly to their bosom as they possibly can, already have those protections. Andrew Hastie says the spirit of his amendment is to protect the views of the 39% of Australians who voted no. I am very, very sorry we won't ever get to hear his impassioned defence of the Australians who voted yes, if the survey result went the other way. To be clear, it is just the House lighting that does this. And for those asking, here are the MPs who voted for the amendments. Here is what it looks like when the parliament (largely) works together. Cathy McGowan stands up to ask for members to remember that regional Australia, which is constantly being pointed to as wanting to respect "traditional marriage" given that it is usually used as the example of "real Australia" by conservative politicians when making their points, "voted overwhelmingly in favour" of marriage equality. "The day you start to cherry-pick which human rights are important is a dangerous day," says Kevin Andrews, as he now cites the UN for not having a hierarchy of rights. Yes, you read that correctly. Kevin Andrews just referred to the UN. There was laughter from the gallery as he said it. Can't for the life of me understand why. Adam Bandt smacks down Tony Abbott's attack on safe schools and receives applause from the public gallery Christopher Pyne stands up to say he doesn't want to be the "Christmas grinch" and he understands everyone is excited, but they need to settle down. Kevin Andrews is now talking about protecting human rights. We have three more amendments to go after this. Sigh. Tony Abbott has risen again to support the Hastie amendments. He brings up Safe Schools. Which a) has nothing to do with this legislation; b) is deliberately misrepresented for political purposes; and c) was rolled out under his government; and d) HAS NOTHING TO DO WITH THIS LEGISLATION. He has another go at Malcolm Turnbull for not putting religious freedoms in place before this vote. He then does the parliamentary equivalent of yelling at clouds, by wondering why the House is so concerned with what the Senate decided. "What would Paul Keating say?" he says. Meanwhile in Queensland, the Greens are celebrating winning their first seat in the state parliament. Michael Berkman took the seat of Maiwar from the LNP Lucy Wicks is standing to support Andrew Hastie's amendments. Tim Wilson can be seen waving to the public gallery behind her. You can guess which interaction those in the gallery are enjoying more. Again, if you want to see the amendments being put forward, you can see them here. They are very similar to the ones which were voted down in the Senate. All of the amendments will be voted down. This is just a taste of what we are in for when the Philip Ruddock review comes down next year. Basically, everyone is putting their views on the record as a symbolic gesture now, and indicating where the battle lines will be drawn once that review is handed down. Meanwhile, Tim Wilson, Trent Zimmerman and Craig Kelly are looking as though they are having best time ever behind Wicks. Terri Butler explains why Labor won't be supporting the amendments. One - because it is delaying the vote and everyone has waited long enough Two - because any big changes to Australian law should be properly considered and consulted on. That sound you hear is Malcolm Turnbull dusting off his leather jacket - the PM has been confirmed as the guest on Q&A next Monday. Andrew Hastie is moving his amendments now. He keeps talking about protecting "traditional marriage". For a reminder, here is what he believes "traditional marriage" is for: Warning: what has been heard can never not be heard. The division result is in: Ayes - 43 Noes - 97 There is applause from the public gallery and from some of those in the chamber who voted against the amendments. Looking at the chamber, it is quite amazing to see so many Coalition and Labor MPs on the same side. Given the laughter coming from that side of the chamber, they know it. From the chamber: Just ducking out of the chamber to update you on other matters - Andrew Leigh has criticised the appointment of Gary Johns to the ACNC: Mr Johns has been a foe of charities and he has been one of the strongest critics of charities in Australia. He has attacked Indigenous charities, he has attacked mental health charities and he has attacked charities that attempt to engage in advocacy. That's the thing about this government, they have a "charities should be seen and not heard" approach. They think that charities are OK so long as they're running soup kitchens, but once they start talking about poverty and inequality, they're overstepping their mark and they should go back to the kitchen. It's that sort of anti-advocacy approach in legal charities, in environmental charities, in social service charities that characterises the worst aspects of this government sand which characterises Gary Johns' views on charities throughout his career. A leopard doesn't change its spots. Gary Johns will not cease being a foe to charities in this new role. Charities will be horrified by this appointment. This is somebody being appointed to head the charities commission who is a critic of theirs, not a supporter of theirs. This is like putting Dracula in charge of the bloodbank. It's like putting Ned Kelly in charge of bank security. The public gallery has been told to calm down the clapping. But the feeling, we are told, is electric. It is absolutely packed in there. Poor Michael Sukkar tried to defend his amendments (which are in the process of being voted down in a division) but all attention was on Kate Ellis's newborn baby Charlie, who is also in the chamber. He looked almost disappointed to have his moment overtaken by a baby. Trevor Evans has also spoken out against the amendment to alter the definition of marriage to essentially two categories, marriage between a man and a woman and marriage between two people. Evans asks his colleagues who are in support of the amendment whether those two categories are equal. And whether it is a legal change or a symbolic one. If this is symbolic, then this is a pointless and unnecessary amendment with no legal effect and there is no justification to support it. Pointless regulation is illiberal regulation. This government is philosphically opposed to pointless regulation. Our statute books are not the place for symbolism and gestures; we have Sky News for that. The Liberal MP Trevor Evans then summed up why the amendments were bupkis: To best understand why these amendments are ill-considered, let's remember how this bill formed its current positions. Both with respect to the definition of marriage and on celebrants. This started as a government bill. An exposure draft prepared by our attorney general, it subsequently went through a Senate committee, a comprehensive process, with extensive consultation with many of Australia's religious organisations and other community leaders and organisations. Four hundred submissions. 40-something witnesses and significant scrutiny by all of those senators and that consultation led to a unanimous set of findings. That is unanimous agreement from senators across the political spectrum, including government senators. So what is proposed in these amendments goes against the informed and unanimous findings of those senators from right across the political spectrum. And given these amendments are essentially the same as those defeated recently in the Senate, they should be rejected again here, for similar reasons ... To be clear, the bill in front of us protects civil celebrants. The bill allows existing civil celebrants who have strong religious beliefs against same-sex marriage to identify as religious marriage celebrants, which then gives them the right to refuse to solemnise same-sex marriages. What the amendments propose to do is create a carve-out which would be ongoing and would allow not just religious objections to same-sex marriage, but non-religious objections as well and, to be clear, that approach has been strongly rejected by the associations representing civil celebrants. I have taken the time to meet with some of them to confirm this; the civil celebrants' organisations do not want this. Tony Abbott has risen in support of Michael Sukkar's amendments. No surprise there. These amendments are not designed to frustrate this bill, they are not designed to delay this bill, they are designed to improve this bill and make this bill a unifying occasion, as unifying as can be, under all the circumstances. "Almost 8 million Australians voted yes, almost 5 million Australians voted no, all Australians, whichever way they voted, deserve to have their views respected and as far as is possible, accommodated in the legislation. "I suspect that many of the 8 million who voted yes did not want to exclude traditional marriage, they simply wanted to embrace same-sex marriage too. (Note from Amy: because Tony Abbott has obviously proven to have his finger is on the pulse on this, and so many other issues.) Then Abbott had his dig at Malcolm Turnbull: In the course of the campaign, when both the prime minister and the leader of the ***opposition*** pledged that before same-sex marriage became law there would be adequate freedoms of conscience, religion expression in place, that is simply what these amendments seek to do. To make the words of the prime minister and the leader of the ***opposition*** become a reality. Adam Bandt's contributions are proving quite popular with the public gallery. He and Anthony Albanese got into a little verbal skirmish earlier, when Albo, who explained that Labor would not be supporting the Greens amendments because "you can't always get what you want, but you can get what you need", said he was part of a major party because it supported things which were important to people. He was criticising the Greens amendment to change the name of the bill to reflect marriage equality. Albanese said that what wasn't important to people, and it was taking up time. Bandt fired back that the only reason we were here was because Labor supported John Howard's change to the marriage laws, and he would not be lectured. But we have moved on. The public gallery is packed. There is a pretty big feeling of anticipation in this building today. Everyone is waiting on that final vote. The Greens amendments are voted down on the voices. Now to the amendments from Michael Sukkar. These will also be defeated. There are four other amendments after this - you can find them here. All of them will be voted down. There is also a loose agreement to keep speeches against them short. For those playing along at home, you can follow the bill's progress here. At this stage, it looks like we will get a vote just before question time, or just after. All the amendments are being quickly dealt with and dismissed by both major parties, who are very firmly of the mind that it is time to "just get it done". As for the need for protections, Trevor Evans has made his views clear: Australia is not America... the case for the homophobic baker in Australia remains unfulfilled. Evans said he doubts a case like the US is now dealing with would be seen in Australia, because, basically, he doesn't think anyone would be bothered - they would just take their business elsewhere is the basic gist. The Labor MP Terri Butler moved to the other side of the chamber to support Warren Entsch and the other members of the Coalition's "rainbow rebels" who helped move the bill through the party room, while Senator Dean Smith watches. The Greens have responded to the US decision to recognise Jerusalem as Israel's capital. From the party statement: The Greens condemn in the strongest possible terms US President Donald Trump's decision to recognise Jerusalem as the capital of Israel and relocate the US Embassy from Tel Aviv, said Leader of the Australian Greens Dr Richard Di Natale. Australia now stands alone in its craven refusal to join those in Europe, Asia and the Middle East in standing against this move, which will devastate the peace process. "This decision by President Trump is a body blow for the peace process and for the Palestinian people," Di Natale said. "Trump's announcement has been universally condemned - by the United Nations, European and Middle Eastern leaders and religious leaders. "Yet the Australian Government stands alone in maintaining that this is a matter only for the United States. "It is shameful that Malcolm Turnbull cannot even display the leadership to stand with our allies in Europe and Asia to publicly urge Trump not to proceed with this deeply unfair and dangerous decision. "If it wasn't enough to see Donald Trump's inflammatory tweets on North Korea, or his decision to pull out of the Paris Climate Agreement, surely this latest move is all the evidence needed to prove that we are shackled to an unhinged ally intent on making the world far more dangerous." \*end statement\* Julie Bishop has repeated her confirmation from yesterday that Australia would continue to keep its diplomatic presence in Tel Aviv. Labor has also given its support for Australia's position. The Petrie MP Luke Howarth's decision to retweet this, then, has raised a couple of eyebrows: This week Labor announced it would not support the extension of the cashless welfare card to any other communities unless there were amendments. Here's Alan Tudge reflecting on that on 6PR Perth radio: I am so deeply disappointed, because Labor has people that have been there. They know the issues. They know the damage which alcohol does, paid for by the welfare dollar. They know the impact which this cashless welfare card is having on the ground up in the east Kimberley, and yet they have clearly got too much pressure from their Melbourne and Sydney representatives who are scared about the Green votes in Melbourne and Sydney, and so they are willing to chase those votes and abandon the children in the Goldfields and abandon the women. That's what they are doing. I am flabbergasted, I am disappointed, but we are not going to let them slow us down because the leaders there, including Rick Wilson, the federal member, have been so strong on wanting to give this a go there to address some of the issues there, and so we are going to press ahead. We wanted bipartisan support for this. We are not going to get that now, but we will press ahead nevertheless and back those community leaders, back the children, and back the women. Here is what the man himself has to say about his amendments. Warren Entsch commends the bill to the house and there is a smattering of applause. Tony Abbott's amendments, designed to protect "religious freedoms", which critics have called an attempt to "legalise discrimination" were moved and lost on the voices. Abbott did not call for a division. So it looks as though the intervention to separate the amendments from this bill, and instead have them dealt with by the Ruddock review within the Coalition party room, worked. The pious debate would have have delayed the marriage equality legislation vote considerably - and potentially have made the parliament sit longer to make sure the government could meet its promise to legislate by the end of the year, which is why there was an intervention in the first place. The house has moved on to other amendments, including the Greens amendments to ensure civil celebrants can't reject same-sex marriage. These will also fail. The Dean Smith bill will go through unadulterated now. Warren Entsch is calling out Bob Katter for his speech. Katter left the chamber as Entsch began. He can barely hold back his fury. Here's Entsch: This was parliament at its best, with so many people on their feet, standing up for what they believe is right and doing is in a dignified and a very, very respectful manner. However, there was one contribution - and I'm disappointed to see that he has left the chamber - that was the exception and it deserves special mention, and that was the contribution of the member for Kennedy, Bob Katter, who was the last speaker on the second reading last night. His pathetic attempts to humour, insensitivity and grossly misleading comments were devoid of any facts and were highly offensive, embarrassing and cringeworthy. They need to be called out for what they are. His speech exemplifies what the LGBTI community have had to endure for so long. I've got to say that member for Kennedy's speech needs to be taken in isolation and does not represent the views of the parliament and certainly does not represent the views of the overwhelming majority of Australians. Entsch also says no amendments to the bill are necessary. This bill gives so much and takes from no one. The Queensland MP has taken the floor to give the final speech on the marriage equality legislation. He is wearing his rainbow tie again and holding back tears. Oh boy. Michael Sukkar has just confirmed that Dr Gary Johns will take over as the full-time commissioner of the Australian Charities and Not-for-profits Commission, and well, though he might be a former Keating government MP, his views haven't exactly endeared himself to the sector over the years. Here he is referring to Indigenous women as "cash cows". And here he is on LGBTI rates of depression. Johns has made his opinions made on quite a few points over the years. Expect a lot of people to have a lot of opinions on this appointment. Bridget McKenzie's ***win*** also means she will be elevated to the cabinet. We'll let you know what portfolio she'll hold when we hear. She gave a brief speech in front of the media and paid homage to Fiona Nash, who previously held the post, before she was found to be ineligible by the high court for being a dual citizen: I would just like to briefly mention Fiona Nash, a great friend and a colleague, who yesterday [had her return] ruled out and I guess, um, Nashy, I love you. And I can't wait to get on the golf course with you as soon as possible, and I know Fiona has a great future in public service in whatever field she chooses. But I guess I would like to say thank you to my party room. Now it's about getting on with the job of delivering for regional Australia within the Coalition government." McKenzie was referring to the high court handing down its reasons for finding Hollie Hughes ineligible to fill Nash's spot (short version, when George Brandis appointed her to the AAT, he ruined her chances under section 44 to fill the Senate spot) and that will most likely see Jim Molan fill the spot. But don't rule Nash out. She might not fill that Senate spot, but most believe she'll be back - and sooner rather than later. And the winner of the Nationals deputy ballot is ... Bridget McKenzie (Entirely my fault that her name was left of the original post on this - when I went to bold her name, I accidentally ***deleted*** it and my tired brain didn't pick that up until right now.) Penny Wong is ready for the vote. Beyond ready I would say. We will wait for the vote but judging by the people who have spoken we are in a good place. Obviously, if not all, then the overwhelming majority of Labor will be supporting and we will have enough Liberals and crossbench people to get it over the line. It will be the end of a very long journey. It's an outcome that will have been achieved because of the Australian people and in this, as I said in my third reading speech, we are their representatives but they have been our leaders. They have demonstrated grace and decency and I hope we demonstrate that today. The Queensland election race has not officially been called but Labor has its majority, with Annastacia Palaszczuk winning the 47 seats she needs for a majority government. That has led the Queensland senator and federal resources minister, Matt Canavan, to lash out, again, about Palaszczuk's decision to veto the billion-dollar rail line loan. Speaking to the Courier-Mail, Canavan accused Labor of "racism" and "xenophobia" in making the decision. The Labor party has a long and colourful history of xenophobia and racism and this is just the latest chapter in that book. If it was a British company building this rail line, or the Australian government building the rail line, I don't think we would have the controversy it has attracted. It's down to that it is an Indian company. A spokesman for Bill Shorten returned fire, telling AAP: Matt is clearly unhinged and lashing out." Adani is still waiting on funding for its Queensland mine. After saying it did not need the federal government loan to move ahead, it has since changed tack and said it does. There were reports it was set to receive Chinese funding, but Bob Carr, who has been lobbying Chinese organisations on behalf of the Australian Conservation Foundation, said on Wednesday he had it confirmed from the Chinese embassy no funding commitments had been made. Palaszczuk has confirmed the veto against the loan stands and said she will not facilitate any taxpayer funds being spent on the mine. Adani was one of the biggest issues in the Queensland election campaign, with the veto dominating much of the first half of the campaign, before being judged as helping Labor ***win*** Brisbane seats, which in turn, helped it ***win*** the election. As I said, Bob Katter was the last speaker on the marriage equality bill overnight. It went places. And all of them were terrible. I'm only going to put a little of it here, and only for context, because I expect Warren Entsch, who is from a similar part of the world as Katter, will want to correct the many, many wrongs in this speech. Here's a taste: The people advocating this proposition tonight, the LGBTIs, have maybe 60 years on their side. I have 3.5m years of genetic programming on my side, because we human beings, they tell us, have been around for 3.5m years. One thing that is absolutely certain is that we've all developed from heterosexual couples. That is one thing we know absolutely - up until the last 40 years, anyway. So, genetically, we are programmed that way. If you want to make a young lad between the age of nine or 10 and 15 go to school wearing a dress, you'll seriously mess with his head. If you are looking for reasons why, there are distinguishing factors of the incredible race of people, as I call us in my book - and I think we are. We always get there in the end, but, jeez, we run off the rails badly at times. If you analyse why this country continuously has the highest male juvenile suicide rates in the world - why is that? - there is something going wrong here. We have an extraordinary incidence of homosexual behaviour in Australia compared with other nations, and I think the people who have been speaking for this bill would agree with me on that. The action started early this morning. The Equality Campaign held an event at 7am with ambassadors Magda Szubanski, Ian Thorpe, Daniel Kowalski, Prof Kerryn Phelps and Christine Forster on the lawns outside parliament. There was dancing but also a serious message - get the vote done. Understandable, really. Barnaby Joyce is back and he's looking for a deputy. Basically the entire Nationals party room has put up their hands. The ballot is at 9am, with a result at 9.30. Look out for the battle between Matt Canavan, Nigel Scullion and Michael McCormack. Donald Trump has confirmed diplomacy's worst-kept secret- he has decided, despite warnings from almost every Middle Eastern ally, to recognise Jerusalem as the capital of Israel. It took about 39 minutes into his speech to get there, but he says it is "the right thing to do". Australia doesn't agree. Julie Bishop hasn't criticised Trump but she has made clear Australia will be sticking with Tel Aviv and, this morning, reiterated what she said yesterday. The Australian government is committed to a two-state solution whereby the Israeli people and the Palestinian people can live in peace, side by side within internationally recognised boundaries. That remains our foreign-policy objective in relation to the issues in Israel with the Israeli state and the Palestinian authority. We will not be taking steps to move our embassy. It will continue to offer diplomatic representation in Tel Aviv. Welcome to the last scheduled sitting day of the year. And it looks set to be one for the history books. After years, YEARS, of faffing around, disappointment, ridiculous arguments and just straight-up stupidity, the Australian parliament is ready to pass marriage equality. Bob Katter became the second last speaker (there were 120 or so MPs who spoke on this debate) overnight, and well, the less said about what he had to say, the better. Today Warren Entsch will close off the speeches and then we move on to the amendment debate, for which Peter Dutton yesterday all but confirmed Tony Abbott's amendments don't have the numbers. That is because the conservatives have been appeased by the Philip Ruddock review into religious freedoms. It doesn't mean it's over, just delayed. But today is a day about getting it done. Finally. With that in mind, make sure you follow Mike Bowers as he makes sure I get across the line. You'll catch him @mpbowers and @mikepbowers. I'll be watching the comments, but you'll have better luck catching me at @amyremeikis. Political tragics and those interested in Queensland political news can also follow along with my story here. So with the world's biggest coffee in hand, I'm ready to get started. Hope you are too! 73557 false The ayes. The nos. Cathy McGowan, Adam Bandt and Andrew Wilkie celebrate. Celebrations after the bill to amend the marriage act passes through the House of Representatives. Penny Wong celebrates. As the bill passed... And the party goes on. The final division. Celebrations after the bill to amend the marriage act passed. As the public gallery sang... The Liberal MP Warren Entsch lifts up Labor MP Linda Burney as they celebrate the passing of the marriage amendment bill. Penny Wong blows a kiss to the gallery. Mwah The member for Indi Cathy McGowan passes senator Jordan Steele-John The prime minister Malcolm Turnbull as the debate on amendments to the marriage amendment bill continues The member for Lindsay Emma Husar and the member for Longman Susan Lamb during question time Labor's Stephen Jones, Claire O' Neil, Ed Husic and Tim Hammond during question time. Rainbow socks belonging to the feet of Mark Dreyfus and Jenny Macklin during question time. Leader of the house Christopher Pyne and the manager of ***opposition*** business Tony Burke talk to speaker Tony Smith Mark Dreyfus and his rainbow socks during a division on amendments. The leader of the House, Christopher Pyne, with Anthony Albanese during a division. Votes are counted on amendments to the bill to amend the marriage act. Cully 10, from Rainbow Families ahead of the debate Tony Abbott speaks on amendments to the bill The yes amendment voters The chamber divides on amendments to the bill to amend the marriage act Josh Frydenberg talks with Michael Sukkar, Jason Wood and Craig Kelly as debate winds up on the bill to amend the Marriage Act. Tony Abbott leaves the house as debate winds up. Kate Ellis arrives with Charlie. Warren Entsch, surrounded by supporters from both sides of the house and watched by Senator Dean Smith, as debate winds up on the bill to amend the Marriage Act.

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[***Doing Politics in the Recent Arab Uprisings: Towards a Political Discourse Analysis of the Arab Spring Slogans***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:6BH2-VXY1-JBMY-H3YR-00000-00&context=1516831)

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**ABSTRACT**

The present paper aims to analyse a number of those slogans collected from the sit-in quarters in Egypt, Libya and Yemen. Using political discourse analysis, it unravels various typical discourse structures and strategies that are used in slogans in the construction of a sub-genre of political discourse in the Arab world. Drawing data from several mediums, including banners, wall graffiti, audio-visual instruments, chanting, speeches and songs, this paper tries to show the extent to which the slogans serve as a medium by which political complaints and comments are dispensed and consumed. This paper draws on a rhetorical analysis to find out their persuasive effect on shaping the Arab intellect and on the change of the political atmosphere in the region. Lastly, this paper attempts to show to what extent the slogans meet the standards of political discourse and whether they can be considered as a sub-genre of political discourse or not.

**FULL TEXT**

**Introduction**

The revolutionary tsunami which has broken out in several countries of the Middle East in the last few years has brought about a massive number of slogans and has initiated a new sub-genre of political discourse in the Arab world. Such slogans have been introduced via many mediums, including banners, wall graffiti, audio-visual instruments, chanting, speeches and songs. The present paper aims to analyse a number of slogans collected from the sit-in quarters in Egypt, Libya and Yemen. Using critical discourse analysis (CDA), particularly van Dijk’s (1997) political discourse analysis (PDA), various typical discourse structures and strategies that are used in slogans in the construction of a sub-genre of political discourse in the Arab world are unravelled (See Appendix for some relevant background internet sources).

In fact, slogans are not something new. The etymology of the word shows that the term is derived from the Gaelic *slaughghairm* which means ‘army cry’ or ‘war cry’ (Sharp, 1984). The word was used by the Scottish clan with a view to inspiring the members of the clan to fight fiercely for its protection or the extension of its glory (Sharp, 1984: v). Similarly, slogans have also played a vital role in inspiring people to unite and achieve the interests of their countries and to restore their national pride.

In general, although the slogans under investigation are crafted in different countries, they do represent the socio-cultural concerns of the Arab Nation at large. This paper classifies the slogans under several categories and comes out with a discourse analysis of them. It shall assume that the slogans reflect the use of language in the Arab society. At the same time, it is noted that the slogans are not attributable to known authors. However, they serve as a medium through which a considerable number of socio-political issues that are likely to be unmentionable elsewhere are raised. The slogans provide the medium through which message composers can state their cases in the knowledge they are on the safe side and are shielded from political or social sanctions that are likely to be imposed by authorities and the community on members with opposing views. Such sanctions or political revenges are very widespread in different Middle Eastern countries.

The present paper aims to find out to what extent the slogans which have reverberated in the uprisings of the Middle East serve as a medium by means of which political complaints and comments may be transmitted. In turn, the paper aims to find out whether those slogans meet the standards of political discourse (van Dijk, 1997) and whether they can be considered as a sub-genre of political discourse or not.

**Literature review**

Several studies have dealt with political discourse in general. The use of rhetoric operations, for instance, has been the focus of a considerable number of studies (e.g. Billig, 1991, 1995; Bitzer, 1981; Campbell and Jamieson, 1990; Chilton, 1988; Dolan and Dumm, 1993; Hirschman, 1991; Kiewe, 1994; Tetlock, 1993; Windt and Ingold, 1987).

Slogans have also attracted the attention of many scholars. Denton (1980), Sharp (1984) and Urdang and Robbins (1984) among others have examined their use in political discourse. The use of slogans as a means of displaying dominant ideology has also been investigated in a number of studies such as Condit and Lucaites (1993), Denton (1980), Kaul (2010)Lu (1999) and Lu (2004).

Studies on the Arab Spring slogans, however, are a rarity in proportion to the great bulk of the slogans produced. It can be safely said that the slogans of the Egyptian uprising have been given a special attention by a considerable number of scholars. A collection of papers on the translation of the discourse used by protesters in Al-Tahrir Square of Egypt was published in 2012: Keraitim and Mehrez (2012) have discussed the semiotics of the Egyptian revolution; Taba and Combs (2012) have dealt with the transformation discourse of the revolution; the translation of the visual output of the Tahrir and the street art of the revolution have been examined by Gribbon and Hawns (2012) and Sanders IV (2012); and the poetics of the uprising have been examined by Sanders IV and Visona (2012).

Another collection of studies on the language of the Arab Spring was published by Orient-Institut Studies in 2013. The collection includes papers that deal with the various arts of the revolution. Gonzalez-Quijano (2013) has dealt with the use of rap as an art of the revolution, Dubois (2013) has discussed the street songs of the Syrian revolution and Abaza (2013) has conducted a study on the use of satire, laughter and mourning in Cairo’s Graffiti. The volume also includes Srage’s (2013) study, which deals with the phenomenon of the ‘clause equivalent’ of the slogan ‘Irḥal’, meaning go/get out/leave. Srage (2013) has argued that this one-word statement formulates a highly significant, semantically condensed verbal clause and concluded that young people adopted the form and content of this concise imperative in order to affirm their awareness of the priorities of political change, i.e. the departure of the regime.

Neggaz (2013) has analysed the linguistic transformations of Syrian Arabic that have been taking place since the start of the revolution in March 2011. That study has concluded that the Arabic language and its Syrian dialectal forms have witnessed some transformations such as new word formations, semantic changes and the creation of new proverbs. Although the title of the Neggaz study implies that it is concerned with linguistic transformations in general, that study is more concerned with the semantic change Syrian Arabic has witnessed because of the revolution.

In a similar vein, Lahlali (2014) has analysed some textual, social, cultural and political aspects of the slogans used during the Egyptian revolution of 2011. That analysis has shown that the slogans reflect a variety of themes and a diversity of political perspectives. It has concluded that the political orientation of Egyptian society has shaped the slogans. Furthermore, Lahlali (2014: 12) has pointed out that the language register used ‘echoes the diversity of Egyptian society and the different political orientations of its groups, including, amongst others, Islamic, secularist and liberal views’.

In addition, Al-Haq and Hussein (2012) have attempted a sociolinguistic analysis of four hundred slogans collected from different places in Tunisia and Egypt using the internet, TV channels, and newspapers with a view to investigating the language functions that the slogans convey. Their analysis has revealed that slogans fulfil twenty linguistic functions among which humiliation constituted the prevailing one.

Colla (2012) has also conducted a study on the Arab Spring slogan ‘the people want’, pointing out that the slogan has been used excessively to the extent that it loses its glamour. Colla (2012) has argued that ambiguity has shadowed this slogan almost from the beginning and the slogan has been used as the discursive scaffolding for hanging every new demand, even though those demands are sometimes incoherent and contradictory.

It seems that most of the above studies are more concerned with the various art forms of the revolution rather than slogans in particular. Even those studies that deal with the Arab Spring slogans are more concerned with the topical and ideological aspects of the slogans rather than their linguistic features. In other words, they deal with the predominant topics involved in the slogans such as hope and aspiration, the call for reprimand and prosecution, the call for immediate resignation of presidents as well as the call for freedom and liberty. As a result, the above studies seem more related to political science rather than to PDA.

The current study is different from the studies available in the literature in a number of aspects. Firstly, the scope of study goes beyond the discourse of Egyptian revolution to the discourse used in other Arab countries. Despite the fact that all Arab Spring countries have gone through similar sufferings and troubles, some slogans have exhibited clear ideological and varietal differences. Secondly, unlike the above-mentioned studies, the current study does not only investigate the thematic aspects of the slogans; it rather attempts a detailed PDA of them with a view to finding out the strategies adopted by protesters to persuade the audience of the validity of their claims and to achieve what Chomsky and Herman (1988) called ‘manufacturing consent’. As far as the current authors are aware, there are no studies that attempt a CDA or a PDA of the slogans. The current study is a PDA of the slogans because it is interested in ‘tying language to politically, socially, or culturally contentious issues and in intervening in these issues in some way’ (Gee and Handford, 2012: 5).

**Theoretical considerations**

Critical discourse analysis is used theoretically and analytically to unravel the ideologies and attitudes and power relations behind discourses whether written, oral or both. According to Fairclough (1995: 133), CDA is: discourse analysis which aims to systematically explore often opaque relationships of causality and determination between (a) discursive practices, events and texts, and (b) wider social and cultural structures, relations and processes; to investigate how such practices, events and texts arise out of and are ideologically shaped by relations of power and struggles over power; and to explore how the opacity of these relationships between discourse and society is itself a factor in securing power and hegemony.

Although many studies have been done using CDA, especially in unravelling hegemonic discourses, ideologies, and the role and power structure embedded in both oral and written texts, there is a dearth of studies using PDA. However, the analytical framework for this paper is influenced by PDA as suggested by van Dijk (1997).

van Dijk has extensively published on CDA and he has particularly focused on ‘the role of discourse in the (re)production and challenge of dominance’ (van Dijk, 1993: 283). van Dijk (1997) has introduced PDA as an extension of CDA admitting that it is a broad and an ambiguous concept that may refer to the analysis of ‘political discourse’ or to a political approach to discourse and discourse analysis, as is the case with CDA. PDA, within the framework of CDA is mainly concerned with the ‘the reproduction of political *power, power abuse* or *domination* through political discourse, including the various forms of resistance or counter-power against such forms of discursive dominance’ (van Dijk, 1997: 11).

According to van Dijk (1997), political discourse is determined by its actors such as politicians (e.g. the presidents, the prime ministers, political institutions, etc.). This refers to the kind of discourse generated by politicians in fulfilling their political mandates, as in addressing political meetings.

Despite his argument that PDA can be narrowed down to the set of activities politicians engage in, van Dijk (1997) has pointed out that politicians are not the only participants in the domain of politics and thus PDA should also include ‘the various *recipients* in political communicative events, such as the public, the people, citizens, the masses, and other groups or categories’ (van Dijk, 1997: 13).

That is to say, political discourse may go beyond the circles of professional politicians and political institutions to involve different recipients of the communicative event such as the public.

Defining political discourse is, therefore, not a straightforward matter. While some analysts restrict it to politicians and core political events, other analysts define it so broadly that almost any discourse may be considered political. van Dijk (1997: 15) has warned against the extension of the scope of political discourse saying: However, in order to avoid the extension of politics and political discourse to a domain that is so large that it would coincide with the study of public discourse in general we shall not treat such forms of discourse-with-possible-political-effects as political discourse. That is, corporate, medical or educational discourse, even when public and even when affecting the life of (many) citizens, will here not be included as forms of political discourse. And although we may readily subscribe to the well-known feminist slogan that the personal is political, we shall similarly not take all interpersonal talk (not even of gender) as political discourse.

Based on the participants and the content of the slogans, it can be argued that the Arab Spring slogans constitute a political discourse. The context of the political discourse of the study under investigation involves a myriad of participants. That is to say, political parties, the mass people, work unions, educators, students, proletarians, women associations, ethnic groups, etc. are involved in various political activities including peaceful demonstrating, protesting, civil disobedience and long marches. In terms of content, the slogans deal with a range of politically-related issues such as political change, dictatorship, oppression, democracy, justice, freedom, equality, accountability, reconciliation, toppling the regimes and trialling their officials, etc. However, participants and content may not be sufficiently decisive factors to label slogans as a political discourse. A consideration of the text and its context is a basic criterion to determine whether a text or discourse is a proper political discourse or not.

Hence, to locate the Arab Spring slogans in the realm of political discourse, the focus should not only be on the participants or the topics, but rather there is a need to investigate other discourse structures. Although van Dijk (1997: 25) has argued that the structures of political discourse are seldom exclusive, he has emphasized that ‘typical and effective discourse in political contexts may well have *preferred structures and strategies* that are functional in the adequate accomplishment of political actions in political contexts’ (van Dijk, 1997: 25). Those various levels and dimensions of discourse structure need to be examined if seeking the typical discourse structures and strategies that have ‘this status of preferred discursive methods of doing politics’ (van Dijk, 1997: 25).

Since the early 1980s, political discourse has been tackled from different perspectives (e.g. descriptive, psychological and critical). However, following a descriptive approach or a psychological approach is not sufficient to have a detailed PDA of any political event. The approach of discourse structures advocated by van Dijk has been chosen because it strikes a balance between linguistic analysis and political analysis. PDA can have a lot to offer political science and can contribute to answering genuine political questions if it focuses on features of discourse that are relevant to the purpose or function of the political process or event whose discursive dimension is being analysed (van Dijk, 1997: 38). It is argued here that focusing on the discourse structures of slogans is relevant in precisely this sense, as the purpose of the slogans may be to convince the audience (i.e. citizens, the Arab nation and the international community) that a certain course of action or view is right. The predominant role of language and discourse structures in PDA is also echoed by Wilson (2003: 13) who has argued that ‘certain core features will, and must, remain constant in the field of political discourse, and central to this is the role of language and language structure, and its manipulation for political message construction and political effect’.

In terms of discourse structures, van Dijk (1997) has argued that political discourse is often organized around particular topics, superstructures or textual ‘schemata’, local semantics, lexicon, syntax, rhetorical operations, expression structures and speech acts. The current paper seeks to determine to what extent some of these discourse structures are deployed in the Arab Spring slogans.

**Methodological issues**

**Data collection**

The data of the study consists of the transcripts of a number of slogans that were used by the demonstrators in some Arab countries, namely, Egypt, Libya and Yemen. The slogans appeared on the banners raised by demonstrators or were repeatedly verbally chanted during demonstrations. The slogans were widely circulated by various TV channels (e.g. Aljazeera, Al-Arabiya and BBC Arabic) and in various media articles, blogs, videos and social networks including Facebook and Twitter. The collected slogans deal with various socio-political issues in the three Arab countries mentioned above but have implications for the entire Arab world in general. They straddle colloquial and standard Arabic and serve as a microcosm for the slogans used in other Arab Spring countries. The current study totally agrees with Colla (2012) who has argued that the Egyptians like the Tunisians before them were aware that ‘they were not only singing to themselves – they were self-consciously performing revolution for the entire Arab world’. Thus the selection of the slogans is not motivated by political considerations (e.g. failing states vs. non-failing ones), simply because all the Arab states that witnessed uprisings are failing in the eyes of the protesters. It can be claimed that the Arab Spring slogans are homogeneous and they share a lot in common even though their discursive content is sometimes slightly localized (i.e. looks more Egyptian, Yemeni or Libyan ).

All the slogans were kept intact and they did not undergo any modifications or corrections. In this paper, 62 tokens of the slogans collected are used as the database for analysis.

**Data analysis**

The co-evolution of language and politics is undeniable. Chilton (2004: 16) has aptly pointed out that ‘political actors themselves are well aware of the importance of how language is used even in the act of denying the fact’. The protesters have therefore employed a lengthy list of politico-linguistic devices to resist the power of the regimes in their relevant countries. The current analysis attempts to find out the various discourse structures used by protesters with a view to representing their ideological square ‘de/emphasize good/bad things of US/Them’ (van Dijk, 1998).

The slogans will be analysed within the framework of CDA. In particular, van Dijk’s (1997) PDA will be used. As suggested by van Dijk (1997) the various typical discourse structures and strategies that pertain to political discourse at various levels and dimensions will be discussed. The focus is on the slogan’s topics, textual schemata, local semantics, lexicon, syntax, rhetoric, expression structures and speech acts. In doing so, the current study will be in a position to show how Arab protesters who have been powerless for quite some time used the ‘loaded weapon’ (Bolinger, 1980) called language to mock, oppose and resist the discourse of the totalitarian regimes that have used language to control, marginalize, assimilate and eliminate them for decades. It has to be made clear that although this study’s analysis is politico-linguistic, it is more concerned with the manipulation of language in the slogans since, in general, this is what differentiates PDA from other areas of political research found, say, in political science.

**Discussion**

**Topics**

van Dijk argues that ‘topica’ or ‘typology’ is not given enough attention in discourse analysis. Topica refers to the analysis of diverse discourses, what they mean, the situations surrounding them and the contexts in which they occur (van Dijk, 1997: 26). Based on their contents, the Arab Spring slogans can be analysed under a number of topics relevant to protesters’ religious, socio-economic, cultural and political perspectives.

**Political humour and satire**

van Dijk (1997: 28) suggests that political topics are mainly about political actors. Arab ex-leaders and their actions were a matter of ridicule in a number of slogans. A considerable number of humorous and satirical slogans were on the lips of Arab protesters. The current study finds that protestors use their knowledge of Arab culture and rhetoric to generate satirical messages embedded in political humour. In Libya, for instance, some of the slogans read as in (1):

*1. Al-shaʿb yūrīd ʿilāj al-zaʿīm*. [The people want the treatment of the leader.] *Al-shaʿb yurīd tafsīr al-khiṭāb*. [The people want to interpret the speech of Qathafi.] *Al-shaʿb yurīd ḥubūb halwasah mārikat Al-Qadhāfi*. [The People want Qathafi Brand hallucination tablets.]

In each case, the famous Arab-world-wide slogan *al-shaʿb yurīd isqāṭ al-niẓām* ‘The people want the fall of the regime’ has been twisted and modified satirically. In the first slogan, the addresser wants to say that the Libyan people want to treat their leader as insane. This slogan is released as a response to the first speech delivered by Qadhafi in the aftermath of the outbreak of the Libyan uprising in Bani Ghazi and Al-Baiḍa’a. In that speech, he appeared stressed and bizarre. He incoherently talked about different issues and thus the slogan refers to this aspect of the speech. In the same speech, Qadhafi accused the ***opposition*** of providing the youth with drugs and thus they were fighting him because they were in a state of intoxication. Therefore, the revolutionaries satirically responded to him saying that they have given up hashish and are really looking for Qadhafi-brand drugs.

Expression of political humour and satire is not only through linguistic means alone, but also through multimodality, which combines verbal and visual semiotic materials to generate political messages. Consider the multimodal political humour in (2):

*2. Al-shaʿb yurīd taghyīr al-ṭaʿām*. [The people want the change of the food.]

In Egypt, the above slogan appears under a picture of a bowl of butter beans to refer to the famous national dish in the Sudan and Egypt. Thus, the message is that protesters, here, no longer wish the fall or the change of the regime but rather the change of the food they have been eating day and night. The multimodal discourse structures suggest that mere change in regime is nothing if the well-being of the people remains a matter of great concern.

In the slogans above, *al-shaʿb* ‘the people’ is the participant; the action of changing the regime, the opinion of having Qadhafi drug, or changing the food all have ‘a general, official, institutional or public nature’ (van Dijk, 1997: 26). The slogans show a general decision taken by the people to control the political process and to oppose and challenge its policies, as well as to point at a different and better future for the ordinary citizens.

**Political evaluation**

van Dijk (1997: 28) posits that topics often feature typical polarized appraisals of ‘politicians, public figures, and organizations and their actions’. The corpus shows several instances of references to politicians and their actions. Some of the evaluations are in the form of swear words directed at presidents, their wives or at their political systems as a whole. Consider, for example, slogan (3):

*3. Ṣāhib al-ḍarbah al-jawiyah hua kabīr al-balṭajiyah*. [The person who led the air strike [on Israel and of whom we were proud] is the greatest of thugs.]

In (3), Mubarak of Egypt has been described to be *balṭaji* ‘a thug’. This word has been widely circulated throughout the Arab World. It is a swear and colloquial word that means the person who takes advantage of power and abuses or mistreats others verbally, emotionally or physically. Thus, Mubarak, the pilot, who is believed to be the leader of the successful 1973 air strike on Israel, is described as the greatest of all thugs. Another example of political insult is given in (4):

*4. Ya Muʿamar ya abu shafshufah al-shaʿb al-lībi tauwah tashufah*. [O Muamar, whose hair can never be combed, you will see now how easily the Libyan people can topple you.]

Here, *abu shafshufah* is a relatively new term in Arabic. It has not been in use before the Libyan uprising. It refers to the uncombed hair of Qadhafi, which is part of his strange personality as they claim.

The slogans above depict what van Dijk describes as the ‘***strategic*** principle of all ideological and political discourse…Emphasis/de-emphasis of Our/Their Good/Bad Actions’ (van Dijk, 1997: 28). Thus, Qadhafi’s apparently unkempt hair is exaggerated to emphasize his strange characteristics.

**Political threats**

Political discourse is also replete with political threats aimed at real or perceived political opponents. Threats of revolt or insurrection against the regime are used in the predicates of several slogans and in all the countries that witnessed the uprisings. Consider, for example, the following slogans:

*5. Lāzim lāzim Ḥusni yaghūr … qāʿidīn huna 9 shuhūr*. [Husni must step down. [For this cause], we are ready to stay [in squares] for nine months.]

*6. Mush ḥanihd*a *mush ḥaninām ḥata yasquṭ al-niẓām*. [We will neither slow down [the pace of our protest] nor will we have a wink of sleep till the fall of the regime.]

In these slogans, threats are directed to the Egyptian former president personally and to his regime. In (5), Mubarak must disappear and leave power; otherwise, the protesters will patiently remain in the freedom squares for months. In (6), however, the whole regime is threatened by the protesters who are determined to escalate their activities until the fall of the regime.

**Nationalism, resentment of current policies and accountability**

Slogans have also dealt with various aspects of the political domain. The demands of the protesters are not confined to their domestic affairs. National issues in general and the Palestinian Cause in particular have found their own place in the slogans. Egyptians, who are viewed as the pioneers of Arab Nationalism, are not pleased with their country’s stance towards the Palestinians, as is clear in (7):

*7. Ḥusni biyh Ḥusni biyh quli muḥāṣir Ghazah liyh*. [Hosni, Bey! Hosni, Bey, tell me, ‘why do you siege Gaza?’]

Here, the demonstrators are trying to find out a justified and convincing answer from Mubarak for the blockade they claim he put on Gaza. The slogan exhibits their resentment at what they deem a savage policy that aggravates the sufferings of their Palestinian brothers. Even worse, their regime prevents the flow of essential needs for the Palestinians while it supplies Israel with gas at trivial prices. This issue of selling gas to Israel provokes the Egyptians even more and they chanted:

*8. Bāʿū al-dawlah wa bāʿū al-ghāz … dūl ʿawizīn al-walʿah bi-jāz*. [They sold out the state, the sold out the gas. We need to ignite gas and burn them to death.]

That is, the regime needs to be burnt because it wastes the natural resources of the country by selling the gas for low prices that are not in harmony with the global prices.

**Standard of living**

Political discourse does not refer only to various elements of the political domain; it usually combines its topics with those from other societal domains (van Dijk, 1997: 25). A considerable number of people in the Arab Spring countries live under or just above the poverty line, which the World Bank sets at $2 a day (The World Bank, 2013). The standard of living and the miserable conditions of most of the Arabs are, therefore, reflected in the slogans, as is clear in (9):

*9. Ya Suzān qulī li-al-biyh kilo al-ʿds bi-ʿasharah jiniyh*. [O Suzan! tell the Bey, one kg of lentils costs ten Egyptian pounds.]

Here, people who are afflicted with poverty cannot even get their essential needs. Lentils, which is the national dish for a high percentage of Egyptians is no longer affordable. A kilo of lentils costs ten Egyptian pounds. Another example is given in (10):

*10. Hū yalbas ākhar mawḍah wa-ḥna ni-nām al-ʿashrah bi-ʾuḍah*. [While [the president] wears the latest fashion trends, ten of us sleep in a stuffy room.]

Here, the housing crisis that bothers most of the Egyptians is highlighted in the slogans. In (10), while the president is very wealthy and leads a very comfortable life wearing the latest fashion, the poor citizens cannot find a proper accommodation. Ten people share a single room.

**Superstructures or textual ‘schemata’**

Each discourse genre is characterized by schematic forms that differ according to the communicative goal, audience, information load, etc. (Grabe and Kaplan, 1996: 54ff; Swales, 1990; van Dijk, 1997: 29). Political slogans like any other genre have their own schematic patterning. That is to say, they have particular canonical and conventional forms that define their genre membership. Protesters promote their ideas by using brief, clear, eye-catching and musical slogans that easily stick to minds due to their special sound pattern. Parallelism, antimetabole, colloquialism, alliteration, assonance and antithesis are all devices of the textual schemata of political slogans. A detailed analysis of these devices is given in the Rhetorical Operations section.

Another schematic feature resides in the tendency of the composers of slogans to violate syntactic, stylistic and rhetorical norms to communicate particular political messages. In fact, this is not a disadvantage of slogans; it is rather a merit. As Crystal points out ‘there are several situations where it is perfectly in order to be strange, and indeed where the breaking of linguistic rules is seen as a positive feature of communication’ (Crystal, 2003: 400). Thus, by violating certain linguistic and rhetorical norms slogans are able to communicate their message efficaciously. Besides, slogans can be multimodal in the sense that they convey their communicative goal through both image and text. Some slogans are painted onto banners along with pictures of martyrs or/and opponents. Multimodal slogans tend to promote the image of the revolutionaries and to distort the image of opponents. A Yemeni slogan, for example, contains a photograph of one of the martyrs and a distorted photograph of the Yemeni former president in which he appears burnt beyond recognition along with his notorious nickname *ʿafāsh*. The slogan reads *al-shaʿab yurīd muḥakamat al-safāḥ* ‘the people want the trail of the shedder of blood’. Other slogans are even supplemented with some cartoons as in the following:

Source: Sublat ʿumān (2011)

Here, the slogan ‘the people want to topple the regime’ is represented in the form of a cartoon. A hand is shown and two fingers are up, a well-known symbol of victory or martyrdom. The slogan *al-shaʿab qāla kalimatah* ‘the people has said his say’ is emphasized in the cartoon by a bold and large font and a rope was hanging around the neck of Qathafi. The cartoon has made meanings more ‘prominent for obvious partisan reasons’ (van Dijk, 1997: 29).

It can be argued that the slogans genre has some schematic features that do not even concur with logical reasoning. However, slogans become catchier when they deviate from the norms. Besides, slogans can be flexible in their schematic forms. Although brevity is a canonical feature of slogans, the Arab Spring brings with it some intertexual slogans that cite the opening lines of famous Arab poets such as Abu Al-Qasim Al-Shābi’s 1933 poem,‘The will to live’.

In brief, the schematic forms of slogans tend to emphasize some meaning for obvious partisan reasons (i.e. to promote their beliefs, ideas, etc.) and thus they foreground them. They, however, hide significant information if it is negative to their cause by putting it in less prominent textual categories or by ***deleting*** it altogether (van Dijk, 1997: 29).

**Local semantics and lexicon**

Those involved in political discourse, according to van Dijk (1997: 30) ‘tend to emphasize all meanings that are positive about themselves and their own group (nation, party, ideology, etc.) and negative about the Others, while they will hide, mitigate, play-down, leave implicit, etc. information that will give them a bad impression and their opponents a good impression’. A cursory look at the slogans shows that the slogans related to the revolutionaries carry positive meanings. They present the anti-regime activists as the Utopian and unified group that aspires to change the society for the best. In reality, however, political parties that participated in the uprising embrace different ideologies and policies and they never act as a unified group. For instance, while the socialists, Islamists, communists, Nasserites and many others played a vital role in the uprisings and there is a long history of conflict and poor governance among those groups, the slogans do not contain information that may bring bad fame to those forces. Despite the fact that some of those factions, as noted above have been in power before and they did not rule their countries properly too, there is not even a single slogan that refers to their past.

At the lexical level, the choice of the words shows a very clear kind of bias for ‘partisan principles of the Ideological Square’ (van Dijk, 1997: 33). While the youth in all the Arab countries are *thuwār* ‘revolutionaries’, the pro-regimes are *balātigah* ‘thugs’. While the youth are *musālimīn* ‘peaceful’, the others are *ʾirhābiyīn* ‘terrorists’, *qatalah* ‘murderers’ and *safāḥīn* ‘manslayers’. In addition, the youth are described in the slogans as *al-shabāb al-ḥilu* ‘the good people’ and their opponents as *al-shabāb al-waḥish* ‘the bad people’. On the contrary, the regimes’ alliances have described the ‘peaceful revolution’ of the youth as *fawḍah* ‘chaos’, *takhrīb* ‘vandalism’ and *fitnah* ‘sabotage’. *Saḥāt al-tagh*y*īr* ‘Change squares’ (where demonstrators rally), are described by opponents as *saḥāt al-taghrīr* ‘delusion or misguidance squares’. Even the people who have been killed are sometimes called *shuhadā* ‘martyrs’ and at other times, they do not deserve that rank and they are just *qatla* ‘killed people’.

Moreover, violent actions by both sides have been euphemized. In Yemen, for instance, some of the protesters have attacked the official institutions and have called them *suquṭ silmi li-al-muʾasāsāt al-rasmiyah* ‘a peaceful fall of official institutions’. Thus, the attack on public institutions is a peaceful occupation (see: [*http://www.al-tagheer.com/news28542.html*](http://www.al-tagheer.com/news28542.html)); the use of ‘peaceful’ in the previous collocation is a euphemized expression for a hostile act. Similarly, in all the Arab Spring countries, a considerable number of innocent people, protesters and security forces have been killed, but such killing of innocents is sometimes called *difāʿan ʿan anafs* ‘self-defence’ or *qatl ghayr* ʿ*amd* ‘collateral killing’.

Hence, the anti-regimes and pro-regimes demonstrators have used a massive repertoire of words/expressions that should be collected and compiled. They have managed to ‘create new sets of words to talk about things for which they previously used the same words as everybody else’ (Fawcett, 1997: 5).

**Syntax and pro-forms**

van Dijk (1997) lists a number of morpho-syntactic features that are related to political discourse in English. These include the use of pronouns, variations of word order, the use of specific syntactic categories, active and passive constructions, nominalizations, clause embedding, sentence complexity and other ways to express underlying meanings in sentence structures. The current study’s data show that the syntactic style is subtly manipulated in the slogans to project particular ideologies and stances.

**Use of pronouns**

One of the syntactic features in political slogans is the use of deictic pronouns *naḥnu vs. hum* (van Dijk, 1997). Such use of pronouns serves pragmatic and semantic functions (van Dijk, 1997). Consider, for instance, the slogan given in (10) above, in which, *hū* ‘he’ is used to refer to Mubarak and *wiḥna* ‘we’ refers to the Egyptian youth or the Egyptians in general. The slogan differentiates between the luxurious life of the president and the collective misery of the other Egyptians.

In other cases, the plural pronoun *hum* ‘they’ is used to refer to the whole regime, as is obvious in (11):

*11. Huma bi yaklū ḥamām wa baṭ… wa kul al-shaʿab jaluh al-ḍaghṭ*. [While they [the regime] eat pigeons and ducks, all the people get hypertension.]

In some other cases, the cataphoric pronoun *naḥnu* is used and followed directly with its reference as in (12):

*12. Ya yaman***naḥnu shabābik**

*fatiḥīn li-thawrah bābik*

*lā ḥizbyah wa lā aḥzāb*

*thawratana thawrat shabāb*

 [O Yemen! **We** are **your youth**

 We are opening your door to the uprising

 No partisanship! No parties,

 Our uprising is the uprising of the Youth.]

All the examples above clearly state the sense of solidarity and inclusion when it comes to the youth or the people and the sense of exclusion of the regime and its supporters.

**Use of vocatives**

Name-calling is widely used by politicians on different occasions. This strategy has been widely used in the slogans. The corpus shows a number of instances where the revolutionaries or the pro-regime supporters use vocatives followed by a name with a view to gaining advantage over, or defending themselves from opponents. The examples given below state this strategy:

*13. Ya Qadhāfī ya jabān, al-shaʿab Al-lībī lā yuhān*. [O Qathafi! O Coward! The Libyan people will not be disgraced.]

*14. Ya ʿali ya safāḥ, baqi dahfah wa nirtāḥ*. [O Ali! O shedder of blood! There is little time left and we will get rid of you.]

*15. Ya Jamāl qūl la-būk … al-shaʿab al-miṣri yikrahūk*. [O Jamal, Tell your father, ‘the Egyptian people hate you’.]

In the above examples, the technique of name-calling is used by protesters to intentionally deride the Libyan, Yemeni and Egyptian former presidents and to construct negative impressions or opinions about them. Qadhafi is described as a coward, Saleh is viewed as a man indulging in bloodshed and Mubarak is hated and detested by his people. On other occasions, name-calling has been used in a sympathetic manner where people sympathize with political icons who actively participated in the development of their countries. An example of such icons is the late Yemeni president, whom the protesters address in (16):

*16. Ya Ḥamdi ʿud ʿud … shaʿbak yishḥat ʿa-al-ḥudūd*. [Oh Hamdi [the former president of Yemen], Come back! Come back! Your people are begging on the borders.]

In (16), the former president of Yemen, the Late Ibrahim Al-Hamdi is called. The slogan emotionally addresses him and tells him about the miserable conditions of his people. The people who used to have a thriving life during his reign have been turned into beggars.

**Imperative sentences**

Halliday (1994: 69) points out that there are four basic speech roles: giving information; demanding information; giving goods and services; and demanding goods and services. The last one refers to what is traditionally called Command. Demanding goods and services has been the mainstay of many slogans, as is clear in both (17) and (18):

*17.**Irḥal irḥal ya jabān … ya ʿamīl Al-Amrikān*. [Depart! Depart! Coward. You are the agent of the Americans.]

*18. Khudh ʿilatak wa itlaʿ bara Libya ḥa-tibqa ḥurah*. [Take your family and get out, Libya will remain free.]

In the two examples above, the command verbs **Ir***ḥal* and *Khudh* have been used to address the former Egyptian and Libyan presidents respectively to step down and to leave their countries. The use of such verbs reflects the defiant spirit of the protesters as well as their self-confidence of victory. In other words, it reflects their power as revolutionaries against the regime.

Halliday (1970) states that one function of imperative clauses is to command others to do something, as in (17) and (18); the other function is to invite the audience to do something together. The latter is usually indicated by the format ‘Let’s’. An example of this function is the slogan given below:

*19. Nuḍī nuḍī ya Bani Ghāzī jalakī al-yawm alī titraji*. [ Let’s Revolt, Let’s Revolt, Bani Ghazi! What you wish has come true today.]

**Antimetabole**

Antimetabole is defined as ‘Figure of emphasis in which the words in one phrase or clause are replicated, exactly or closely, in reverse grammatical order in the next phrase or clause; an inverted order of repeated words in adjacent phrases or clauses (A–B, B–A)’ (see: [*http://www.americanrhetoric.com/figures/antimetabole.htm*](http://www.americanrhetoric.com/figures/antimetabole.htm)). An example of antimetabole is given in (20):

*20. Raʾīs min ajl al-yaman lā yaman min ajl al-raʾīs*. [A president for the sake of Yemen rather than Yemen for the sake of the president.]

**Ellipsis**

Ellipsis is a cohesive device in which part of a structure is omitted. The use of ellipsis is common in the slogans as is obvious in (21) and (22) respectively:

*21. Ya Qadhāfī dawrak ja ḍum al-khaymah wa dīr ʿazā*. [O Qathafi, your turn has come! Remove your tent and start a mourning ceremony.]

*22. Thawrah thawrah ḥata al-naṣr … bukra Libya tuḥaṣil Maṣr*. [Our uprising will continue until we gain victory. Tomorrow Libya will follow Egypt.]

Slogan (21) can be interpreted as ‘Oh, Qathafi, your turn to step down has come’, but the part after *dawrak* ‘turn’ has been elipticized. Similarly, in (22), *bukra Libya tuḥaṣil maṣr* ‘tomorrow, Libya will follow Egypt’ contains an elliptical part that can be interpreted as ‘tomorrow Libya will follow the track of revolution like Egypt.’

**Nominalization**

Some of the slogans are nominalized in the sense that the verb has been turned into a noun. Such verbs are followed by an expanded noun phrase. This kind of structure is called *iḍāfa* or annexion phrase. Consider, for instance, (23) and (24):

*23. Isqāṭ al-niẓām al-fardī al-ʾusarī al-istibdādī huwa maṭlabuna*. [Toppling the authoritarian individual family regime is our demand.]

*24. Maṭlabuna huwa tanḥyat al-raʾīs ʾali ʿbda-allah Ṣaliḥ ʿan al-riʾasah wa kāfat aqāribah min al-marākiz al-qiyādiyah fī al-muʾsāsāt al-ʿaskiryah wa al-madan*i*yah*. [Our demand is removing President Ali Abdullah Saleh from presidency and [removing] all his relatives from leadership positions in the military and civil institutions.]

Another common nominalization structure found in the slogans is that of a verbless nominal clause where a verb is elipticized, as (25) shows:

*25. Libiya fī alqalb makānik*. [Libya! in our hearts you are.]

In the above example, the verb that can be semantically interpreted as *is* or *exists* is omitted.

**Shifting word order**

Some slogans deviate from the standard word order of Arabic for topicalization purposes. In other words, the verbal clause can be nominalized by changing the verb–subject–object order to the subject–object–verb order. This shift in word order puts emphasis on the topic of the slogan.

In addition, the verb is used in the imperfect aspect in order to show the immediacy of the action even though the event has already occurred (Watson, 1999: 170). An example of this type of structure is the famous and widely-circulated slogan given in (26):

*26. Al-shaʿb yurīd taghyīr al-niẓām*. [The people want to change the regime.]

In the above example, the normal word order is *yurīd al-shaʿb taghyīr al-niẓām*, ‘want the people the change of the regime’.

Although the people have already made up their mind and taken the initiative to topple the regimes, the imperfect aspect has been used.

In fact, *al-shaʿb* has been topicalized by all parties with a view to foregrounding their demands. While *al-shaʿb* has been thematized in the slogans of the revolutionaries to emphasize the demand of toppling the regime, the same word has been thematized by the pro-regime allies to emphasize several demands, as is clear in the following slogans:

*27. Al-shaʿb yurīd ikhlā al-maydān*. [The people want to evacuate the square [of protesters]].

*28. Al-shaʿb yurīd inhā al-ʾiʿtiṣām*. [The people want to end sit-ins/protests.]

*29. Al-shaʿb yurīd ḥifẓ al-dimā*. [The people want to preserve lives.]

Topicalization has also been used by revolutionaries with an aim to emphasize the bad things of outgroups, as is obvious in (30):

*30. Al-imām Yaḥya 16 sanah… Al-imām Aḥmid 13 sanah… Al-imām ʿali 33 sanah*. [Imam Yahia [has ruled for] 16 years… Imam Ahmed [for] 13 years… Imam Ali [for] 33 years.]

In (30), the former president of Yemen has been foregrounded and described as an imam because he has ruled for more years than the notorious kings of Yemen, namely Imam Yahya and Imam Ahmed. This kind of syntactic topicalization emphasizes the president’s lust for power and his tyranny. In line with van Dijk’s (1997: 34) ideological square, syntactic topicalization emphasizes the good aspects of the anti-regime supporters and the bad ones of the regime and its supporters.

**Rhetorical operations**

The main goal of politics is to persuade. Rhetoric, therefore, plays a very vital role in this process of persuasion. The Arab Spring slogans are characterized by the employment of a ‘smash hits’ selection of rhetorical devices. The use of rhetorical devices makes slogans memorable and easy to be chanted and remembered. It is through those devices that the slogans reach a broad potential audience. Various Arab Spring slogans were also heavy in the extensive use of figures of speech. A few of these are illustrated below.

**Alliterations, rhyme and morphological repetition**

Many slogans have employed deliberate use of phonic patterns for expressive purposes. Alliteration, for instance, is widely used. Alliteration is the repetition of the same sound in two or more words. This kind of sound repetition creates a musical tone that embellishes the language and helps the listeners or addressees enjoy it. Some slogans that use alliteration are given below:

*31. Bin ʿali bi-yunad***īk***… funduq Jadah mustan***īk**. [The son of Ali [the toppled Tunisian president] calls you…. Jeddah’s hotel awaits you.]

*32. Wa yadīna fī yadīn baʿḍīna wa Al-Qadhāfī mā yurhbna*. [As long as we join hands, Qathafi will never intimidate us.]

Rhyme is also widely used in Arabic political discourse to embellish it and to attract the attention of addressees. In the slogans under investigation, rhyme has been used over again and again. Some examples are given below:

*33. Libya fī al-qalb makānik… Libya namūt ʿala shanik*. [Libya! You are in our hearts! For your sake we shall die.]

*34. Niḥna lā khawnah wa lā kilāb… niḥna maʿākum ya shabāb*. [We are neither disloyal [citizens] nor dogs, we are supporting you, the Youth.]

*35. Ya ima naʿīsh suʿadā fawqa al-arḍ au shuhadā taḥta al-arḍ*. [We shall either live happily on earth or martyrs under the earth.]

In addition, different types of morphological repetitions have been noticed in the slogans. Arabic abounds in the use of both pattern repetition and root repetition to fulfil stylistic and rhetorical purposes or as a means of textual cohesion. In (35), the same pattern *fuʿalā* is used in two words *suʿadā ‘*happy’ and *shuhadā* ‘martyrs’ in close proximity. Root repetition is also common in the slogans. Yemeni revolutionaries who established their camps in a close area to Sana’a University, the top university in the country, chanted:

*36. Lā dirāsah wa lā tadrīs ḥata yasquṭ al-raʾīs*. [We will neither study nor teach till the president steps down.]

Here, both *dirāsah* ‘study’ and *tadrīs* ‘teaching’ are derived from the same root *darasa ‘*to learn’.

**Simile**

Simile is an aesthetic and rhetorical device that is frequently used in the slogans. In a simile, a given entity is compared with another in praise, dispraise, ornamentation, or repugnance using particular words/particles like *as* or *like* in English and *mithl* or *ka* or *kʾai* in Arabic. The corpus shows that there is a tendency to use single similes in dispraise of the regimes as is shown in (37):

*37. Bism kuli al-fanānīn ḥukmak zift wa zai al-ṭīn*. [By the name of all artists your reign is dirty and as filthy as a pigsty/rag.]

In Egyptian Arabic, the word *ṭīn* is commonly used to refer to something disguisable and bad. Therefore, the reign of Mubarak is compared with *ṭīn* ‘mud’. The colloquial word *zai* ‘like’ is used as a simile particle. Thus, both the likened-to and the likened share one feature (i.e. filthiness).

Another example of simile is used by Yemeni protestors, as in (38):

*38. Ya ʿali ya safāḥ … lā tabki mithla al-timsāḥ*. [O Ali, the shedder of blood … weep not like a crocodile.]

The slogan refers to Saleh of Yemen, who was bitterly condemned by opponents for giving orders to shoot the innocent demonstrators in Sana’a. More than 50 people were dead and dozens of them were injured. As a result, Saleh has formed an investigation committee to probe into the matter. The protesters consider this step by him as an attempt to hide the heinous crime of killing the peaceful citizens. In their view, the president’s weeping and alleged sadness are compared to the tears of the crocodile. Here again, both the likened-to and the likened share one feature (i.e. shedding fake tears).

**Hyperbole**

The slogan composers have used this mode of semantic embellishment to make excessive exaggeration about the state of someone or something, as in (39) and (40):

*39. Ya ʿali irḥal irḥal al-kursi tiḥtak dhaḥal*. [O Ali, Step down! Step down! Your throne has got rusted.]

*40. Qul li-Muʿamar wa ṣigharah al-shaʿab al-Lībi bukrah fī darah*. [Say to Muamar and his family, the Libyan people will be in his house tomorrow.]

In (39), the protesters have chanted that president Saleh must leave power and they claim that his presidential seat got rusted due to the long term he spent in power. In (40), the slogan indicates that the Libyan people as a whole will flood Qadafi’s home the following day. The use of this figurative device shows that a considerable number of furious Libyan protestors will reach his palace and will be able to topple him.

**Metonymy**

Metonymy is frequently used in political discourse in Arabic. It is a figure of speech in which a thing or concept is replaced with the name of something intimately connected to it. Metonymy differs from metaphor. While metaphor’s *association* is by similarity between two concepts, that of metonymy is by *contiguity* (Courtney, 1990: 75). An example of the use of metonymy is given in (41):

*41. Ya ʿali ʿataf farshak… min taʿiz yasquṭ ʿarshak*. [O, Ali! Fold your bed… Your throne will certainly fall by the Taizi revolutionaries.]

In the above instance, *ʿarshak* ‘your throne’ that is associated with royalty and power has been used as metonym for it. A kind of metonymy is synecdoche (i.e. a part of speech in which a specific part of something is used to refer to the whole). This figure of speech has also been frequently used in the slogans, as is obvious in the example above, wherein the phrase *ʿataf farshak* ‘pack and fold your mattress’ has been used to refer to the whole process of leaving power. Saleh is not required to pack his bed but to step down. Another example is shown in (42):

*42. Ya mubārak ya khasīs dam Al-Miṣri mush rakhīṣ*. [O Mubarak, the wicked! the blood of the Egyptian is never cheap.]

The expression *dam Al-Miṣri* has been used as synecdoche, in the sense that it is not only the blood of the Egyptians that is not cheap but the Egyptians as a whole are not cheap.

According to Abdul-Roaf (2006: 234) ‘the major function of metonymy is to allude to a characteristic feature of someone and cover it up with a given linguistic expression instead of explicitly mentioning it. This pragmatic function is employed by the communicator in both praise and dispraise’. In both (43) and (44), metonymy of attribute is used to refer to the characteristic traits of both Saleh and Qadhafi respectively:

*43. Allah yumhil wa lā yuhmil ya ʿali ya ʿaf āsh*. [O, Afash! God’s mill grinds slow but sure.]

*44. Ya Muʿamar ya bu shafshufah…* [Oh Qaddafi abu shafsufah! [a man of shaggy hair].]

Saleh is described as *ʿaf āsh* ‘a floating useless thing’ and Qadhafi is disparagingly called *abū shafshufah*, or a man with messy and shaggy hair.

**Antithesis**

Antithesis is a semantic embellishment, which means the combination of two ***opposite*** things whether they are allegorical or non-allegorical. This device is also used in the slogans. Consider, for instance, the following example used by the Libyan protestors:

*45. Lā ʾilāh ʾila Allah Al-Qadhāfi ʿadu* A*llah… Lā ʾilāh ʾila Allah al-shahīd ḥabīb Allah*. [There is no God but Allah, Qathafi is the enemy of God… There is no God but Allah, the martyr is the beloved of God.]

Here, the antithesis is represented by the occurrence of two contradictory statements: the first is that Qadhafi is the enemy of God and the second is that the martyr is the beloved of Him.

**Parallelism**

The persuasiveness of the slogans is sometimes heightened through the use of parallel structures, as (46) shows:

*46. Thawrah fī tunis thawra fī maṣr thawra fī libiya ḥata al-naṣr*. [An uprising in Tunisia… An uprising in Egypt and an uprising in Libya until we gain victory.]

Here, three successive clauses within the sentence have employed the same syntactic structure. Another example is illustrated in (47):

*47. Ya shabāb ma tikhafush … Qathāfi ma nibush*

*Ya banāt lā tabkūsh … al-shuhadā mā yamutūsh*.

[Oh Youth! Never get scared, we do not want Qathafi anymore. Oh girls, never weep, Martyrs never die.]

Here, the parallel syntactic structure (vocative + noun+ negation particle + present verb, noun + negative particle + present verb) is used in the two sentences of the slogan.

**Repetition**

The rhetorical strategy of repetition is employed in the slogans for a number of reasons including, emphasis, emotional effect, amplification, etc. An example of rhetorical repetition is given in (48):

*48. ʿahdak wala wala wa raḥ… lā ṭawārʾ ya safāḥ*

*Thawra thawra silmiyah … min saḥāt al-ḥuriyah*

*Ya ʿali zūl zūl… ḥukmak ma ʿād lu mafʿūl*.

[Your rule has gone has gone … [There is] no emergency, Blood shedder!

An uprising, a peaceful uprising has started in the squares of freedom.

Oh Ali depart, depart, your regime no longer exists.]

**Expression structures**

Another element valued in a political discourse is that of expression structures. There is no exaggeration if it is claimed that the protesters left no stone unturned to present their slogans. The way the expression structures of sounds and graphics are shown plays ‘an indirect function in emphasizing or de-emphasizing partisan meanings’ (van Dijk, 1999: 36).

While some of the slogans were written to be chanted, they were presented in a skillful graphic manner. Bold fonts and eye-catching colours have been used. The demonstrators have employed and initiated various means through which they express their slogans. The ideational meaning has been expressed through banners, craving in bread, tattoo, graffitists, photographs and drawings. Some slogans have even been written with blood. Thus, different semiotic systems have been used and they worked together semantically (Halliday and Hasan, 1985: 4). This makes slogans a representative genre of social semiotics where meanings are projected via a range of modes, such as language, images, comics, televisions and the like. It has been customary to notice protesters carrying banners with images and texts as has been mentioned earlier. Some slogans have been written, sung and represented visually.

**Speech acts and interaction**

A speech act can be defined as the action performed by a speaker with an utterance. A pragmatic analysis of the Arab Spring slogans indicates that the slogans’ composers employ several speech illocutionary forces. Many slogans are directives in the form of commands and orders as noticed in (49):

*49.* *Irhal yaʿni imshi … wila mā tifhamshi*. [Depart means leave… Do not you understand?]

Encouragement is also a very common speech act in the slogans, as is clear in (50):

*50. Zīd taḥadi zīd ya ṣaqrī al-waḥīd*. [Go on in your challenge [to the protesters], Go on, mighty falcon!]

Here, Qadhafi is encouraged by his supporters to be more stubborn and to take the challenge.

Some slogans have featured advice and warning as in (51), where the youth are advised to continue their uprising until change is attained. At the same time, the slogan warns them not to launch a long-term uprising because the continuous revolution is destructive chaos:

*51. Thawra ḥata al-naṣr wa al-taghyīr wa laysat thawra īla al-ʾabad fa-al-thawra al-mustimarah fauḍah mudamirah*. [The uprising should continue until it ***wins*** victory and change is fulfilled. It should not be longer because the continuous uprising means continuous chaos.]

Threat as a speech act is also very prevalent in the slogans, as is stated in (52):

*52. ʾah ya ḥukumat hishik bishik… bukrah al-shaʿb Al-Miṣri yakushik*. [Oh, incompetent/unworthy government, tomorrow the Egyptian people will throw you out.]

Here, Mubarak’s incompetent government is threatened to be swept away. In addition, some slogans serve an assertive function as in (53):

*53. Mush ḥanihda mush ḥaninām ḥata yasquṭ alniẓām*. [We will neither slow down [the pace of our protest] nor will we have a wink of sleep till the fall of the regime.]

In (53), the protesters assert that they will not calm down till the fall of the regime.

Other speech acts frequently used in the slogans are accusation and counter-accusation. In (54), for example, the pro-Qadhafi demonstrators accuse the Qatar-based Al-Jazeera channel of being notoriously ignoble:

*54. Ya jazīrah ya ḥaqīrah al-qāʾid mā nibu ghairah*. [O Jazeera, how ignoble are you! We accept none but our leader.]

On the other hand, the anti-regime protesters have apologized to it for the false accusations of Qadhafi supporters, as is clear in (55):

*55. Wa* A*llah manik ḥaqīrah naʿtadhir lik ya Al-Jazīrah*. [We swear by God you are a channel of vaunted reputation. We apologize to you, Jazeera.]

Denial of accusations raised by opponents is also reflected in a number of other slogans, as is obvious in (34) above and (56):

*56. Khazaytana ya ʿali … ayn Amrīka ayn ṭali*. [You brought us a bad name, Ali… Neither America nor others is behind our uprising.]

In (34), the anti-regime Libyans deny being treacherous and in (57), the anti-regime Yemenis deny the former president’s accusation that they are backed by America.

Another political act common in the slogans is that of legitimation. Disclaimer has sometimes been used as a discursive strategy. Several slogans present something positive at first, and then reject it by employing a particular term such as *lakin* (van Dijk, 1995, 1998). This serves as a positive representation of self-legitimation and negative representation of other-de-legitimation (van Dijk, 1995, 1998, 2006). Consider, for example, the slogan given in (57):

*57. Taʿiz musalimah wa lakinaha sa-tantafiḍ wa tashtaʿil radan ʿala maḥraqatikum*. [Taʿiz is a city of peace. However, it will revolt in response to your holocaust.]

The slogan shows that the Yemeni province of *Taʿiz* is peaceful in nature and in practice, but its people will carry the arm to defend themselves as a reaction to attacking the freedom square in *Taʿiz*. Such an incident has been called *al-maḥraqah* ‘the Holocaust’ as a reminder of the Holocaust of the Jews at the hands of the Nazi leader, Hitler. The slogan clearly legitimates the use of the arm in the face of the security forces. Similarly, religion has been used as a discourse strategy of legitimizing self-defence and war. The Qurāʾnic verse ‘*kutba ʿlikum al-qitāl wa hwa kurh lakum*’ ‘Fighting is prescribed for you, and ye dislike it’ has been used by protesters in many Arab Spring countries.

As van Dijk (1997: 37) points out legitimization is not ‘a speech act in the strict sense, but a complex social act or process that may be accomplished by other speech acts, such as assertions, denials, counter-accusations, and so on’. Consider, for example (58), in which Saleh’s supporters chant for him to continue in power in compliance with the constitutional and election legitimation. The supporters have counter-argued Saleh’s opponents who call for the fall of Saleh’s regime. For instance, several speech acts are in play in (58), such as assertion and the denial of the opponents’ claim that Saleh is no longer the legitimate president of the Republic:

*58. Al-shʿab yurīd ʿali ʿabdallah Ṣāliḥ wa yujasid baqāʾah iḥtirām al-sharʿiyah al-dustūriyah wa al-intikhābiyah alti istmadha min fawzih fī intikhābāt tanafusiyah li-al-riyasah al-yamanyah*. [The people want Ali Abdullah Saleh. [His presence embodies respect for the constitutional and election legitimacy he drew from his victory in competitive elections for the presidency of Yemen.]

As opposed to *al-sharʿiyah al-dustūriyah* ‘constitutional legitimation’ of the regime, the revolutionaries have also legitimated their uprising calling it, *al-sharʿiyah al-thawriyah* ‘revolutionary legitimation’.

Some slogans have also taken the form of questions. The toppled presidents have been questioned on more than one occasion. Mubarak, for example, has been asked by the protesters to clarify how he possessed 70 billion dollars in (59):

*59. Ya Mubārak ya ṭayār minlak 70 milyār*. [O Mubarak! The pilot, how can you accumulate a wealth of 70 billion dollar?]

The question here is not a question in the strict sense (i.e. it does not need any answer from the respondent). It rather intends to show how corrupt Mubarak is.

Another illocutionary act in the slogans is that of appeal to God. Both pro- and anti-regime in Yemen, for example, appeal and pray to God to help them. While the protesters supplicate to God to assist them to get rid of the president, as is obvious in (60), Saleh’s supporters pray to God to grant him victory and success as in (61):

*60. Ya Allah ya allah yasquṭ ʿali ʿabdallah*. [We pray to you God! We pray to you God! Ali Abdullah will fall.]

*61. Ya Allah ya Allah inṣur ʿali ʿabdallah*. [We pray to you God! We pray to you God! Grant Ali Abdullah your victory.]

It is obvious then that Arab Spring slogans exhibit universal features. Although the current study is not concerned with finding out the specificity of the Arab slogans and their differences from the slogans used worldwide, it would be useful to show some of those differences. In terms of linguistic features, Arab Spring slogans, like slogans used elsewhere, are mapped onto the various levels of linguistics from lexis to pragmatics to enable the demonstrators to coerce, represent and misrepresent, legitimize and delegitimize (Chilton and Schäffner, 1997: 211–215). In terms of the macropropositions or topics of the slogans, the Arab Spring slogans show some difference. Arabs are really preoccupied with the concept of leadership and thus the slogans tend to be more revolutionary. This is somewhat different from slogans produced in other regions, which are for the most part reformist. In addition, the topics of slogans in other regions are likely to be semantically modalized (Lycan, 1994; van Dijk, 1997) in the sense that events and actions may be permitted or obligatory, wished or regretted, and so on (Coates, 1990; Maynard, 1993). Most of the Arab slogans, however, encompass actions that must be fulfilled. In other words, Arab Spring slogans are less semantically modalized for permission, wish or regret. Most of the slogans show the obligatory actions of toppling the regimes, trailing them and humiliating them.

Therefore, it can be claimed that the format of the Arab Spring slogans and slogans in other regions have become rather homogeneous even though their discursive content is increasingly localized. Slogans are widely used in the entire world and their spread can be parallel to McDonaldization (Machin and van Leeuwen, 2004: 99). That is to say, while the formats of McDonald’s burgers are the same in the whole world, local versions of McDonald’s burgers are sold in different regions in the world.

**Conclusion**

The Arab Spring slogans have become an evolving sub-genre of political discourse. The slogans collected from different parts of the Arab world have shown that the slogans meet the various typical discourse structures and strategies that pertain to political discourse at various levels and dimensions. The slogans’ topics, textual schemata, local semantics, lexicon, syntax and pro-forms, rhetorical operations and expression structures justify that they are an essential element of the overall political discourse (van Dijk, 1997). The slogans deal with political as well as social topics. They have their own unique schematic structures and superstructures. The local semantics of the slogans tend to better the image of the in-groups and distort the image of out-groups. A lengthy list of words has come into existence during the uprisings. The syntax of the slogan is characterized by brevity, the avoidance of complex sentences, nominalization, special use of pronouns (i.e. positive use of the pronoun ‘we’ and negative association with the pronoun ‘they’), and unique use of foregrounding and backgrounding with a view to emphasizing or de-emphasizing something. Besides, the slogans employ a ‘smash hits’ selection of rhetorical devices. The slogans are full of similes, metaphors, metonymies, antithesis, etc. Prosodic features decorate almost all the slogans. Cohesive devices such as parallelism, ellipsis and morphological repetition are craftily and skilfully used. As for expression structure, slogans appear in different forms and shapes. Some of the slogans are multimodal where text, image and music go hand in hand. Finally, slogans serve multiple speech acts. Directives, questions, appeal and pray, accusation and counter-accusations, legitimation, etc. are found in the slogans.

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**Body**

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EN EN EUROPEAN COMMISSION Brussels, 4.10.2017 COM(2017) 477 final/2 2017/0225 (COD) CORRIGENDUM This document corrects document COM(2017)477 final of 13.09.2017 Concerns the English language version. Correction of errors of a clerical and formatting nature, as well as correction of crossreferences and the use of certain defined terms. The text shall read as follows: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on ENISA, the 'EU Cybersecurity Agency', and repealing Regulation (EU) 526/2013, and on Information and Communication Technology cybersecurity certification (''Cybersecurity Act'') (Text with EEA relevance) {SWD(2017) 500} {SWD(2017) 501} {SWD(2017) 502} EN 2 EN EXPLANATORY MEMORANDUM 1. CONTEXT OF THE PROPOSAL • Reasons for and objectives of the proposal The European Union has taken a number of actions to increase resilience and enhance its cybersecurity preparedness. The first EU Cybersecurity Strategy1 adopted in 2013 set out ***strategic*** objectives and concrete actions to achieve resilience, reduce cybercrime, develop cyberdefence policy and capabilities, develop industrial and technological resources and establish a coherent international cyberspace policy for the EU. In that context, important developments have taken place since then, including in particular the second mandate for the European Union Agency for Network and Information Security (ENISA)2 and the adoption of the Directive on security of network and information systems3 (the 'NIS Directive'), which form the basis for the present proposal.

Furthermore, in 2016 the European Commission adopted a Communication on Strengthening Europe's Cyber Resilience System and Fostering a Competitive and Innovative Cybersecurity Industry4, in which further measures were announced to step-up cooperation, information and knowledge sharing and to increase the EU’s resilience and preparedness, also taking into account the prospect of large scale incidents and a possible pan-European cybersecurity crisis. In this context, the Commission announced that it would bring forward the evaluation and review of Regulation (EU) No 526/2013 of the European Parliament and of the Council concerning ENISA and repealing Regulation (EC) No 460/2004 ('ENISA Regulation'). The evaluation process could lead to a possible reform of the Agency and an enhancement of its capabilities and capacities to support Member States in a sustainable manner. It would therefore give it a more operational and central role in achieving cybersecurity resilience and would acknowledge in its new mandate the Agency’s new responsibilities under the NIS Directive. The NIS Directive is a first essential step with a view to promoting a culture of risk management, by introducing security requirements as legal obligations for the key economic actors, notably operators providing essential services (Operators of Essential Services – OES) and suppliers of some key digital services (Digital Service Providers – DSPs). With security requirements being seen as essential to safeguard the benefits of the evolving digitalisation of society, and given the rapid proliferation of connected devices (the Internet of Things – IoT), the 2016 Communication also put forward the idea of establishing a framework for security certification for ICT products and services in order to increase trust and security in the digital single market. ICT cybersecurity certification becomes particularly relevant in view of the increased use of technologies which require a high level of cybersecurity, such as connected and automated cars, electronic health or industrial automation control systems (IACS). 1 Joint Communication of the European Commission and the European External Action Service: Cybersecurity Strategy of the European Union: An Open, Safe and Secure Cyberspace - JOIN(2013). 2 Regulation (EU) 526/2013 concerning the European Union Agency for Network and Information Security (ENISA) and repealing Regulation (EC) No 460/2004 3 Directive (EU) 2016/1148 concerning measures for a high common level of security of network and information systems across the Union 4 Commission Communication on Strengthening Europe's Cyber Resilience System and Fostering a Competitive and Innovative Cybersecurity Industry, COM/2016/0410 final. EN 3 EN These policy measures and announcements were further reinforced by the 2016 Council Conclusions, which acknowledged that 'cyber threats and vulnerabilities continue to evolve and intensify which will require continued and closer cooperation, especially in handling large-scale cross-border cybersecurity incidents'. The conclusions reaffirmed that 'the ENISA Regulation is one of the core elements of an EU cyber resilience framework'5 and called upon the Commission to take further steps to address issue of certification at the European level. The establishment of a certification system would require the setting-up of an appropriate governance system at EU level, including thorough expertise provided by an independent EU agency. In this respect, the present proposal identifies ENISA as the natural EU-level body competent on cybersecurity matters which should take up such role to bring together, and coordinate the work of, national competent bodies in the field of certification. In its Communication on the DSM Strategy Mid-term Review of May 2017, the Commission further specified that by September 2017 it would review the mandate of ENISA. This in order to define its role in the changed cybersecurity ecosystem and develop measures on cybersecurity standards, certification and labelling to make ICT-based systems, including connected objects, more cyber-secure.6 The European Council conclusions in June 20177 welcomed the Commission's intention to review the Cybersecurity Strategy in September and to propose further targeted actions before the end of 2017. The proposed Regulation provides for a comprehensive set of measures that build on previous actions and fosters mutually reinforcing specific objectives:  Increasing capabilities and preparedness of Member States and businesses;  Improving cooperation and coordination across Member States and EU institutions, agencies and bodies;  Increasing EU level capabilities to complement the action of Member States, in particular in the case of cross-border cyber crises;  Increasing awareness of citizens and businesses on cybersecurity issues;  Increasing the overall transparency of cybersecurity assurance8 of ICT products and services to strengthen trust in the digital single market and in digital innovation; and  Avoiding fragmentation of certification schemes in the EU and related security requirements and evaluation criteria across Member States and sectors. The following part of the Explanatory Memorandum explains the rationale for the initiative with respect to the proposed actions for ENISA and cybersecurity certification in more detail. 5 Council Conclusions on Strengthening Europe's Cyber Resilience System and Fostering a Competitive and Innovative Cybersecurity Industry - 15 November 2016. 6 Commission Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy - COM(2017) 228. 7 European Council meeting (22 and 23 June 2017) – Conclusions EUCO 8/17. 8 Transparency of cybersecurity assurance means providing users with sufficient information on cybersecurity properties which enables users to objectively determine the level of security of a given ICT product, service or process. EN 4 EN ENISA ENISA acts as a centre of expertise dedicated to enhancing network and information security in the Union and supporting capacity building of Members States. ENISA was set up in 20049 to contribute to the overall goal of ensuring a high level of network and information security within the EU. In 2013, Regulation (EU) No 526/2013 established the new mandate of the Agency for a period of seven years, until 2020. The Agency has its offices in Greece, notably the administrative seat in Heraklion (Crete) and the core operations in Athens. ENISA is a small agency with a low budget and number of staff compared to all EU agencies. It has a fixed-term mandate. ENISA supports the European institutions, the Member States and the business community in addressing, responding and especially in preventing network and information security problems. It does so through a series of activities across five areas identified in its strategy10:  Expertise: provision of information and expertise on key network and information security issues.  Policy: support to policy making and implementation in the Union.  Capacity: support for capacity building across the Union (e.g through trainings, recommendations, awareness raising activities).  Community: foster the network and information security community (e.g support to the Computer Emergency Response Teams (CERTs), coordination of pan-European cyber exercises).  Enabling (e.g engagement with the stakeholders and international relations). In the course of the negotiations of the NIS Directive, the EU co-legislators decided to attribute important roles to ENISA in the implementation of this Directive. In particular, the Agency provides the secretariat to the CSIRTs Network (established to promote swift and effective operational cooperation between Member States on specific cybersecurity incidents and sharing information about risks), and it is also called on to assist the Cooperation Group in the execution of its tasks. In addition, the Directive requires ENISA to assist Member States and the Commission by providing expertise and advice and by facilitating the exchange of best practices. In accordance with the ENISA Regulation, the Commission has carried out an evaluation of the Agency which includes an independent study as well as a public consultation. The evaluation assessed the relevance, impact, effectiveness, efficiency, coherence and EU added value of the Agency with regard to its performance, governance, internal organisational structure and working practices during the period 2013-2016. The overall performance of ENISA was positively assessed by a majority of respondents11 (74%) in the public consultation. A majority of respondents furthermore considered ENISA to 9 Regulation (EC) n° 460/2004 of the European Parliament and of the Council of 10 March 2004 establishing the European Network and Information Security Agency, OJ L 77, 13.3.2004, p. 1. 10 [*https://www.enisa.europa.eu/publications/corporate/enisa-strategy*](https://www.enisa.europa.eu/publications/corporate/enisa-strategy) EN 5 EN be achieving its different objectives (at least 63% for each of the objectives). ENISA’s services and products are regularly (monthly or more often) used by almost half of the respondents (46%) and are appreciated for the fact that they stem from an EU-level body (83%) and for their quality (62%). However, a large majority (88%) of respondents considered the current instruments and mechanisms available at EU level to be insufficient or only partially adequate in addressing the current cybersecurity challenges. A large majority of respondents (98%) indicated that an EU body should address these needs, and among them ENISA was considered to be the right organisation to do so by 99% of the respondents. In addition, 67.5 % of respondents expressed the view that ENISA could play a role in establishing a harmonized framework for security certification of IT products and services. The overall evaluation (based not only on the public consultation but also on a number of individual interviews, additional targeted surveys and workshops) reached the following conclusions:  ENISA's objectives remain relevant today. In a context of fast technological developments and evolving threats and in view of the growing global cybersecurity risks, there is a clear need in the EU for fostering and further reinforcing high-level technical expertise on cybersecurity issues. Capacities need to be built in the Member States to understand and respond to threats and stakeholders need to cooperate across thematic fields and across institutions.  Despite its small budget, the Agency has been operationally efficient in the use of its resources and in the implementation of its tasks. The location split between Athens and Heraklion has, however, also generated further administrative costs.  In terms of effectiveness, ENISA partially met its objectives. The Agency successfully contributed to improving network and information security in Europe by offering capacity building in 28 Member States12, enhancing cooperation between Member States and network and information security stakeholders, and by providing expertise, community building and support to the development of policies. Overall, ENISA diligently focused on the implementation of its work programme and acted as a trusted partner for its stakeholders, in a field which has only recently been recognised to have such strong cross-border relevance.  ENISA managed to make an impact, at least to some extent, in the vast field of network and information security, but it has not fully succeeded in developing a strong brand name and gaining sufficient visibility to become recognised as 'the' 11 90 stakeholders from 19 Member States replied to the consultation (88 responses and 2 position papers), including national authorities from 15 Member States and 8 umbrella organisations representing a significant number of European enterprises. 12 Respondents to the public consultation were asked to comment on what they perceived as ENISA’s main achievements over 2013-2016. Respondents from all groups (in total 55, including 13 from national authorities, 20 from private sector and 22 from 'other') perceived the following as ENISA’s main achievements: 1) The coordination of the Cyber Europe exercises; 2) The provision of support to CERTs/CSIRTs through training and workshops fostering coordination and exchange; 3) ENISA’s publications (guidelines and recommendations, threat landscape reports, strategies for incident reporting and crisis management etc.) that were considered as useful to create and update national security frameworks, as well as for reference to policy makers and cyber practitioners; 4) Assisting with the promotion of the NIS Directive; 5) Efforts to increase awareness on cybersecurity via the cybersecurity month. EN 6 EN centre of expertise in Europe. The explanation for this lies in the broad mandate of ENISA, which was not equipped with proportionally sufficient resources. Furthermore, ENISA remains the only EU agency with a fixed-term mandate, thus limiting its ability to develop a long-term vision and support its stakeholders in a sustainable manner. This also contrasts with the provisions of the NIS Directive, which entrust ENISA with tasks with no end date. Finally, the assessment found that this limited effectiveness can partly be explained by the high reliance on external expertise over in-house expertise, and by the difficulties in recruiting and retaining specialised staff.  Last but not least, the evaluation concluded that ENISA’s added value lies primarily in the Agency’s ability to enhance cooperation mainly between Member States, and especially with related network and information security communities (in particular between CSIRTs). There is no other actor at EU level that supports such broad scope of network and information security stakeholders. However, due to the need to strictly prioritise its activities, ENISA’s work programme is mostly guided by the needs of Member States. As a result, it does not sufficiently address the needs of other stakeholders, in particular the industry. It also made the Agency reactive to fulfilling the needs of its key stakeholders, preventing it from achieving a bigger impact. Therefore, the added value provided by the Agency varied according to the diverging needs of its stakeholders and to the extent to which the Agency was able to respond to them (e.g large versus small Member States; Member States versus industry). In summary, the results of the stakeholders' consultations and evaluation suggested that ENISA's resources and mandate need to be adapted so that it can play an adequate role in responding to present and future challenges. In view of these findings, the present proposal reviews the current mandate of ENISA and lays down a renewed set of tasks and functions, with a view to effectively and efficiently supporting Member States, EU institutions and other stakeholders' efforts to ensure a secure cyberspace in the European Union. The new proposed mandate seeks to give the Agency a stronger and more central role, in particular by also supporting Member States in implementing the NIS Directive and to counter particular threats more actively (operational capacity) and by becoming a centre of expertise supporting Member States and the Commission on cybersecurity certification. Under this proposal:  ENISA would be granted a permanent mandate and thus be put on a stable footing for the future. The mandate, objectives and tasks should still be subject to regular review.  The proposed mandate further clarifies the role of ENISA as the EU agency for cybersecurity and as the reference point in the EU cybersecurity ecosystem, acting in close cooperation with all the other relevant bodies of such an ecosystem.  The organisation and the governance of the Agency, which were positively judged in the course of the evaluation, would be moderately reviewed, in particular to make sure that the needs of the wider stakeholders' community are better reflected in the work of the Agency.  The suggested scope of the mandate is delineated, strengthening those areas where the agency has shown clear added value and adding those new areas where support is needed in view of the new policy priorities and instruments, in particular the NIS EN 7 EN Directive, the review of the EU Cybersecurity Strategy, the upcoming EU Cybersecurity Blueprint for cyber crisis cooperation and ICT security certification:  EU policy development and implementation: ENISA would be tasked with proactively contributing to the development of policy in the area of network information security, as well as to other policy initiatives with cybersecurity elements in different sectors (e.g energy, transport, finance). To this end, it would have a strong advisory role, which it could fulfil by providing independent opinions and preparatory work for the development and the update of policy and law. ENISA would also support the EU policy and law in the areas of electronic communications, electronic identity and trust services, with a view to promoting an enhanced level of cybersecurity. In the implementation phase, in particular in the context of the NIS Cooperation Group, ENISA would assist Member States in achieving a consistent approach on the implementation of the NIS Directive across borders and sectors, as well as in other relevant policies and laws. In order to support the regular review of policies and laws in the area of cybersecurity, ENISA would also provide regular reporting on the state of implementation of the EU legal framework.  Capacity building: ENISA would be contributing to the improvement of EU and national public authorities' capabilities and expertise, including on incident response and on the supervision of cybersecurity related regulatory measures. The Agency would also be required to contribute to the establishment of Information Sharing and Analysis Centres (ISACS) in various sectors by providing best practices and guidance on available tools and procedures, as well as by appropriately addressing regulatory issues related to information sharing.  Knowledge and information, awareness raising: ENISA would become the information hub of the EU. This would imply the promotion and sharing of best practices and initiatives across the EU by pooling information on cybersecurity deriving from the EU and national institutions, agencies and bodies. The Agency would also make available advice, guidance and best practices on the security of critical infrastructures. In the aftermath of significant cross-border cybersecurity incidents, ENISA would furthermore compile reports with a view of providing guidance to businesses and citizens across the EU. This stream of work would also involve the regular organisation of awareness raising activities in coordination with Member States authorities.  Market related tasks (standardisation, cybersecurity certification): ENISA would perform a number of functions specifically supporting the internal market and cover a cybersecurity 'market observatory', by analysing relevant trends in the cybersecurity market to better match demand and supply, and by supporting the EU policy development in the ICT standardisation and ICT cybersecurity certification areas. With regard to standardisation in particular, it would facilitate the establishment and uptake of cybersecurity standards. ENISA would also execute the tasks foreseen in the context of the future framework for certification (see below section).  Research and innovation: ENISA would contribute its expertise by advising EU and national authorities on priority-setting in research and development, including in the context of the contractual public-private partnership on cybersecurity (cPPP). ENISA's advice on research would feed into the new EN 8 EN European Cybersecurity Research and Competence Centre under the next multi-annual financial framework. ENISA would also be involved, when asked to do so by the Commission, in the implementation of research and innovation EU funding programmes.  Operational cooperation and crisis management: this stream of work should build on strengthening the existing preventive operational capabilities, in particular upgrading the pan-European cybersecurity exercises (Cyber Europe) by having them on a yearly basis, and on a supporting role in operational cooperation as secretariat of the CSIRTs Network (as per NIS Directive provisions) by ensuring, among others, the well-functioning of the CSIRTs Network IT infrastructure and communication channels. In this context, a structured cooperation with CERT-EU, European Cybercrime Centre (EC3) and other relevant EU bodies would be required. Furthermore, a structured cooperation with CERT-EU, in close physical proximity, should result in a function to provide technical assistance in case of significant incidents and to support incident analysis. Member States that would request it would receive assistance to handle incidents and support for the analysis of vulnerabilities, artefacts and incidents in order to strengthen their own preventive and response capability.  ENISA would also play a role in the EU cybersecurity blueprint presented as part of this package and setting the Commission's recommendation to Member States for a coordinated response to large-scale cross-border cybersecurity incidents and crises at the EU level13. ENISA would facilitate the cooperation between individual Member States in dealing with emergency response by analysing and aggregating national situational reports based on information made available to the Agency on a voluntary basis by Member States and other entities.  Cybersecurity certification of ICT products and services In order to establish and preserve trust and security, ICT products and services need to directly incorporate security features in the early stages of their technical design and development (security by design). Moreover, customers and users need to be able to ascertain the level of security assurance of the products and services they procure or purchase. Certification, which consists of the formal evaluation of products, services and processes by an independent and accredited body against a defined set of criteria standards and the issuing of a certificate indicating conformance, plays an important role in increasing trust and security in products and services. While security evaluations are quite a technical area, certification serves the purpose to inform and reassure purchasers and users about the security properties of the ICT products and services that they buy or use. As mentioned above, this is particularly relevant for new systems that make extensive use of digital technologies and which require a 13 The 'blueprint' will apply to cybersecurity incidents whose disruption is more extensive than any Member State can handle on its own or affects two or more Member States with such a wide-ranging and significant impact or political significance that they require timely policy coordination and response at Union political level. EN 9 EN high level of security, such as e.g connected and automated cars, electronic health, industrial automation control systems (IACS)14 or smart grids. Currently, the landscape of cybersecurity certification of ICT products and services in the EU is quite patchy. There are a number of international initiatives, such as the so-called Common Criteria (CC) for Information Technology Security Evaluation (ISO 15408), which is an international standard for computer security evaluation. It is based on third party evaluation and envisages seven Evaluation Assurance Levels (EAL). The CC and the companion Common Methodology for Information Technology Security Evaluation (CEM) are the technical basis for an international agreement, the Common Criteria Recognition Arrangement (CCRA), which ensures that CC certificates are recognized by all the signatories of the CCRA. However, within the current version of the CCRA only evaluations up to EAL 2 are mutually recognized. Moreover, only 13 Member States have signed the Arrangement. The certification authorities from 12 Member States have concluded a mutual recognition agreement regarding the certificates issued in conformity with the agreement on the basis of the Common Criteria15. Moreover, a number of ICT certification initiatives currently exist or are being established in Member States. Even if important, these initiatives bear the risk of creating market fragmentation and interoperability issues. As a consequence, a company may need to undergo several certification procedures in various Member States to be able to offer its product on multiple markets. For example, a smart meter manufacturer who wants to sell its products in three Member States, e.g Germany, France and UK, currently needs to comply with three different certification schemes. These are the Commercial Product Assurance (CPA) in the UK, Certification de Sécurité de Premier Niveau in France (CSPN) and a specific protection profile based on Common Criteria in Germany. This situation leads to higher costs and constitutes a considerable administrative burden for companies operating in several Member States. While the cost of certification may vary significantly depending on the product/service concerned, the evaluation assurance level sought and/or other components, in general this tends to be quite considerable for businesses. For the BSI “Smart Meter Gateway” certificate, for example, the cost is more than EUR one million (highest level of test and assurance, concerns not only one product but the whole infrastructure around it as well). The cost for smart meters certification in the UK is almost EUR 150 000. In France, the cost is similar to the UK, about EUR 150 000 or more. Key public and private stakeholders recognised that in the absence of an EU-wide cybersecurity certification scheme, companies in many circumstances have to be certified individually in each Member State, thus leading to market fragmentation. Most importantly, in the absence of EU harmonisation legislation for ICT products and services, differences in cybersecurity certification standards and practices in Member States are liable to create 28 separate security markets in the EU in practice, each one with its own technical requirements, testing methodologies and cybersecurity certification procedures. These divergent approaches at national level are liable to cause – should no adequate action be taken at EU level – a 14 DG JRC has published a report that proposes an initial set of common European requirements and broad guidelines related to cybersecurity certification of IACS components. Available at:   [*https://erncip-project.jrc.ec.europa.eu/documents/introduction-european-iacs-components-cybersecurity-certification-framework-iccf*](https://erncip-project.jrc.ec.europa.eu/documents/introduction-european-iacs-components-cybersecurity-certification-framework-iccf) 15 The Senior Officials Group on Information Systems Security (SOG-IS) includes 12 Member States plus Norway and has developed a few protection profiles on a limited number of products such as digital signature, digital tachograph and smart cards. Participants work together to coordinate the standardisation of CC protection profiles and coordinate the development of protection profiles. Member States often request SOG-IS certification for national public procurement tenders. EN 10 EN significant setback in the achievement of the digital single market, slowing down or preventing the connected positive effects in terms of growth and jobs. Building on the above developments, the proposed Regulation establishes a European Cybersecurity Certification Framework (the 'Framework') for ICT products and services and specifies the essential functions and tasks of ENISA in the field of cybersecurity certification. The present proposal lays down an overall framework of rules governing European cybersecurity certification schemes. The proposal does not introduce directly operational certification schemes, but rather create a system (framework) for the establishment of specific certification schemes for specific ICT products/services (the 'European cybersecurity certification schemes'). The creation of European cybersecurity certification schemes in accordance with the Framework will allow certificates issued under those schemes to be valid and recognised across all Member States and to address the current market fragmentation. The general purpose of a European cybersecurity certification scheme is to attest that the ICT products and services that have been certified in accordance with such scheme comply with specified cybersecurity requirements. This for instance would include their ability to protect data (whether stored, transmitted or otherwise processed) against accidental or unauthorised storage, processing, access, disclosure, destruction, accidental loss or alteration. EU cybersecurity certification schemes would make use of existing standards in relation to the technical requirements and evaluation procedures that the products need to comply with and would not develop the technical standards themselves16. For instance, an EU-wide certification for products such as smart cards, which are currently tested against international CC standards under the multilateral SOG-IS scheme (and described previously), would mean making this scheme valid throughout the EU. In addition to outlining a specific set of security objectives to be taken into account in the design of a specific European cybersecurity certification scheme, the proposal provides what the minimum content of such schemes should be. Such schemes will have to define, among others, a number of specific elements setting out the scope and object of the cybersecurity certification. This includes the identification of the categories of products and services covered, the detailed specification of the cybersecurity requirements (for example by reference to the relevant standards or technical specifications), the specific evaluation criteria and methods, and the level of assurance they are intended to ensure (i.e basic, substantial or high). European cybersecurity certification schemes will be prepared by ENISA, with the assistance, expert advice and close cooperation of the European Cybersecurity Certification Group (see below), and adopted by the Commission by means of implementing acts. When the need for a cybersecurity certification scheme is identified, the Commission will request ENISA to prepare a scheme for specific ICT products or services. ENISA will work on the scheme in close cooperation with national certification supervisory authorities represented in the Group. Member States and the Group may propose to the Commission that it requests ENISA to prepare a particular scheme. Certification can be a very expensive process, which in turn could lead to h

igher prices for customers and consumers. The need to certify may also vary significantly according to the specific context of use of the products and services and fast pace of technological change. 16 In the case of European standards, this is done through the European standardisation organisations and endorsed by the European Commission in the publication in the Official Journal (see Regulation 1025/2012). EN 11 EN Recourse to European cybersecurity certification should therefore remain voluntary, unless otherwise provided in Union legislation laying down security requirements of ICT products and services. In order to ensure harmonisation and avoid fragmentation, national cybersecurity certification schemes or procedures for the ICT products and services covered by a European cybersecurity certification scheme will cease to apply from the date established in the implementing act adopting the scheme. Member States should furthermore not introduce new national cybersecurity certification schemes for the ICT products and services covered by an existing European cybersecurity certification scheme. Once a European cybersecurity certification scheme is adopted, manufacturers of ICT products or providers of ICT services will be able to submit an application for certification of their products or services to a conformity assessment body of their choice. Conformity assessment bodies should be accredited by an accreditation body if they comply with certain specified requirements. Accreditation will be issued for a maximum of five years and may be renewed on the same conditions provided that the conformity assessment body meets the requirements. Accreditation bodies will revoke an accreditation of a conformity assessment body where the conditions for the accreditation are not, or are no longer, met, or where actions taken by a conformity assessment body infringe this Regulation. Under the proposal, the monitoring, supervisory and enforcement tasks lie with the Member States. Member States will have to provide for one certification supervisory authority. This authority will be tasked with supervising the compliance of conformity assessment bodies, as well as of certificates issued by conformity assessment bodies established in their territory, with the requirements of this Regulation and the relevant European cybersecurity certification schemes. National certification supervisory authorities will be competent to handle complaints lodged by natural or legal persons in relation to certificates issued by conformity assessment bodies established in their territories. To the appropriate extent, they will investigate the subject matter of the complaint and inform the complainant of the progress and the outcome of the investigation within a reasonable time period. Moreover, they will cooperate with other certification supervisory authorities or other public authorities, for instance by sharing information on possible non-compliance of ICT products and services with the requirements of this Regulation or with the specific European cybersecurity certification schemes. Finally, the proposal establishes the European Cybersecurity Certification Group (the 'Group'), consisting of national certification supervisory authorities of all Member States. The main task of the Group is to advise the Commission on issues concerning cybersecurity certification policy and to work with ENISA on the development of draft European cybersecurity certification schemes. ENISA will assist the Commission in providing the secretariat of the Group and maintain an updated public inventory of schemes approved under the European Cybersecurity Certification Framework. ENISA would also liaise with standardisation bodies to ensure the appropriateness of standards used in approved schemes and to identify areas in need of cybersecurity standards. The European Cybersecurity Certification Framework ('Framework') will provide several benefits for citizens and for undertakings. In particular:  The creation of EU-wide cybersecurity certification schemes for specific products or services will provide companies with a 'one-stop-shop' for cybersecurity certification in the EU. Such companies will be able to certify their product only once and obtain a certificate valid in all Member States. They will not be obliged to re-certify their products under different national certification bodies. This will significantly reduce costs for companies, facilitate cross-border operations and EN 12 EN ultimately reduce and avoid a fragmentation of the internal market for the products concerned.  The Framework establishes the primacy of European cybersecurity certification schemes over national schemes: under this rule, the adoption of a European cybersecurity certification scheme will supersede all existing parallel national schemes for the same ICT products or services at a given level of assurance. This will bring further clarity, reducing the current proliferation of overlapping and possibly conflicting national cybersecurity certification schemes.  The proposal supports and complements the implementation of the NIS Directive by providing the undertakings subject to the Directive with a very useful tool to demonstrate compliance with the NIS requirements in the whole Union. In developing new cybersecurity certification schemes, the Commission and ENISA will pay particular attention to the need to ensure that the NIS requirements are reflected in the cybersecurity certification schemes.  The proposal will support and facilitate the development of a European cybersecurity policy, by harmonising the conditions and substantive requirements for the cybersecurity certification of ICT products and services in the EU. European cybersecurity certification schemes will refer to common standards or criteria of evaluation and testing methodologies. This will contribute significantly, albeit indirectly, to the take-up of common security solutions in the EU, thereby also removing barriers to the internal market.  The Framework is designed in such a way to ensure the necessary flexibility for cybersecurity certification schemes. Depending on the specific cybersecurity needs, a product or service may be certified against higher or lower levels of security. European cybersecurity certification schemes will be designed with this flexibility in mind and will therefore provide for different levels of assurance (i.e basic, substantial or high) so that they may be used for different purposes or in different contexts.  All the above elements will make the cybersecurity certification more attractive for businesses as an effective means to communicate the level of cybersecurity assurance of ICT products or services. To the extent that cybersecurity certification becomes less expensive, more effective and commercially attractive, businesses will have greater incentives to certify their products against cybersecurity risks, thereby contributing to the spread of better cybersecurity practices in the design of ICT products and services (cybersecurity by design). • Consistency with existing policy provisions in the policy area Under the NIS Directive, operators in sectors which are vital for our economy and society, such as energy, transport, water, banking, financial market infrastructures, healthcare and digital infrastructure, as well as digital service providers (i.e search engines, cloud computing services and online marketplaces) are required to take measures to appropriately manage security risks. The new rules of this proposal complement, and ensure consistency with the provisions of the NIS Directive, in order to pursue still further the cyber resilience of the EU through enhanced capabilities, cooperation, risk management and cyber awareness. Moreover, the rules on cybersecurity certification provide an essential tool for companies subject to the NIS Directive, as they will be able to certify their ICT products and services EN 13 EN against cybersecurity risks on the basis of cybersecurity certification schemes valid and recognised throughout the EU. They will also be complementary to security requirements mentioned in the eIDAS Regulation17 and the Radio Equipment Directive18. • Consistency with other Union policies The Regulation (EU) 2016/679 (the General Data Protection Regulation, 'GDPR')19 lays down provisions to establish certification mechanisms and data protection seals and marks for the purpose of demonstrating compliance with this Regulation of processing operations by controllers and processors. The present Regulation is without prejudice to the certification of data processing operations, including when such operations are embedded in products and services, under the GDPR. The proposed Regulation will ensure compatibility with Regulation 765/2008 on accreditation and market surveillance requirements20 by referring to the rules of that framework on national accreditation bodies and conformity assessment bodies. As far as supervisory authorities are concerned, the proposed Regulation will require Member States to designate national certification supervisory authorities with responsibilities for supervision, monitoring and enforcement of the rules. Those bodies will remain separate from conformity assessment bodies, as prescribed by Regulation 765/2008. 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY • Legal basis The legal basis for EU action is Article 114 of the Treaty on the Functioning of the European Union (TFEU), which deals with the approximation of laws of the Member States in order to achieve the objectives of Article 26 TFEU, namely, the proper functioning of the internal market. The internal market legal basis for establishing ENISA has been upheld by the Court of Justice (in case C-217/04 United Kingdom vs. European Parliament and Council) and was further confirmed by the 2013 Regulation which set the current mandate of the Agency. In addition, activities that would reflect the objectives to increase cooperation and coordination among Member States and those adding EU level capabilities to complement the action of Member States would fall under the category of 'operational cooperation'. This is specifically identified by the NIS Directive (for which Article 114 TFEU is the legal basis) as an objective to be pursued in the context of the CSIRTs Network where 'ENISA shall provide the secretariat and shall actively support the cooperation' (Article 12(2)). In particular, Article 17 Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC. 18 Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC 19 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1–88). 20 Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. EN 14 EN 12(3)(f) further outlines the identification of further forms of operational cooperation as task of the CSIRTs Network, including in relation to: (i) categories of risks and incidents; (ii) early warnings; (iii) mutual assistance; and (iv) principles and modalities for coordination, when Member States respond to cross-border risks and incidents.  The current fragmentation of the certification schemes for ICT products and services is also a result of the lack of a common legally binding and effective framework process applicable to the Member States. This hinders the creation of an internal market for ICT products and services and hampers the competitiveness of the European industry in this sector. The present proposal aims to address the existing fragmentation and the related obstacles to the internal market by providing a common framework for the establishment of cybersecurity certification schemes valid across the EU. Subsidiarity (for non-exclusive competence) The subsidiarity principle requires the assessment of the necessity and the added value of the EU action. The respect of subsidiarity in this area was already recognised when adopting the current ENISA Regulation21. Cybersecurity is an issue of common interest of the Union. The interdependencies between networks and information systems are such that individual actors (public and private, including citizens) very often cannot face the threats, manage the risks and the possible impacts of cyber incidents in isolation. On the one hand, the interdependencies across Member States, including with regard to the operation of critical infrastructures (energy, transport, water, just to name a few) make public intervention at the European level not only beneficial, but also needed. On the other hand, EU intervention can bring a positive 'spill over' effect due to the sharing of good practices across Member States, which can result in an enhanced cybersecurity of the Union. In summary, in the current context and looking at the future scenarios, it appears that to increase collective cyber-resilience of the Union individual actions by EU Member States and a fragmented approach to cybersecurity will not be sufficient. EU action is also deemed necessary to address the fragmentation of the current cybersecurity certification schemes. It would allow manufacturers to fully benefit from an internal market, with significant savings regarding testing and redesign costs. While the current Senior Officials Group – Information Systems Security (SOG-IS) Mutual Recognition Agreement (MRA) has for instance achieved important results in this respect, it has also shown important limitations which stand in the way of its suitability in being able to provide a longer term sustainable solutions in fulfilling the full potential of the internal market. The added value of acting at EU level, in particular to enhance cooperation between Member States, but also between network and information security communities, has been recognised by the 2016 Council Conclusions22 and it also clearly emerges from the evaluation of ENISA. 21 Regulation (EU) No 526/2013 of the European Parliament and of the Council of 21 May 2013 concerning the European Union Agency for Network and Information Security (ENISA) and repealing Regulation (EC) No 460/2004. 22 Council Conclusions on Strengthening Europe's Cyber Resilience System and Fostering a Competitive and Innovative Cybersecurity Industry - 15 November 2016. EN 15 EN • Proportionality The proposed measures do not go beyond what is necessary to achieve its policy objectives. Furthermore, the scope of EU intervention does not impede any further national actions in the field of national security matters. EU action is therefore justified on grounds of subsidiarity and proportionality. • Choice of the instrument The present proposal reviews Regulation (EU) No 526/2013 which sets the current mandate and tasks for ENISA. Furthermore, given ENISA's important role in the setting up and management of an EU cybersecurity certification framework, ENISA's new mandate and the said Framework are best established under one single legal instrument, using the instrument of a Regulation. 3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS Ex-post evaluations/fitness checks of existing legislation The Commission, according to the evaluation roadmap23, assessed the relevance, impact, effectiveness, efficiency, coherence and the added value of the Agency with regard to its performance, governance, internal organisational structure and working practices in the period 2013-2016. The main findings can be summarised as follows (for more see the Staff Working Document on the subject, accompanying the impact assessment).  Relevance: In a context of technological developments and evolving threats and considering the significant need for increased cybersecurity in the EU, ENISA's objectives proved to be relevant. Indeed, Member States and EU bodies rely on its substantial expertise on cybersecurity matters. Moreover, capacities need to be built in the Member States to better understand and respond to threats, and stakeholders need to cooperate across thematic fields and across institutions. Cybersecurity continues to be a key political priority of the EU to which ENISA is expected to respond; however, ENISA’s design as EU agency with a fixed-term mandate: (i) does not allow for long-term planning and sustainable support to Member States and EU institutions; (ii) may lead to a legal vacuum as the provisions of the NIS Directive entrusting ENISA with tasks are of a permanent nature24; (iii) lacks coherence with a vision linking ENISA to an enhanced EU cybersecurity ecosystem.  Effectiveness: ENISA overall met its objectives and implemented its tasks. It made a contribution to increased network and information security in Europe through its main activities (capacity building, provision of expertise, community building, and support to policy). It, however, showed potential for improvement in relation to each. The evaluation concluded that ENISA has effectively created strong and trustful relationships with some of its stakeholders, notably with the Member States and the CSIRTs community. Interventions in the area of capacity building were perceived as effective in particular for less resourced Member States. Stimulating broad cooperation has been one of the highlights, with stakeholders widely agreeing on the 23 [*http://ec.europa.eu/smart-regulation/roadmaps/docs/2017\_cnect\_002\_evaluation\_enisa\_en.pdf*](http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_cnect_002_evaluation_enisa_en.pdf) 24 Reference to Articles 7, 9, 11, 12, 19 of the Directive on Security of Network and Information Systems (NIS Directive). EN 16 EN positive role ENISA plays in bringing people together. However, ENISA faced difficulties to make a big impact in the vast field of network and information security. This was also due to the fact it had fairly limited human and financial resources to meet a very broad mandate. The evaluation also concluded that ENISA partially met the objective of providing expertise, linked to the problems in recruiting experts (see also below in the efficiency section).  Efficiency: Despite its small budget – among the lowest compared to other EU agencies – the Agency has been able to contribute to targeted objectives, showing overall efficiency in the use of its resources. The evaluation concluded that processes generally were efficient and a clear delineation of responsibilities within the organisation led to a good execution of the work. One of the main challenges to the Agency’s efficiency relates to ENISA’s difficulties in recruiting and retaining highly qualified experts. The findings show that this can be explained by a combination of factors, including the general difficulties across the public sector to compete with the private sector when trying to hire highly specialised experts, the type of contracts (fixed term) that the Agency could mostly offer and the somewhat low level of attractiveness related to ENISA's location, for example linked to difficulties encountered by spouses to find work. A location split between Athens and Heraklion required additional efforts of coordination and generated additional costs, but the move to Athens in 2013 of the core operations department increased the Agency's operational efficiency.  Coherence: ENISA’s activities have been generally coherent with the policies and activities of its stakeholders, at national and EU level, but there is a need for a more coordinated approach to cybersecurity at EU level. The potential for cooperation between ENISA and other EU bodies has not been fully utilised. The evolution in the EU legal and policy landscape make the current mandate less coherent today.  EU-added value: ENISA’s added value lies primarily in the Agency’s ability to enhance cooperation, mainly between Member States but also with related network and information security communities. There is no other actor at EU level that supports the cooperation of the same variety of stakeholders on network and information security. The added value provided by the Agency varied according to the diverging needs and resources of its stakeholders (e.g large versus small Member States; Member States versus industry) and the need for the Agency to prioritise its activities according to the work programme. The evaluation concluded that a potential discontinuation of ENISA would be a lost opportunity for all Member States. It will not be possible to ensure the same degree of community building and cooperation across the Member States in the field of cybersecurity. Without a more centralised EU agency the picture would be more fragmented, with bilateral or regional cooperation stepping in to fill a void left by ENISA. With specific regard to ENISA’s past performances and future, the main trends emerging from the 2017 consultation are the following25: 25 90 stakeholders from 19 Member States replied to the consultation (88 responses and 2 position papers), including national authorities from 15 Member States including France, Italy, Ireland and Greece and 8 umbrella organisations representing a significant number of European organisations, for example the European Banking Federation, Digital Europe (representing the digital technology industry in Europe), European Telecommunications Network Operators' Association (ETNO). The ENISA public consultation was complemented by several other sources, including; (i) in-depth interviews, with EN 17 EN  The overall performance of ENISA during the period 2013 to 2016 was positively assessed by a majority of respondents (74%). A majority of respondents furthermore considered ENISA to be achieving its different objectives (at least 63% for each of the objectives). ENISA’s services and products are regularly (monthly or more often) used by almost half of the respondents (46%) and are appreciated for the fact that they stem from an EU-level body (83%) and for their quality (62%).  Respondents identified a number of gaps and challenges for the future of cybersecurity in the EU, in particular the top five (in a list of 16) were: cooperation across Member States; capacity to prevent, detect and resolve large scale cyber-attacks; cooperation across Member States in matters related to cyber security; cooperation and information sharing between different stakeholders, including public-private cooperation; protection of critical infrastructure from cyber-attacks.  A large majority (88%) of respondents considered the current instruments and mechanisms available at EU level to be insufficient or only partially adequate to address these. A large majority of respondents (98%) indicated that an EU body should respond to these needs and among them ENISA was considered to be the right organisation to do so by 99%. Stakeholder consultations  The Commission organised a public consultation for the review of ENISA between 12 April and 5 July, 2016 and received 421 replies26. According to the results, 67.5 % of respondents expressed the view that ENISA could play a role in establishing a harmonised framework for security certification of IT products and services. The results from the 2016 consultation on cybersecurity cPPP27 on the section on certification show that:  50,4% (e.g 121 out of 240) of respondents do not know whether national certification schemes are mutually recognised across EU Member States. 25.8% (62 out of 240) replied 'No', while 23.8% (57 out of 240) replied 'Yes'.  37,9% of respondents (91 out of 240) think that existing certification schemes do not support the needs of Europe's industry. On the other hand, 17, 5% (42 out of 240) – mainly global companies operating on the European market - expressed the ***opposite*** view.  49.6% (119 out of 240) of respondents says that it is not easy to demonstrate equivalence between standards, certification schemes, and labels. 37.9% (91 out of 240) replied 'I do not know', while only 12,5% (30 out of 240) replied ‘Yes’. approximatively 50 key players in the cybersecurity community; (ii) survey to the CSIRTs Network; (iii) survey to the ENISA Management Board, Executive Board, Permanent Stakeholder Group. 26 162 contributions from citizens, 33 from civil society and consumer organisations; 186 from industry and 40 from public authorities, including competent authorities enforcing the ePrivacy Directive. 27 240 stakeholders from national public administrations, large businesses, SMEs, microbusinesses and research bodies responded to the section on certification. EN 18 EN Collection and use of expertise The Commission relied on the following external expert advice:  Study on the Evaluation of ENISA (Ramboll/Carsa 2017; SMART no. 2016/0077),  Study on ICT Security Certification and Labelling – Evidence gathering and impact assessment (PriceWaterhouseCoopers 2017; SMART no. 2016/0029). Impact assessment  The Impact Assessment report on this initiative identified the following main problems to be addressed:  Fragmentation of policies and approaches to cybersecurity across Member States;  Dispersed resources and fragmentation of approaches to cybersecurity across EU institutions, agencies and bodies; and  Insufficient awareness and information of citizens and companies, coupled with the growing emergence of multiple national and sectoral certification schemes. The report assessed the following possible options with regard to ENISA's mandate:  preservation of the status quo, meaning an extended mandate still limited in time (baseline option);  expiry of ENISA’s current mandate without renewal and termination of ENISA (no policy intervention);  a 'reformed ENISA'; and  an EU cybersecurity agency with full operational capabilities. The report assessed the following possible options with regard to cybersecurity certification:  no policy intervention (baseline option);  non-legislative ('soft law') measures;  an EU legislative act to create a mandatory system for all Member States based on the SOG-IS system; and  an EU general ICT cybersecurity security certification framework. The analysis led to the conclusion that a 'reformed ENISA' in combination with an EU general ICT cybersecurity certification framework is the preferred option. The preferred option has been assessed as the most effective for the EU to reach the identified objectives of: increasing cybersecurity capabilities, preparedness, cooperation, awareness, transparency and avoiding market fragmentation. It has also been assessed as the most coherent with policy priorities of the EU Cybersecurity Strategy and related policies (e.g NIS Directive), and the Digital Single Market Strategy. In addition, from the consultation process, it emerged that the preferred option enjoys the support of the majority of stakeholders. Furthermore, the analysis conducted in the impact assessment showed that the preferred option would reach the objectives through a reasonable employment of resources. The Commission’s Regulatory Scrutiny Board delivered initially a negative opinion on 24 July, then a positive opinion on 25 August 2017 upon resubmission. The amended Impact Assessment report included additional supporting evidence, the final conclusions of the EN 19 EN evaluation of ENISA and additional explanations on the policy options and their impact. Annex 1 to the final Impact Assessment report summarizes how the comments of the Board in the second opinion have been addressed. In particular, the report was updated to present in greater detail the EU cybersecurity context, including the measures that are included in the Joint Communication 'Resilience, Deterrence and Defence: Building strong cybersecurity for the EU', (JOIN(2017) 450) and have a special relevance for ENISA: the EU cybersecurity blueprint and the European Cybersecurity Research and Competence Centre, to which the Agency would link its advisories on EU research needs. The report explains how the reform of the Agency, including the new tasks, the better conditions of employment and the structural cooperation with EU bodies in the field, would improve its attractiveness as employer and help tackle problems related to the recruitment of experts. Annex 6 to the report also presents a revised estimate of costs associated to the policy options for ENISA. With regard to the topic of certification, the report has been revised to provide a more detailed explanation, including graphic presentation, of the preferred option, as well as to provide estimates on the costs for Member States and the Commission related to the new certification framework. The rationale for the choice of ENISA as key actor in the framework has been further explained based on its expertise in the field and the fact that it is only EU level agency on cybersecurity. Finally, the sections on certification were reviewed to clarify aspects related to the difference between the current SOG-IS system, the benefits associated to the different policy options and explain that fact that the type of ICT product and service covered by a European certification scheme will be defined in the approved scheme itself. Regulatory fitness and simplification Not applicable Impact on fundamental rights Cybersecurity has an essential role in protecting the privacy and personal data of individuals in accordance with Articles 7 and 8 of the Charter of Fundamental Rights of the EU. In case of cyber incidents the privacy and the protection of our personal data are clearly exposed. Cybersecurity is thus a necessary condition for the respect of privacy and confidentiality of our personal data. Under this perspective, by aiming to reinforce cybersecurity in Europe, the proposal provides an important complement to the existing legislation protecting the fundamental right to privacy and personal data. Cybersecurity is also essential for protecting the confidentiality of our electronic communications and thus for exercising the freedom of expression and information and other related rights, such as the freedom of thought, conscience and religion. 4. BUDGETARY IMPLICATIONS See financial fiche 5. OTHER ELEMENTS • Implementation plans and monitoring, evaluation and reporting arrangements The Commission will monitor the application of the Regulation and submit a report on its evaluation to the European Parliament and to the Council and the European Economic and EN 20 EN Social Committee every five years. These reports will be public and detail the effective application and enforcement of this Regulation. • Detailed explanation of the specific provisions of the proposal Title I of the Regulation contains the general provisions: the subject matter (Article 1), the definitions (Article 2), including references to relevant definitions from other EU instruments, such as the Directive (EU) 2016/1148 of the European Parliament and of the Council concerning measures for a high common level of security of network and information systems across the Union (NIS Directive), Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, and Regulation (EU) No 1025/2012 of the European Parliament and of the Council on European standardisation. Title II of the Regulation contains the key provisions related to the ENISA, the EU Cybersecurity Agency. Chapter I under this Title outlines the mandate (Article 3), objectives (Article 4) and tasks of the Agency (Articles 5 to 11). Chapter II outlines the organisation of ENISA and includes key provisions on its structure (Article 12). It addresses the composition, voting rules and functions of the Management Board (Section 1, Articles 13 to 17), Executive Board (Section 2, Article 18) and Executive Director (Section 3, Article 19). It also includes provisions on the composition and role of the Permanent Stakeholders' Group (Section 4, Article 20). Last but not least, Section 5 under this Chapter details the operational rules for the Agency, including in relation to programming its operations, conflict of interest, transparency, confidentiality and access to documents (Articles 21-25). Chapter III concerns the establishment and structure of the Agency's budget (Articles 26 and 27), as well as rules guiding its implementation (Articles 28 and 29). It also includes the provisions facilitating the combating of fraud, corruption and other unlawful activities (Article 30). Chapter IV relates to the staffing of the Agency. It includes general provisions on the Staff Regulations and the Conditions of Employment and rules guiding privileges and immunity (Article 31 and 32). It also details the rules of engagement and appointment of the Executive Director of the Agency (Article 33). Last but not least, it includes the provisions guiding the use of seconded national experts or other staff not employed by the Agency (Article 34). Finally, Chapter V contains the general provisions related to the Agency. It outlines the legal status (Article 35) and includes provisions regulating the issues of liability, language arrangements, protection of personal data (Articles 36-38), as well as the security rules on the protection of classified and sensitive non-classified information (Article 40). It describes the rules guiding the Agency's cooperation with third countries and international organisations (Article 39). Last but not least, it also contains provisions regarding the Agency's headquarters and operating conditions, as well as administrative control by the Ombudsman (Articles 41 and 42). Title III of the Regulation establishes the European cybersecurity certification framework (the 'Framework') for ICT products and services as lex generalis (Article 1). It defines the general purpose of European cybersecurity certification schemes, i.e to ensure that ICT products and services comply with specified cybersecurity requirements as regards their ability to resist, at a given level of assurance, action that compromise the availability, EN 21 EN authenticity, integrity or confidentiality of stored, transmitted or processed data or the related functions or of services (Article 43). Moreover, it lists the security objectives that European cybersecurity certification schemes shall aim to address (Article 45), such as among others the ability to protect data against accidental or unauthorised access or disclosure, destruction or alteration, and the content (i.e elements) of European cybersecurity certification schemes, such as the detailed specification of their scope, the security objectives, evaluation criteria etc. (Article 47). Title III also establishes the main legal effects of European cybersecurity certification schemes, namely (i) the obligation to implement the scheme at national level and the voluntary nature of certification; (ii) the invalidating effect of European cybersecurity certification schemes on national schemes for the same products or services (Articles 48 and 49). This Title further lays down the procedure for the adoption of European cybersecurity certification schemes and the respective roles of the Commission, ENISA and the European Cybersecurity Certification Group – the 'Group' - (Article 44). Finally, this Title lays down the provisions governing conformity assessment bodies, including their requirements, powers and tasks, national certification supervisory authorities, as well as penalties. The Group is also established in this Title as an essential body consisting of representatives of national certification supervisory authorities whose main function is to work with ENISA on the preparation of European cybersecurity certification schemes and to advise the Commission on general or specific issues concerning cybersecurity certification policy. Title IV of the Regulation includes the final provisions describing the exercise of delegation, evaluation requirements, repeal and succession, as well as the entry into force. EN 22 EN 2017/0225 (COD) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on ENISA, the 'EU Cybersecurity Agency', and repealing Regulation (EU) 526/2013, and on Information and Communication Technology cybersecurity certification (''Cybersecurity Act'') (Text with EEA relevance) THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee28, Having regard to the opinion of the Committee of the Regions29, Acting in accordance with the ordinary legislative procedure, Whereas: (1) Network and information systems and telecommunications networks and services play a vital role for society and have become the backbone of economic growth. Information and communications technology underpins the complex systems which support societal activities, keep our economies running in key sectors such as health, energy, finance and transport, and in particular support the functioning of the internal market. (2) The use of network and information systems by citizens, businesses and governments across the Union is now pervasive. Digitisation and connectivity are becoming core features in an ever growing number of products and services and with the advent of the Internet of Things (IoT) millions, if not billions, of connected digital devices are expected to be deployed across the EU during the next decade. While an increasing number of devices are connected to the Internet, security and resilience are not sufficiently built in by design, leading to insufficient cybersecurity. In this context, the limited use of certification leads to insufficient information for organisational and individual users about the cybersecurity features of ICT products and services, undermining trust in digital solutions. (3) Increased digitisation and connectivity lead to increased cybersecurity risks, thus making society at large more vulnerable to cyber threats and exacerbating dangers faced by individuals, including vulnerable persons such as children. In order to 28 OJ C , , p. . 29 OJ C , , p. . EN 23 EN mitigate this risk to society, all necessary actions need to be taken to improve cybersecurity in the EU to better protect network and information systems, telecommunication networks, digital products, services and devices used by citizens, governments and business – from SMEs to operators of critical infrastructures – from cyber threats. (4) Cyber-attacks are on the increase and a connected economy and society that is more vulnerable to cyber threats and attacks requires stronger defences. However, while cyber-attacks are often cross-border, policy responses by cybersecurity authorities and law enforcement competences are predominantly national. Large-scale cyber incidents could disrupt the provision of essential services across the EU. This requires effective EU level response and crisis management, building upon dedicated policies and wider instruments for European solidarity and mutual assistance. Moreover, a regular assessment of the state of cybersecurity and resilience in the Union, based on reliable Union data, as well as systematic forecast of future developments, challenges and threats, both at Union and global level, is therefore important for policy makers, industry and users. (5) In light of the increased cybersecurity challenges faced by the Union, there is a need for a comprehensive set of measures that would build on previous Union action and foster mutually reinforcing objectives. These include the need to further increase capabilities and preparedness of Member States and businesses, as well as to improve cooperation and coordination across Member States and EU institutions, agencies and bodies. Furthermore, given the borderless nature of cyber threats, there is a need to increase capabilities at Union level that could complement the action of Member States, in particular in the case of large scale cross-border cyber incidents and crises. Additional efforts are also needed to increase awareness of citizens and businesses on cybersecurity issues. Moreover, the trust in the digital single market should be further improved by offering transparent information on the level of security of ICT products and services. This can be facilitated by EU-wide certification providing common cybersecurity requirements and evaluation criteria across national markets and sectors. (6) In 2004, the European Parliament and the Council adopted Regulation (EC) No 460/200430 establishing ENISA with the purpose of contributing to the goals of ensuring a high level of network and information security within the Union, and developing a culture of network and information security for the benefit of citizens, consumers, enterprises and public administrations. In 2008, the European Parliament and the Council adopted Regulation (EC) No 1007/200831 extending the mandate of the Agency until March 2012. Regulation (EC) No 580/201132 extended further the mandate of the Agency until 13 September 2013. In 2013, the European Parliament and the Council adopted Regulation (EU) No 526/201333 concerning ENISA and 30 Regulation (EC) No 460/2004 of the European Parliament and of the Council of 10 March 2004 establishing the European Network and Information Security Agency (OJ L 77, 13.3.2004, p. 1). 31 Regulation (EC) No 1007/2008 of the European Parliament and of the Council of 24 September 2008 amending Regulation (EC) No 460/2004 establishing the European Network and Information Security Agency as regards its duration (OJ L 293, 31.10.2008, p. 1). 32 Regulation (EU) No 580/2011 of the European Parliament and of the Council of 8 June 2011 amending Regulation (EC) No 460/2004 establishing the European Network and Information Security Agency as regards its duration (OJ L 165, 24.6.2011, p. 3). 33 Regulation (EU) No 526/2013 of the European Parliament and of the Council of 21 May 2013 concerning the European Union Agency for Network and Information Security (ENISA) and repealing Regulation (EC) No 460/2004 (OJ L 165, 18.6.2013, p.41). EN 24 EN repealing Regulation (EC)No 460/2004, which extended the Agency's mandate until June 2020. (7) The Union has already taken important steps to ensure cybersecurity and increase trust in digital technologies. In 2013, an EU Cybersecurity Strategy was adopted to guide the Union's policy response to cybersecurity threats and risks. In its effort to better protect Europeans online, in 2016 the Union adopted the first legislative act in the area of cybersecurity, the Directive (EU) 2016/1148 concerning measures for a high common level of security of network and information systems across the Union (the 'NIS Directive'). The NIS Directive put in place requirements concerning national capabilities in the area of cybersecurity, established the first mechanisms to enhance ***strategic*** and operational cooperation between Member States, and introduced obligations concerning security measures and incident notifications across sectors which are vital for economy and society such as energy, transport, water, banking, financial market infrastructures, healthcare, digital infrastructure as well as key digital service providers (search engines, cloud computing services and online marketplaces). A key role was attributed to ENISA in supporting implementation of this Directive. In addition, effective fight against cybercrime is an important priority in the European Agenda on Security, contributing to the overall aim of achieving a high level of cybersecurity. (8) It is recognised that, since the adoption of the 2013 EU Cybersecurity Strategy and the last revision of the Agency's mandate, the overall policy context has changed significantly, also in relation to a more uncertain and less secure global environment. In this context and within the framework of the new Union cybersecurity policy, it is necessary to review the mandate of ENISA to define its role in the changed cybersecurity ecosystem and ensure it contributes effectively to the Union's response to cybersecurity challenges emanating from this radically transformed threat landscape, for which, as recognised by the evaluation of the Agency, the current mandate is not sufficient. (9) The Agency established by this Regulation should succeed ENISA as established by Regulation (EU) No 526/2013. The Agency should carry out the tasks conferred on it by this Regulation and legal acts of the Union in the field of cybersecurity by, among other things, providing expertise and advice and acting as a Union centre of information and knowledge. It should promote the exchange of best practices between Member States and private stakeholders, offering policy suggestions to the European Commission and Member States, acting as a reference point for Union sectoral policy initiatives with regard to cybersecurity matters, fostering operational cooperation between the Member States and between the Member States and the EU institutions, agencies and bodies. (10) Within the framework of Decision 2004/97/EC, Euratom, adopted at the meeting of the European Council on 13 December 2003, the representatives of the Member States decided that ENISA would have its seat in a town in Greece to be determined by the Greek Government. The Agency’s host Member State should ensure the best possible conditions for the smooth and efficient operation of the Agency. It is imperative for the proper and efficient performance of its tasks, for staff recruitment and retention and to enhance the efficiency of networking activities that the Agency be based in an appropriate location, among other things providing appropriate transport connections and facilities for spouses and children accompanying members of staff of the Agency. The necessary arrangements should be laid down in an agreement between the Agency EN 25 EN and the host Member State concluded after obtaining the approval of the Management Board of the Agency. (11) Given the increasing cybersecurity challenges the Union is facing, the financial and human resources allocated to the Agency should be increased to reflect its enhanced role and tasks, and its critical position in the ecosystem of organisations defending the European digital ecosystem. (12) The Agency should develop and maintain a high level of expertise and operate as a point of reference establishing trust and confidence in the single market by virtue of its independence, the quality of the advice it delivers and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in carrying out its tasks. The Agency should proactively contribute to national and Union efforts while carrying out its tasks in full cooperation with the Union institutions, bodies, offices and agencies and the Member States. In addition, the Agency should build on input from and cooperation with the private sector as well as other relevant stakeholders. A set of tasks should establish how the Agency is to accomplish its objectives while allowing flexibility in its operations. (13) The Agency should assist the Commission by means of advice, opinions and analyses on all the Union matters related to policy and law development, update and review in the area of cybersecurity, including critical infrastructure protection and cyber resilience. The Agency should act as a reference point of advice and expertise for Union sector-specific policy and law initiatives where matters related to cybersecurity are involved. (14) The underlying task of the Agency is to promote the consistent implementation of the relevant legal framework, in particular the effective implementation of the NIS Directive, which is essential in order to increase cyber resilience. In view of the fast evolving cybersecurity threat landscape, it is clear that Member States must be supported by more comprehensive, cross-policy approach to building cyber resilience. (15) The Agency should assist the Member States and Union institutions, bodies, offices and agencies in their efforts to build and enhance capabilities and preparedness to prevent, detect and respond to cybersecurity problems and incidents and in relation to the security of network and information systems. In particular, the Agency should support the development and enhancement of national CSIRTs, with a view of achieving a high common level of their maturity in the Union. The Agency should also assist with the development and update of Union and Member States strategies on the security of network and information systems, in particular on cybersecurity, promote their dissemination and track progress of their implementation. The Agency should also offer trainings and training material to public bodies, and where appropriate 'train the trainers' with a view to assisting Member States in developing their own training capabilities. (16) The Agency should assist the Cooperation Group established in the NIS Directive in the execution of its tasks, in particular by providing expertise, advice and facilitate the exchange of best practices, notably with regard to the identification of operators of essential services by Member States, including in relation to cross-border dependencies, regarding risks and incidents. (17) With a view to stimulating cooperation between public and private sector and within the private sector, in particular to support the protection of the critical infrastructures, the Agency should facilitate the establishment of sectoral Information Sharing and EN 26 EN Analysis Centres (ISACs) by providing best practices and guidance on available tools, procedure, as well as providing guidance on how to address regulatory issues related to information sharing. (18) The Agency should aggregate and analyse national reports from CSIRTs and CERT-EU, setting up common rules, language and terminology for exchange of information. The Agency should also involve the private sector, within the framework of the NIS Directive which laid down the grounds for voluntary technical information exchange at the operational level with the creation of the CSIRTs Network. (19) The Agency should contribute to an EU level response in case of large-scale cross-border cybersecurity incidents and crises. This function should include gathering relevant information and acting as facilitator between the CSIRTs Network and the technical community as well as decision makers responsible for crisis management. Furthermore, the Agency could support the handling of incidents from a technical perspective by facilitating relevant technical exchange of solutions between Member States and by providing input into public communications. The Agency should support the process by testing modalities of such cooperation through yearly cybersecurity exercises. (20) To perform its operational tasks, the Agency should make use of the available expertise of CERT-EU through a structured cooperation, in close physical proximity. The structured cooperation will facilitate the necessary synergies and build-up of ENISA's expertise. Where appropriate, dedicated arrangements between the two organisations should be established to define the practical implementation of such cooperation. (21) In compliance with its operational tasks, the Agency should be able to provide support to Member States, such as by providing advice or technical assistance, or ensuring analyses of threats and incidents. The Commission's Recommendation on Coordinated Response to Large-Scale Cybersecurity Incidents and Crises recommends that Member States cooperate in good faith and share amongst themselves and with ENISA information on large-scale cybersecurity incidents and crises without undue delay. Such information should further help ENISA in performing its operational tasks. (22) As part of the regular cooperation at technical level to support Union situational awareness, the Agency should on regular basis prepare the EU Cybersecurity Technical Situation Report on incidents and threats, based on publicly available information, its own analysis and reports shared with it by Member States' CSIRTs (on a voluntary basis) or NIS Directive Single Points of Contact, European Cybercrime Centre (EC3) at Europol, CERT-EU and, where appropriate, European Union Intelligence Centre (INTCEN) at the European External Action Service (EEAS). The report should be made available to the relevant instances of the Council, the Commission, the High Representative of the Union for Foreign Affairs and Security Policy and the CSIRTs Network. (23) Ex-post technical enquiries into incidents with significant impact in more than one Member State supported or undertaken by the Agency upon request or with the agreement of the concerned Member States should be focused on the prevention of future incidents and be carried out without prejudice to any judicial or administrative proceedings to apportion blame or liability. (24) The Member States concerned should provide the necessary information and assistance to the Agency, for the purposes of the enquiry without prejudice to Article EN 27 EN 346 of the Treaty on the Functioning of the European Union or other public policy reasons. (25) Member States may invite undertakings concerned by the incident to cooperate by providing necessary information and assistance to the Agency without prejudice to their right to protect commercially sensitive information. (26) To understand better the challenges in the field of cybersecurity, and with a view to providing ***strategic*** long term advice to Member States and Union institutions, the Agency needs to analyse current and emerging risks. For that purpose, the Agency should, in cooperation with Member States and, as appropriate, with statistical bodies and others, collect relevant information and perform analyses of emerging technologies and provide topic-specific assessments on expected societal, legal, economic and regulatory impacts of technological innovations on network and information security, in particular cybersecurity. The Agency should furthermore support Member States and Union institutions, agencies and bodies in identifying emerging trends and preventing problems related to cybersecurity, by performing analyses of threats and incidents. (27) In order to increase the resilience of the Union, the Agency should develop excellence on the subject of security of internet infrastructure and of the critical infrastructures, by providing advice, guidance and best practices. With a view to ensuring easier access to better structured information on cybersecurity risks and potential remedies, the Agency should develop and maintain the 'information hub' of the Union, a one-stop-shop portal providing the public with information on cybersecurity deriving from the EU and national institutions, agencies and bodies. (28) The Agency should contribute towards raising the awareness of the public about risks related to cybersecurity and provide guidance on good practices for individual users aimed at citizens and organisations. The Agency should also contribute to promote best practices and solutions at the level of individuals and organisations by collecting and analysing publicly available information regarding significant incidents, and by compiling reports with a view to providing guidance to businesses and citizens and improving the overall level of preparedness and resilience. The Agency should furthermore organise, in cooperation with the Member States and the Union institutions, bodies, offices and agencies regular outreach and public education campaigns directed to end-users, aiming at promoting safer individual online behaviour and raising awareness of potential threats in cyberspace, including cybercrimes such as phishing attacks, botnets, financial and banking fraud, as well as promoting basic authentication and data protection advice. The Agency should play a central role in accelerating end-user awareness on security of devices. (29) In order to support the businesses operating in the cybersecurity sector, as well as the users of cybersecurity solutions, the Agency should develop and maintain a 'market observatory' by performing regular analyses and dissemination of the main trends in the cybersecurity market, both on the demand and supply side. (30) To ensure that it fully achieves its objectives, the Agency should liaise with relevant institutions, agencies and bodies, including CERT-EU, European Cybercrime Centre (EC3) at Europol, European Defence Agency (EDA), European Agency for the operational management of large-scale IT systems (eu-LISA), European Aviation Safety Agency (EASA) and any other EU Agency that is involved in cybersecurity. It should also liaise with authorities dealing with data protection in order to exchange know-how and best practices and provide advice on cybersecurity aspects that might EN 28 EN have an impact on their work. Representatives of national and Union law enforcement and data protection authorities should be eligible to be represented in the Agency’s Permanent Stakeholders Group. In liaising with law enforcement bodies regarding network and information security aspects that might have an impact on their work, the Agency should respect existing channels of information and established networks. (31) The Agency, as a Member which furthermore provides the Secretariat of the CSIRTs Network, should support Member State CSIRTs and the CERT-EU in operational cooperation further to all the relevant tasks of the CSIRTs Network, as defined by the NIS Directive. Furthermore, the Agency should promote and support cooperation between the relevant CSIRTs in the event of incidents, attacks or disruptions of networks or infrastructure managed or protected by the CSIRTs and involving or potentially involving at least two CERTs while taking due account of the Standard Operating Procedures of the CSIRTs Network. (32) With a view to increasing Union preparedness in responding to cybersecurity incidents, the Agency should organise yearly cybersecurity exercises at Union level, and, at their request, support Member States and EU institutions, agencies and bodies in organising exercises. (33) The Agency should further develop and maintain its expertise on cybersecurity certification with a view to supporting the Union policy in this field. The Agency should promote the uptake of cybersecurity certification within the Union, including by contributing to the establishment and maintenance of a cybersecurity certification framework at Union level, with a view to increasing transparency of cybersecurity assurance of ICT products and services and thus strengthening trust in the digital internal market. (34) Efficient cybersecurity policies should be based on well-developed risk assessment methods, both in the public and private sector. Risk assessment methods are used at different levels with no common practice regarding how to apply them efficiently. Promoting and developing best practices for risk assessment and for interoperable risk management solutions in public- and private-sector organisations will increase the level of cybersecurity in the Union. To this end, the Agency should support cooperation between stakeholders at Union level, facilitating their efforts relating to the establishment and take-up of European and international standards for risk management and for measurable security of electronic products, systems, networks and services which, together with software, comprise the network and information systems. (35) The Agency should encourage Member States and service providers to raise their general security standards so that all internet users can take the necessary steps to ensure their own personal cybersecurity. In particular, service providers and product manufacturers should withdraw or recycle products and services that do not meet cybersecurity standards. In cooperation with competent authorities, ENISA may disseminate information regarding the level of cybersecurity of the products and services offered in the internal market, and issue warnings targeting providers and manufacturers and requiring them to improve the security, including cybersecurity, of their products and services. (36) The Agency should take full account of the ongoing research, development and technological assessment activities, in particular those carried out by the various Union research initiatives to advise the Union institutions, bodies, offices and agencies EN 29 EN and where relevant, the Member States, at their request, on research needs in the area of network and information security, in particular cybersecurity. (37) Cybersecurity problems are global issues. There is a need for closer international cooperation to improve security standards, including the definition of common norms of behaviour, and information sharing, promoting swifter international collaboration in response to, as well as a common global approach to, network and information security issues. To that end, the Agency should support further Union involvement and cooperation with third countries and international organisations by providing, where appropriate, the necessary expertise and analysis to the relevant Union institutions, bodies, offices and agencies. (38) The Agency should be able to respond to ad hoc requests for advice and assistance by Member States and EU institutions, agencies and bodies falling within the Agency’s objectives. (39) It is necessary to implement certain principles regarding the governance of the Agency in order to comply with the Joint Statement and Common Approach agreed upon in July 2012 by the Inter-Institutional Working Group on EU decentralised agencies, the purpose of which statement and approach is to streamline the activities of agencies and improve their performance. The Joint Statement and Common Approach should also be reflected, as appropriate, in the Agency’s Work Programmes, evaluations of the Agency, and the Agency’s reporting and administrative practice. (40) The Management Board, composed of the Member States and the Commission, should define the general direction of the Agency’s operations and ensure that it carries out its tasks in accordance with this Regulation. The Management Board should be entrusted with the powers necessary to establish the budget, verify its execution, adopt the appropriate financial rules, establish transparent working procedures for decision making by the Agency, adopt the Agency’s Single Programming Document, adopt its own rules of procedure, appoint the Executive Director and decide on the extension of the Executive Director’s term of office and on the termination thereof. (41) In order for the Agency to function properly and effectively, the Commission and the Member States should ensure that persons to be appointed to the Management Board have appropriate professional expertise and experience in functional areas. The Commission and the Member States should also make efforts to limit the turnover of their respective Representatives on the Management Board in order to ensure continuity in its work. (42) The smooth functioning of the Agency requires that its Executive Director be appointed on grounds of merit and documented administrative and managerial skills, as well as competence and experience relevant for cybersecurity, and that the duties of the Executive Director be carried out with complete independence. The Executive Director should prepare a proposal for the Agency’s work programme, after prior consultation with the Commission, and take all necessary steps to ensure the proper execution of the work programme of the Agency. The Executive Director should prepare an annual report to be submitted to the Management Board, draw up a draft statement of estimates of revenue and expenditure for the Agency, and implement the budget. Furthermore, the Executive Director should have the option of setting up ad hoc Working Groups to address specific matters, in particular of a scientific, technical, legal or socioeconomic nature. The Executive Director should ensure that the ad hoc Working Groups’ members are selected according to the highest standards of expertise, taking due account of a representative balance, as appropriate according to EN 30 EN the specific issues in question, between the public administrations of the Member States, the Union institutions and the private sector, including industry, users, and academic experts in network and information security. (43) The Executive Board should contribute to the effective functioning of the Management Board. As part of its preparatory work related to Management Board decisions, it should examine in detail relevant information and explore available options and offer advice and solutions to prepare relevant decisions of the Management Board. (44) The Agency should have a Permanent Stakeholders’ Group as an advisory body, to ensure regular dialogue with the private sector, consumers’ organisations and other relevant stakeholders. The Permanent Stakeholders’ Group, set up by the Management Board on a proposal by the Executive Director, should focus on issues relevant to stakeholders and bring them to the attention of the Agency. The composition of the Permanent Stakeholders Group and the tasks assigned to this Group, to be consulted in particular regarding the draft Work Programme, should ensure sufficient representation of stakeholders in the work of the Agency. (45) The Agency should have in place rules regarding the prevention and the management of conflict of interest. The Agency should also apply the relevant Union provisions concerning public access to documents as set out in Regulation (EC) No 1049/2001 of the European Parliament and of the Council34. Processing of personal data by the Agency should be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data35. The Agency should comply with the provisions applicable to the Union institutions, and with national legislation regarding the handling of information, in particular sensitive non classified information and EU classified information. (46) In order to guarantee the full autonomy and independence of the Agency and to enable it to perform additional and new tasks, including unforeseen emergency tasks, the Agency should be granted a sufficient and autonomous budget whose revenue comes primarily from a contribution from the Union and contributions from third countries participating in the Agency’s work. The majority of the Agency staff should be directly engaged in the operational implementation of the Agency’s mandate. The host Member State, or any other Member State, should be allowed to make voluntary contributions to the revenue of the Agency. The Union’s budgetary procedure should remain applicable as far as any subsidies chargeable to the general budget of the Union are concerned. Moreover, the Court of Auditors should audit the Agency’s accounts to ensure transparency and accountability. (47) Conformity assessment is the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled. For the purposes of this Regulation, certification should be considered as a type of conformity assessment regarding the cybersecurity features of a product, process, service, system, or a combination of those ('ICT products and services') by an independent third party, other than the product manufacturer or service provider. 34 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43). 35 OJ L 8, 12.1.2001, p. 1. EN 31 EN Certification cannot guarantee per se that certified ICT products and services are cyber secure. It is rather a procedure and technical methodology to attest that ICT products and services have been tested and that they comply with certain cybersecurity requirements laid down elsewhere, for example as specified in technical standards. (48) Cybersecurity certification plays an important role in increasing trust and security in ICT products and services. The digital single market, and particularly the data economy and the Internet of Things, can only thrive if there is general public trust that such products and services provide a certain level of cybersecurity assurance. Connected and automated cars, electronic medical devices, industrial automation control systems or smart grids are only some examples of sectors in which certification is already widely used or is likely to be used in the near future. The sectors regulated by the NIS Directive are also sectors in which cybersecurity certification is critical. (49) In the 2016 Communication 'Strengthening Europe's Cyber Resilience System and Fostering a Competitive and Innovative Cybersecurity Industry', the Commission outlined the need for high-quality, affordable and interoperable cybersecurity products and solutions. The supply of ICT products and services within the single market remains very fragmented ***geographically***. This is because the cybersecurity industry in Europe has developed largely on the basis of national governmental demand. In addition, the lack of interoperable solutions (technical standards), practices and EU-wide mechanisms of certification are among the other gaps affecting the single market in cybersecurity. On the one hand, this makes it difficult for European companies to compete at national, European and global level. On the other, it reduces the choice of viable and usable cybersecurity technologies that individuals and enterprises have access to. Similarly, in the Mid-Term Review on the implementation of the Digital Single Market Strategy, the Commission highlighted the need for safe connected products and systems, and indicated that the creation of a European ICT security framework setting rules on how to organise ICT security certification in the Union could both preserve trust in the internet and tackle the current fragmentation of the cybersecurity market. (50) Currently, the cybersecurity certification of ICT products and services is used only to a limited extent. When it exists, it mostly occurs at Member State level or in the framework of industry driven schemes. In this context, a certificate issued by one national cybersecurity authority is not in principle recognised by other Member States. Companies thus may have to certify their products and services in several Member States where they operate, for example with a view to participating in national procurement procedures. Moreover, while new schemes are emerging, there seems to be no coherent and holistic approach with regard to horizontal cybersecurity issues, for instance in the field of the Internet of Things. Existing schemes present significant shortcomings and differences in terms of product coverage, levels of assurance, substantive criteria and actual utilisation. (51) Some efforts have been made in the past in order to lead to a mutual recognition of certificates in Europe. However, they have been only partly successful. The most important example in this regard is the Senior Officials Group – Information Systems Security (SOG-IS) Mutual Recognition Agreement (MRA). While it represents the most important model for cooperation and mutual recognition in the field of security certification, SOG-IS MRA presents some significant shortcomings related to its high costs and limited scope. So far only a few protection profiles on digital products have been developed, such as digital signature, digital tachograph and smart cards. Most EN 32 EN importantly, SOG-IS includes only part of the Union Member States. This has limited the effectiveness of SOG-IS MRA from the point of view of the internal market. (52) In view of the above, it is necessary to establish a European cybersecurity certification framework laying down the main horizontal requirements for European cybersecurity certification schemes to be developed and allowing certificates for ICT products and services to be recognised and used in all Member States. The European framework should have a twofold purpose: on the one hand, it should help increase trust in ICT products and services that have been certified according to such schemes. On the other hand, it should avoid the multiplication of conflicting or overlapping national cybersecurity certifications and thus reduce costs for undertakings operating in the digital single market. The schemes should be non-discriminatory and based on international and / or Union standards, unless those standards are ineffective or inappropriate to fulfil the EU’s legitimate objectives in that regard. (53) The Commission should be empowered to adopt European cybersecurity certification schemes concerning specific groups of ICT products and services. These schemes should be implemented and supervised by national certification supervisory authorities and certificates issued within these schemes should be valid and recognised throughout the Union. Certification schemes operated by the industry or other private organisations should fall outside the scope of the Regulation. However, the bodies operating such schemes may propose to the Commission to consider such schemes as a basis for approving them as a European scheme. (54) The provisions of this Regulation should be without prejudice to Union legislation providing specific rules on certification of ICT products and services. In particular, the General Data Protection Regulation (GDPR) lays down provisions for the establishment of certification mechanisms and data protection seals and marks for the purpose of demonstrating compliance with that Regulation of processing operations by controllers and processors. Such certification mechanisms and data protection seals and marks should allow data subjects to quickly assess the level of data protection of relevant products and services. The present Regulation is without prejudice to the certification of data processing operations, including when such operations are embedded in products and services, under the GDPR. (55) The purpose of European cybersecurity certification schemes should be to ensure that ICT products and services certified under such a scheme comply with specified requirements. Such requirements concern the ability to resist, at a given level of assurance, actions that aim to compromise the availability, authenticity, integrity and confidentiality of stored or transmitted or processed data or the related functions of or services offered by, or accessible via those products, processes, services and systems within the meaning of this Regulation. It is not possible to set out in detail in this Regulation the cybersecurity requirements relating to all ICT products and services. ICT products and services and related cybersecurity needs are so diverse that it is very difficult to come up with general cybersecurity requirements valid across the board. It is, therefore necessary to adopt a broad and general notion of cybersecurity for the purpose of certification, complemented by a set of specific cybersecurity objectives that need to be taken into account when designing European cybersecurity certification schemes. The modalities with which such objectives will be achieved in specific ICT products and services should then be further specified in detail at the level of the individual certification scheme adopted by the Commission, for example by reference to standards or technical specifications. EN 33 EN (56) The Commission should be empowered to request ENISA to prepare candidate schemes for specific ICT products or services. The Commission, based on the candidate scheme proposed by ENISA, should then be empowered to adopt the European cybersecurity certification scheme by means of implementing acts. Taking account of the general purpose and security objectives identified in this Regulation, European cybersecurity certification schemes adopted by the Commission should specify a minimum set of elements concerning the subject-matter, the scope and functioning of the individual scheme. These should include among others the scope and object of the cybersecurity certification, including the categories of ICT products and services covered, the detailed specification of the cybersecurity requirements, for example by reference to standards or technical specifications, the specific evaluation criteria and evaluation methods, as well as the intended level of assurance: basic, substantial and/or high. (57) Recourse to European cybersecurity certification should remain voluntary, unless otherwise provided in Union or national legislation. However, with a view to achieving the objectives of this Regulation and avoiding the fragmentation of the internal market, national cybersecurity certification schemes or procedures for the ICT products and services covered by a European cybersecurity certification scheme should cease to produce effects from the date established by the Commission by means of the implementing act. Moreover, Member States should not introduce new national certification schemes providing cybersecurity certification schemes for ICT products and services already covered by an existing European cybersecurity certification scheme. (58) Once a European cybersecurity certification scheme is adopted, manufacturers of ICT products or providers of ICT services should be able to submit an application for certification of their products or services to a conformity assessment body of their choice. Conformity assessment bodies should be accredited by an accreditation body if they comply with certain specified requirements set out in this Regulation. Accreditation should be issued for a maximum of five years and may be renewed on the same conditions provided that the conformity assessment body meets the requirements. Accreditation bodies should revoke an accreditation of a conformity assessment body where the conditions for the accreditation are not, or are no longer, met or where actions taken by a conformity assessment body infringe this Regulation. (59) It is necessary to require all Member States to designate one cybersecurity certification supervisory authority to supervise compliance of conformity assessment bodies and of certificates issued by conformity assessment bodies established in their territory with the requirements of this Regulation and of the relevant cybersecurity certification schemes. National certification supervisory authorities should handle complaints lodged by natural or legal persons in relation to certificates issued by conformity assessment bodies established in their territories, investigate to the extent appropriate the subject matter of the complaint and inform the complainant of the progress and the outcome of the investigation within a reasonable time period. Moreover, they should cooperate with other national certification supervisory authorities or other public authority, including by sharing information on possible non-compliance of ICT products and services with the requirements of this Regulation or specific cybersecurity schemes. (60) With a view to ensuring the consistent application of the European cybersecurity certification framework, a European Cybersecurity Certification Group (the 'Group') consisting of national certification supervisory authorities should be established. The EN 34 EN main tasks of the Group should be to advise and assist the Commission in its work to ensure a consistent implementation and application of the European cybersecurity certification framework; to assist and closely cooperate with the Agency in the preparation of candidate cybersecurity certification schemes; recommend that the Commission request the Agency to prepare a candidate European cybersecurity certification scheme; and to adopt opinions addressed to the Commission relating to the maintenance and review of existing European cybersecurity certifications schemes. (61) In order to raise awareness and facilitate the acceptance of future EU cyber security schemes, the European Commission may issue general or sector-specific cyber security guidelines, e.g on good cyber security practices or responsible cyber security behaviour highlighting the positive effect of the use of certified ICT products and services. (62) The Agency's support to cybersecurity certification should also include liaising with the Council Security Committee and the relevant national body, regarding the cryptographic approval of products to be used in classified networks. (63) In order to specify further the criteria for the accreditation of conformity assessment bodies, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. The Commission should carry out appropriate consultations during its preparatory work, including at expert level. Those consultations should be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. (64) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission when provided for by this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011. (65) The examination procedure should be used for the adoption of implementing acts on European cybersecurity certification schemes for ICT products and services; on modalities of carrying enquiries by the Agency; as well as on the circumstances, formats and procedures of notifications of accredited conformity assessment bodies by the national certification supervisory authorities to the Commission. (66) The Agency’s operations should be evaluated independently. The evaluation should have regard to the Agency achieving its objectives, its working practices and the relevance of its tasks. The evaluation should also assess the impact, effectiveness and efficiency of the European cybersecurity certification framework. (67) Regulation (EU) No 526/2013 should be repealed. (68) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective, EN 35 EN HAVE ADOPTED THIS REGULATION: EN 36 EN TITLE I GENERAL PROVISIONS Article 1 Subject matter and scope With a view to ensuring the proper functioning of the internal market while aiming at a high level of cybersecurity, cyber resilience and trust within the Union, this Regulation: (a) lays down the objectives, tasks and organisational aspects of ENISA, the 'EU Cybersecurity Agency', hereinafter ‘the Agency’; and (b) lays down a framework for the establishment of European cybersecurity certification schemes for the purpose of ensuring an adequate level of cybersecurity of ICT products and services in the Union. Such framework shall apply without prejudice to specific provisions regarding voluntary or mandatory certification in other Union acts. Article 2 Definitions For the purposes of this Regulation, the following definitions apply: (1) ‘cybersecurity’ comprises all activities necessary to protect network and information systems, their users, and affected persons from cyber threats; (2) ‘network and information system’ means a system within the meaning of point (1) of Article 4 of Directive (EU) 2016/1148; (3) ‘national strategy on the security of network and information systems’ means a framework within the meaning of point (3) of Article 4 of Directive (EU) 2016/1148; (4) ‘operator of essential services’ means a public or private entity as defined in point (4) of Article 4 of Directive (EU) 2016/1148; (5) ‘digital service provider’ means any legal person that provides a digital service as defined in point (6) of Article 4 of Directive (EU) 2016/1148 (6) ‘incident’ means any event as defined in point (7) of Article 4 of Directive (EU) 2016/1148; (7) ‘incident handling’ means any procedure as defined in point (8) of Article 4 of Directive (EU) 2016/1148; (8) ‘cyber threat’ means any potential circumstance or event that may adversely impact network and information systems, their users and affected persons. (9) ‘European cybersecurity certification scheme’ means the comprehensive set of rules, technical requirements, standards and procedures defined at Union level applying to the certification of Information and Communication Technology (ICT) products and services falling under the scope of that specific scheme; (10) ‘European cybersecurity certificate’ means a document issued by a conformity assessment body attesting that a given ICT product or service fulfils the specific requirements laid down in a European cybersecurity certification scheme; EN 37 EN (11) ‘ICT product and service’ means any element or group of elements of network and information systems; (12) ‘accreditation’ means accreditation as defined in point (10), Article 2 of Regulation (EC) No 765/2008; (13) ‘national accreditation body’ means a national accreditation body as defined in point (11), Article 2 of Regulation (EC) No 765/2008; (14) ‘conformity assessment’ means conformity assessment as defined in point (12), Article 2 of Regulation (EC) No 765/2008; (15) ‘conformity assessment body’ means conformity assessment body as defined in point (13), Article 2 of Regulation (EC) No 765/2008; (16) ‘standard’ means a standard as defined in point (1) of Article 2 of Regulation (EU) No 1025/2012. EN 38 EN TITLE II ENISA – the 'EU Cybersecurity Agency' CHAPTER I MANDATE, OBJECTIVES AND TASKS Article 3 Mandate 1. The Agency shall undertake the tasks assigned to it by this Regulation for the purpose of contributing to a high level of cybersecurity within the Union. 2. The Agency shall carry out tasks conferred upon it by Union acts setting out measures for approximating the laws, regulations and administrative provisions of the Member States which are related to cybersecurity. 3. The objectives and the tasks of the Agency shall be without prejudice to the competences of the Member States regarding cybersecurity, and in any case, without prejudice to activities concerning public security, defence, national security and the activities of the state in areas of criminal law. Article 4 Objectives 1. The Agency shall be a centre of expertise on cybersecurity by virtue of its independence, the scientific and technical quality of the advice and assistance it delivers and the information it provides, the transparency of its operating procedures and methods of operation, and its diligence in carrying out its tasks. 2. The Agency shall assist the Union institutions, agencies and bodies, as well as Member States, in developing and implementing policies related to cybersecurity. 3. The Agency shall support capacity building and preparedness across the Union, by assisting the Union, Member States and public and private stakeholders in order to increase the protection of their network and information systems, develop skills and competencies in the field of cybersecurity, and achieve cyber resilience. 4. The Agency shall promote cooperation and coordination at Union level among Member States, Union institutions, agencies and bodies, and relevant stakeholders, including the private sector, on matters related to cybersecurity. 5. The Agency shall increase cybersecurity capabilities at Union level in order to complement the action of Member States in preventing and responding to cyber threats, notably in the event of cross-border incidents. 6. The Agency shall promote the use of certification, including by contributing to the establishment and maintenance of a cybersecurity certification framework at Union level in accordance with Title III of this Regulation, with a view to increasing transparency of cybersecurity assurance of ICT products and services and thus strengthen trust in the digital internal market. EN 39 EN 7. The Agency shall promote a high level of awareness of citizens and businesses on issues related to the cybersecurity. Article 5 Tasks relating to the development and implementation of Union policy and law The Agency shall contribute to the development and implementation of Union policy and law, by: 1. assisting and advising, in particular by providing its independent opinion and supplying preparatory work, on the development and review of Union policy and law in the area of cybersecurity, as well as sector-specific policy and law initiatives where matters related to cybersecurity are involved; 2. assisting Member States to implement consistently the Union policy and law regarding cybersecurity notably in relation to Directive (EU) 2016/1148, including by means of opinions, guidelines, advice and best practices on topics such as risk management, incident reporting and information sharing, as well as facilitating the exchange of best practices between competent authorities in this regard; 3. contributing to the work of the Cooperation Group pursuant to Article 11 of Directive (EU) 2016/1148, by providing its expertise and assistance; 4. supporting: (1) the development and implementation of Union policy in the area of electronic identity and trust services, in particular by providing advice and technical guidelines, as well as facilitating the exchange of best practices between competent authorities; (2) the promotion of an enhanced level of security of electronic communications, including by providing expertise and advice, as well as facilitating the exchange of best practices between competent authorities; 5. supporting the regular review of Union policy activities by providing an annual report on the state of implementation of the respective legal framework regarding: (a) Member States' incident notifications provided by the single point of contacts to the Cooperation Group pursuant to Article 10(3) of Directive (EU) 2016/1148; (b) notifications of breach of security and loss of integrity regarding the trust service providers, provided by the supervisory bodies to the Agency, pursuant to Article 19(3) of Regulation (EU) 910/2014; (c) notifications of breach of security transmitted by the undertakings providing public communications networks or publicly available electronic communications services, provided by the competent authorities to Agency, pursuant to Article 40 of [Directive establishing the European Electronic Communications Code]. EN 40 EN Article 6 Tasks relating to capacity building 1. The Agency shall assist: (a) Member States in their efforts to improve the prevention, detection and analysis, and the capacity to respond to, cybersecurity problems and incidents by providing them with the necessary knowledge and expertise; (b) Union institutions, bodies, offices and agencies, in their efforts to improve the prevention, detection and analysis of and the capability to respond to cybersecurity problems and incidents through appropriate support for the CERT for the Union institutions, agencies and bodies (CERT-EU); (c) Member States, at their request, in developing national Computer Security Incident Response Teams (CSIRTs) pursuant to Article 9(5) of Directive (EU) 2016/1148; (d) Member States, at their request, in developing national strategies on the security of network and information systems, pursuant to Article 7(2) of Directive (EU) 2016/1148; the Agency shall also promote dissemination and track progress of implementation of those strategies across the Union in order to promote best practices; (e) Union institutions in developing and reviewing Union strategies regarding cybersecurity, promoting their dissemination and tracking progress of their implementation; (f) national and Union CSIRTs in raising the level of their capabilities, including by promoting dialogue and exchange of information, with a view to ensuring that, with regard to the state of the art, each CSIRT meets a common set of minimum capabilities and operates according to best practices; (g) the Member States by organising yearly large-scale cybersecurity exercises at the Union level referred to in Article 7(6) and by making policy recommendations based on the evaluation process of the exercises and lessons learned from them; (h) relevant public bodies by offering trainings regarding cybersecurity, where appropriate in cooperation with stakeholders; (i) the Cooperation Group, by exchanging of best practices, in particular with regard to the identification of operators of essential services by Member States, including in relation to cross-border dependencies, regarding risks and incidents, pursuant to Article 11(3)(l) of Directive (EU) 2016/1148. 2. The Agency shall facilitate the establishment of and continuously support sectoral Information Sharing and Analysis Centres (ISACs), in particular in the sectors listed in Annex II of Directive (EU) 2016/1148, by providing best practices and guidance on available tools, procedure, as well as on how to address regulatory issues related to information sharing. EN 41 EN Article 7 Tasks relating to operational cooperation at Union level 1. The Agency shall support operational cooperation among competent public bodies, and between stakeholders. 2. The Agency shall cooperate at operational level and establish synergies with Union institutions, bodies, offices and agencies, including the CERT-EU, those services dealing with cybercrime and supervisory authorities dealing with the protection of privacy and personal data, with a view to addressing issues of common concern, including: (a) the exchange of know-how and best practices; (b) the provision of advice and guidelines on relevant issues related to cybersecurity; (c) the establishment, upon consultation of the Commission, of practical arrangements for the execution of specific tasks. 3. The Agency shall provide the secretariat of the CSIRTs network, pursuant to Article 12(2) of Directive (EU) 2016/1148 and shall actively facilitate the information sharing and the cooperation among its members. 4. The Agency shall contribute to the operational cooperation within the CSIRTs Network providing support to Member States by: (a) advising on how to improve their capabilities to prevent, detect and respond to incidents; (b) providing, at their request, technical assistance in case of incidents having a significant or substantial impact; (c) analysing vulnerabilities, artefacts and incidents. In performing these tasks, the Agency and CERT-EU shall engage in a structured cooperation in order to benefit from synergies, in particular regarding operational aspects. 5. Upon a request by two or more Member States concerned, and with the sole purpose of providing advice for the prevention of future incidents, the Agency shall provide support to or carry out an ex-post technical enquiry following notifications by affected undertakings of incidents having a significant or substantial impact pursuant to Directive (EU) 2016/1148. The Agency shall also carry out such an enquiry upon a duly justified request from the Commission in agreement with the concerned Member States in case of such incidents affecting more than two Member States. The scope of the enquiry and the procedure to be followed in conducting such enquiry shall be agreed by the concerned Member States and the Agency and is without prejudice to any on-going criminal investigation concerning the same incident. The enquiry shall be concluded by a final technical report compiled by the Agency in particular on the basis of information and comments provided by the concerned Member States and undertaking(s) and agreed with the concerned Member States. A summary of the report focussing on the recommendations for the prevention of future incidents will be shared with the CSIRTs network. 6. The Agency shall organise annual cybersecurity exercises at Union level, and support Member States and EU institutions, agencies and bodies in organising exercises following their request(s). Annual exercises at Union level shall include EN 42 EN technical, operational and ***strategic*** elements and help to prepare the cooperative response at the Union level to large-scale cross-border cybersecurity incidents. The Agency shall also contribute to and help organise, where appropriate, sectoral cybersecurity exercises together with relevant ISACs and permit ISACs to participate also to Union level cybersecurity exercises. 7. The Agency shall prepare a regular EU Cybersecurity Technical Situation Report on incidents and threats based on open source information, its own analysis, and reports shared by, among others: Member States' CSIRTs (on a voluntary basis) or NIS Directive Single Points of Contact (in accordance with NIS Directive Article 14 (5)); European Cybercrime Centre (EC3) at Europol, CERT-EU. 8. The Agency shall contribute to develop a cooperative response, at Union and Member States level, to large-scale cross-border incidents or crises related to cybersecurity, mainly by: (a) aggregating reports from national sources with a view to contribute to establishing common situational awareness; (b) ensuring the efficient flow of information and the provision of escalation mechanisms between the CSIRTs Network and the technical and political decision-makers at Union level; (c) supporting the technical handling of an incident or crisis, including facilitating the sharing of technical solutions between Member States; (d) supporting public communication around the incident or crisis; (e) testing the cooperation plans to respond to such incidents or crises. Article 8 Tasks relating to the market, cybersecurity certification, and standardisation The Agency shall: (a) support and promote the development and implementation of the Union policy on cybersecurity certification of ICT products and services, as established in Title III of this Regulation, by: (1) preparing candidate European cybersecurity certification schemes for ICT products and services in accordance with Article 44 of this Regulation; (2) assisting the Commission in providing the secretariat to the European Cybersecurity Certification Group pursuant to Article 53 of this Regulation; (3) compiling and publishing guidelines and developing good practices concerning the cybersecurity requirements of ICT products and services, in cooperation with national certification supervisory authorities and the industry; (b) facilitate the establishment and take-up of European and international standards for risk management and for the security of ICT products and services, as well as draw up, in collaboration with Member States, advice and guidelines regarding the technical areas related to the security requirements for operators of essential services and digital service providers, as well as regarding already existing standards, EN 43 EN including Member States' national standards, pursuant to Article 19(2) of Directive (EU) 2016/1148; (c) perform and disseminate regular analyses of the main trends in the cybersecurity market both on the demand and supply side, with a view of fostering the cybersecurity market in the Union. Article 9 Tasks relating to knowledge, information and awareness raising The Agency shall: (a) perform analyses of emerging technologies and provide topic-specific assessments on expected societal, legal, economic and regulatory impacts of technological innovations on cybersecurity; (b) perform long-term ***strategic*** analyses of cybersecurity threats and incidents in order to identify emerging trends and help prevent problems related to cybersecurity; (c) provide, in cooperation with experts from Member States authorities, advice, guidance and best practices for the security of network and information systems, in particular for the security of the internet infrastructure and those infrastructures supporting the sectors listed in Annex II of Directive (EU) 2016/1148; (d) pool, organise and make available to the public, through a dedicated portal, information on cybersecurity, provided by the Union institutions, agencies and bodies; (e) raise awareness of the public about cybersecurity risks, and provide guidance on good practices for individual users aimed at citizens and organisations; (f) collect and analyse publicly available information regarding significant incidents and compiling reports with a view to providing guidance to businesses and citizens across the Union; (g) organise, in cooperation with the Member States and Union institutions, bodies, offices and agencies regular outreach campaigns to increase cybersecurity and its visibility in the Union. Article 10 Tasks relating to research and innovation In relation to research and innovation, the Agency shall: (a) advise the Union and the Member States on research needs and priorities in the area of cybersecurity, with a view to enabling effective responses to current and emerging risks and threats, including with respect to new and emerging information and communications technologies, and to using risk-prevention technologies effectively; (b) participate, where the Commission has delegated the relevant powers to it, in the implementation phase of research and innovation funding programmes or as a beneficiary. EN 44 EN Article 11 Tasks relating to international cooperation The Agency shall contribute to the Union’s efforts to cooperate with third countries and international organisations to promote international cooperation on issues related to cybersecurity, by: (a) engaging, where appropriate, as an observer in the organisation of international exercises, and analysing and reporting to the Management Board on the outcome of such exercises; (b) facilitating, upon the request of the Commission, the exchange of best practices between the relevant international organisations; (c) providing, upon request, the Commission with expertise. CHAPTER II ORGANISATION OF THE AGENCY Article 12 Structure The administrative and management structure of the Agency shall be composed of the following: (a) a Management Board which shall exercise the functions set out in Article 14; (b) an Executive Board which shall exercise the functions set out in Article 18; (c) an Executive Director who shall exercise the responsibilities set out in Article 19; and (d) a Permanent Stakeholders’ Group which shall exercise the functions set out in Article 20. SECTION 1 MANAGEMENT BOARD Article 13 Composition of the Management Board 1. The Management Board shall be composed of one representative of each Member State, and two representatives appointed by the Commission. All representatives shall have voting rights. 2. Each member of the Management Board shall have an alternate member to represent the member in their absence. 3. Members of the Management Board and their alternates shall be appointed in light of their knowledge in the field of cybersecurity, taking into account relevant managerial, administrative and budgetary skills. The Commission and Member States shall make efforts to limit the turnover of their representatives in the EN 45 EN Management Board, in order to ensure continuity of that Board’s work. The Commission and Member States shall aim to achieve a balanced representation between men and women on the Management Board. 4. The term of office of members of the Management Board and of their alternates shall be four years. That term shall be renewable. Article 14 Functions of the Management Board 1. The Management Board shall: (a) define the general direction of the operation of the Agency and shall also ensure that the Agency works in accordance with the rules and principles laid down in this Regulation. It shall also ensure consistency of the Agency’s work with activities conducted by the Member States as well as at Union level; (b) adopt the Agency’s draft single programming document referred to in Article 21, before its submission to the Commission for its opinion; (c) adopt, taking into account the Commission opinion, the Agency's single programming document by a majority of two-thirds of members and in accordance with Article 17; (d) adopt, by a majority of two-thirds of members, the annual budget of the Agency and exercise other functions in respect of the Agency's budget pursuant to Chapter III; (e) assess and adopt the consolidated annual report on the Agency’s activities and send both the report and its assessment by 1 July of the following year, to the European Parliament, the Council, the Commission and the Court of Auditors. The annual report shall include the accounts and describe how the Agency has met its performance indicators. The annual report shall be made public; (f) adopt the financial rules applicable to the Agency in accordance with Article 29; (g) adopt an anti-fraud strategy that is proportionate to the fraud risks having regard to a cost-benefit analysis of the measures to be implemented; (h) adopt rules for the prevention and management of conflicts of interest in respect of its members; (i) ensure adequate follow-up to the findings and recommendations resulting from investigations of the European Anti-fraud Office (OLAF) and the various internal or external audit reports and evaluations; (j) adopt its rules of procedure; (k) in accordance with paragraph 2, exercise, with respect to the staff of the Agency, the powers conferred by the Staff Regulations of Officials on the Appointing Authority and the Conditions of Employment of Other Servants of the European Union on the Authority Empowered to Conclude a Contract of Employment ('the appointing authority powers'); EN 46 EN (l) adopt rules implementing the Staff Regulations and the Conditions of Employment of Other Servants in accordance with the procedure provided for in Article 110 of the Staff Regulations; (m) appoint the Executive Director and where relevant extend his term of office or remove him from office in accordance with Article 33 of this Regulation; (n) appoint an Accounting Officer, who may be the Commission's Accounting Officer, who shall be totally independent in the performance of his/her duties; (o) take all decisions on the establishment of the Agency's internal structures and, where necessary, their modification, taking into consideration the Agency's activity needs and having regard to sound budgetary management; (p) authorise the conclusion of working arrangements in accordance with Articles 7 and 39. 2. The Management Board shall adopt, in accordance with Article 110 of the Staff Regulations, a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants, delegating relevant appointing authority powers to the Executive Director and defining the conditions under which this delegation of powers can be suspended. The Executive Director shall be authorised to sub-delegate those powers. 3. Where exceptional circumstances so require, the Management Board may by way of a decision temporarily suspend the delegation of the appointing authority powers to the Executive Director and those sub-delegated by the latter and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director. Article 15 Chairperson of the Management Board The Management Board shall elect by a majority of two-thirds of members its Chairperson and a Deputy Chairperson from among its members for a period of four years, which shall be renewable once. If, however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically expire on that date. The Deputy Chairperson shall ex officio replace the Chairperson if the latter is unable to attend to his or her duties. Article 16 Meetings of the Management Board 1. Meetings of the Management Board shall be convened by its Chairperson. 2. The Management Board shall hold at least two ordinary meetings a year. It shall also hold extraordinary meetings at the request of the Chairperson, at the request of the Commission, or at the request of at least a third of its members. 3. The Executive Director shall take part, without voting rights, in the meetings of the Management Board. EN 47 EN 4. Members of the Permanent Stakeholder Group may take part, upon invitation from the Chairperson, in the meetings of the Management Board, without voting rights. 5. The members of the Management Board and their alternates may, subject to its Rules of Procedure, be assisted at the meetings by advisers or experts. 6. The Agency shall provide the secretariat for the Management Board. Article 17 Voting rules of the Management Board 1. The Management Board shall take its decisions by majority of its members. 2. A two-thirds majority of all Management Board members shall be required for the single programming document, the annual budget, the appointment, extension of the term of office or removal of the Executive Director. 3. Each member shall have one vote. In the absence of a member, their alternate shall be entitled to exercise the right to vote. 4. The Chairperson shall take part in the voting. 5. The Executive Director shall not take part in the voting. 6. The Management Board's rules of procedures shall establish more detailed voting arrangements, in particular the circumstances in which a member may act on behalf of another member. SECTION 2 EXECUTIVE BOARD Article 18 Executive Board 1. The Management Board shall be assisted by an Executive Board. 2. The Executive Board shall: (a) prepare decisions to be adopted by the Management Board; (b) ensure, together with the Management Board, the adequate follow-up to the findings and recommendations stemming from investigations of OLAF and the various internal or external audit reports and evaluations; (c) without prejudice to the responsibilities of the Executive Director, as set out in Article 19, assist and advise the Executive Director in implementing the decisions of the Management Board on administrative and budgetary matters pursuant to Article 19. 3. The Executive Board shall be composed of five members appointed from among the members of the Management Board amongst whom the Chairperson of the Management Board, who may also chair the Executive Board, and one of the representatives of the Commission. The Executive Director shall take part in the meetings of the Executive Board, but shall not have the right to vote. 4. The term of office of the members of the Executive Board shall be four years. That term shall be renewable. EN 48 EN 5. The Executive Board shall meet at least once every three months. The chairperson of the Executive Board shall convene additional meetings at the request of its members. 6. The Management Board shall lay down the rules of procedure of the Executive Board. 7. When necessary, because of urgency, the Executive Board may take certain provisional decisions on behalf of the Management Board, in particular on administrative management matters, including the suspension of the delegation of the appointing authority powers and budgetary matters. SECTION 3 EXECUTIVE DIRECTOR Article 19 Responsibilities of the Executive Director 1. The Agency shall be managed by its Executive Director, who shall be independent in the performance of his or her duties. The Executive Director shall be accountable to the Management Board. 2. The Executive Director shall report to the European Parliament on the performance of his or her duties when invited to do so. The Council may invite the Executive Director to report on the performance of his or her duties. 3. The Executive Director shall be responsible for: (a) the day-to-day administration of the Agency; (b) implementing the decisions adopted by the Management Board; (c) preparing the draft single programming document and submitting it to the Management Board for approval before its submission to the Commission; (d) implementing the single programming document and reporting to the Management Board thereon; (e) preparing the consolidated annual report on the Agency’s activities and presenting it to the Management Board for assessment and adoption; (f) preparing an action plan following-up on the conclusions of the retrospective evaluations and reporting on progress every two years to the Commission; (g) preparing an action plan following-up conclusions of internal or external audit reports, as well as investigations by the European Ant-fraud Office (OLAF) and reporting on progress twice a year to the Commission and regularly to the Management Board; (h) preparing draft financial rules applicable to the Agency; (i) preparing the Agency's draft statement of estimates of revenue and expenditure and implementing its budget; (j) protecting the financial interests of the Union by the application of preventive measures against fraud, corruption and any other illegal EN 49 EN activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties; (k) preparing an anti-fraud strategy for the Agency and presenting it to the Management Board for approval; (l) developing and maintaining contact with the business community and consumers’ organisations to ensure regular dialogue with relevant stakeholders; (m) other tasks assigned to the Executive Director by this Regulation. 4. Where necessary and within the Agency’s mandate, and in accordance with the Agency's objectives and tasks, the Executive Director may set up ad hoc Working Groups composed of experts, including from the Member States’ competent authorities. The Management Board shall be informed in advance. The procedures regarding in particular the composition of the Working Groups, the appointment of the experts of the Working Groups by the Executive Director and the operation of the Working Groups shall be specified in the Agency’s internal rules of operation. 5. The Executive Director shall decide whether it is necessary to locate members of staff in one or more Member States for the purpose of carrying out the Agency's tasks in an efficient and effective manner. Before deciding to establish a local office the Executive Director shall obtain the prior consent of the Commission, the Management Board and the Member State(s) concerned. The decision shall specify the scope of the activities to be carried out at the local office in a manner that avoids unnecessary costs and duplication of administrative functions of the Agency. An agreement with the Member State(s) concerned shall be reached, where appropriate or required. SECTION 4 PERMANENT STAKEHOLDERS' GROUP Article 20 Permanent Stakeholders’ Group 1. The Management Board, acting on a proposal by the Executive Director, shall set up a Permanent Stakeholders’ Group composed of recognised experts representing the relevant stakeholders, such as the ICT industry, providers of electronic communications networks or services available to the public, consumer groups, academic experts in the cybersecurity, and representatives of competent authorities notified under [Directive establishing the European Electronic Communications Code] as well as of law enforcement and data protection supervisory authorities. 2. Procedures for the Permanent Stakeholders’ Group, in particular regarding the number, composition, and the appointment of its members by the Management Board, the proposal by the Executive Director and the operation of the Group, shall be specified in the Agency’s internal rules of operation and shall be made public. 3. The Permanent Stakeholders’ Group shall be chaired by the Executive Director or by any person the Executive Director appoints on a case-by-case basis. EN 50 EN 4. The term of office of the Permanent Stakeholders’ Group’s members shall be two-and-a-half years. Members of the Management Board may not be members of the Permanent Stakeholders’ Group. Experts from the Commission and the Member States shall be entitled to be present at the meetings of the Permanent Stakeholders’ Group and to participate in its work. Representatives of other bodies deemed relevant by the Executive Director, who are not members of the Permanent Stakeholders’ Group, may be invited to attend the meetings of the Permanent Stakeholders’ Group and to participate in its work. 5. The Permanent Stakeholders’ Group shall advise the Agency in respect of the performance of its activities. It shall in particular advise the Executive Director on drawing up a proposal for the Agency’s work programme, and on ensuring communication with the relevant stakeholders on all issues related to the work programme. SECTION 5 OPERATION Article 21 Single Programming Document 1. The Agency shall carry out its operations in accordance with a single programming document containing its multiannual and annual programming, which shall include all of its planned activities. 2. Each year, the Executive Director shall draw up a draft single programming document containing multiannual and annual programming with the corresponding human and financial resources planning in accordance with Article 32 of Commission Delegated Regulation (EU) No 1271/201336 and taking into account guidelines set by the Commission. 3. By 30 November each year, the Management Board shall adopt the single programming document referred to in paragraph 1 and forward it to the European Parliament, the Council and the Commission no later than 31 January of the following year, as well as any later updated version of that document. 4. The single programming document shall become definitive after final adoption of the general budget of the Union and, if necessary, shall be adjusted accordingly. 5. The annual work programme shall comprise detailed objectives and expected results including performance indicators. It shall also contain a description of the actions to be financed and an indication of the financial and human resources allocated to each action, in accordance with the principles of activity-based budgeting and management. The annual work programme shall be coherent with the multi-annual work programme referred to in paragraph 7. It shall clearly indicate tasks that have been added, changed or ***deleted*** in comparison with the previous financial year. 36 Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 328, 7.12.2013, p. 42) EN 51 EN 6. The Management Board shall amend the adopted annual work programme when a new task is given to the Agency. Any substantial amendment to the annual work programme shall be adopted by the same procedure as the initial annual work programme. The Management Board may delegate the power to make non-substantial amendments to the annual work programme to the Executive Director. 7. The multi-annual work programme shall set out overall ***strategic*** programming including objectives, expected results and performance indicators. It shall also set out resource programming including multi-annual budget and staff. 8. The resource programming shall be updated annually. The ***strategic*** programming shall be updated wherever appropriate and in particular where necessary to address the outcome of the evaluation referred to in Article 56. Article 22 Declaration of interest 1. Members of the Management Board, the Executive Director and officials seconded by Member States on a temporary basis shall each make a declaration of commitments and a declaration indicating the absence or presence of any direct or indirect interest which might be considered prejudicial to their independence. The declarations shall be accurate and complete, made annually in writing and updated whenever necessary. 2. Members of the Management Board, the Executive Director, and external experts participating in ad hoc Working Groups shall each accurately and completely declare, at the latest at the start of each meeting, any interest which might be considered prejudicial to their independence in relation to the items on the agenda, and shall abstain from participating in the discussion of and voting upon such points. 3. The Agency shall lay down, in its internal rules of operation, the practical arrangements for the rules on declarations of interest referred to in paragraphs 1 and 2. Article 23 Transparency 1. The Agency shall carry out its activities with a high level of transparency and in accordance with Article 25. 2. The Agency shall ensure that the public and any interested parties are given appropriate, objective, reliable and easily accessible information, in particular with regard to the results of its work. It shall also make public the declarations of interest made in accordance with Article 22. 3. The Management Board, acting on a proposal from the Executive Director, may authorise interested parties to observe the proceedings of some of the Agency’s activities. 4. The Agency shall lay down, in its internal rules of operation, the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2. EN 52 EN Article 24 Confidentiality 1. Without prejudice to Article 25, the Agency shall not divulge to third parties information that it processes or receives in relation to which a reasoned request for confidential treatment, in whole or in part, has been made. 2. Members of the Management Board, the Executive Director, the members of the Permanent Stakeholders Group, external experts participating in ad hoc Working Groups, and members of the staff of the Agency including officials seconded by Member States on a temporary basis shall comply with the confidentiality requirements under Article 339 of the Treaty on the Functioning of the European Union (TFEU), even after their duties have ceased. 3. The Agency shall lay down, in its internal rules of operation, the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2. 4. If required for the performance of the Agency’s tasks, the Management Board shall decide to allow the Agency to handle classified information. In that case the Management Board shall, in agreement with the Commission services, adopt internal rules of operation applying the security principles set out in Commission Decisions (EU, Euratom) 2015/44337 and 2015/44438. Those rules shall include provisions for the exchange, processing and storage of classified information. Article 25 Access to documents 1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency. 2. The Management Board shall adopt arrangements for implementing Regulation (EC) No 1049/2001 within six months of the establishment of the Agency. 3. Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may be the subject of a complaint to the Ombudsman under Article 228 TFEU or of an action before the Court of Justice of the European Union under Article 263 TFEU. CHAPTER III ESTABLISHMENT AND STRUCTURE OF THE BUDGET Article 26 Establishment of the budget 1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency’s revenue and expenditure for the following financial year, and shall forward 37 Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41). 38 Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53). EN 53 EN it to the Management Board, together with a draft establishment plan. Revenue and expenditure shall be in balance. 2. Each year, the Management Board shall, on the basis of the draft statement of estimates of revenue and expenditure referred to in paragraph 1, produce a statement of estimates of revenue and expenditure for the Agency for the following financial year. 3. The Management Board shall, by 31 January each year, send the statement of estimates referred to in paragraph 2, which shall be part of the draft single programming document, to the Commission and the third countries with which the Union has concluded agreements in accordance with Article 39. 4. On the basis of that statement of estimates, the Commission shall enter in the draft budget of the Union the estimates it deems necessary for the establishment plan and the amount of the contribution to be charged to the general budget, which it shall submit to the European Parliament and the Council in accordance with Article 313 and 314 TFEU. 5. The European Parliament and the Council shall authorise the appropriations for the contribution to the Agency. 6. The European Parliament and the Council shall adopt the establishment plan for the Agency. 7. Together with the single programming document, the Management Board shall adopt the Agency’s budget. It shall become final following definitive adoption of the general budget of the Union. Where appropriate, the Management Board shall adjust the Agency’s budget and single programming document in accordance with the general budget of the Union. Article 27 Structure of the budget 1. Without prejudice to other resources, the Agency's revenue shall be composed of: (a) a contribution from the Union budget; (b) revenue assigned to specific items of expenditure in accordance with its financial rules referred to in Article 29; (c) Union funding in the form of delegation agreements or ad hoc grants in accordance with its financial rules referred to in Article 29 and with the provisions of the relevant instruments supporting the policies of the Union; (d) contributions from third countries participating in the work of the Agency as provided for in Article 39; (e) any voluntary contributions from Member States in money or in kind; Member States that provide voluntary contributions may not claim any specific right or service as a result thereof. 2. The expenditure of the Agency shall include staff, administrative and technical support, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties. EN 54 EN Article 28 Implementation of the budget 1. The Executive Director shall be responsible for the implementation of the Agency’s budget. 2. The Commission’s internal auditor shall exercise the same powers over the Agency as over Commission departments. 3. By 1 March following each financial year (1 March of year N + 1), the Agency’s accounting officer shall send the provisional accounts to the Commission’s accounting officer and to the Court of Auditors. 4. Upon receipts of the Court of Auditors' observations on the Agency's provisional accounts, the Agency's accounting officer shall draw up the Agency's final accounts under his or her responsibility. 5. The Executive Director shall submit the final accounts to the Management Board for an opinion. 6. The Executive Director shall send, by 31 March of year N + 1, the report on the budgetary and financial management to the European Parliament, the Council, the Commission and the Court of Auditors. 7. The accounting officer shall, by 1 July of year N + 1, transmit the final accounts to the European Parliament, the Council, the accounting officer of the Commission and the Court of Auditors, together with the Management Board's opinion. 8. At the same date as the transmission of his or her final accounts, the accounting officer shall also send to the Court of Auditors a representation letter covering those final accounts, with a copy to the accounting officer of the Commission. 9. The Executive Director shall publish the final accounts by 15 November of the following year. 10. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September of year N + 1 and shall also send a copy of that reply to the Management Board and to the Commission. 11. The Executive Director shall submit to the European Parliament, at the latter’s request, all the information necessary for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 165(3) of the Financial Regulation. 12. The European Parliament, acting on a recommendation from the Council, shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for the year N. Article 29 Financial Rules The financial rules applicable to the Agency shall be adopted by the Management Board after consulting the Commission. They shall not depart from Regulation (EU) 1271/2013 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent. EN 55 EN Article 30 Combating fraud 1. In order to facilitate the combating of fraud, corruption and other unlawful activities under Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council39, the Agency shall, within six months from the day it becomes operational, accede to the Interinstitutional Agreement of 25 May, 1999 concerning internal investigations by the European Anti-fraud Office (OLAF) and shall adopt the appropriate provisions applicable to all the employees of the Agency, using the template set out in the Annex to that Agreement. 2. The Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds from the Agency. 3. OLAF may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council and Council Regulation (Euratom, EC) No 2185/9640 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the Union’ financial interests against fraud and other irregularities with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant or a contract funded by the Agency. 4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and international organisations, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences. CHAPTER IV AGENCY STAFF Article 31 General provisions The Staff Regulations and the Conditions of Employment of Other Servants and the rules adopted by agreement between the Union institutions for giving effect to those Staff Regulations shall apply to the staff of the Agency. 39 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1). 40 Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2). EN 56 EN Article 32 Privileges and immunity Protocol No 7 on the Privileges and Immunities of the European Union annexed to the Treaty on European Union and to the TFEU shall apply to the Agency and its staff. Article 33 Executive Director 1. The Executive Director shall be engaged as a temporary agent of the Agency under Article 2(a) of the Conditions of Employment of Other Servants. 2. The Executive Director shall be appointed by the Management Board from a list of candidates proposed by the Commission, following an open and transparent selection procedure. 3. For the purpose of concluding the contract of the Executive Director, the Agency shall be represented by the Chairperson of the Management Board. 4. Before appointment, the candidate selected by the Management Board shall be invited to make a statement before the relevant committee of the European Parliament and to answer Members’ questions. 5. The term of office of the Executive Director shall be five years. By the end of that period, the Commission shall carry out an assessment which takes into account the evaluation of the performance of the Executive Director and the Agency’s future tasks and challenges. 6. The Management Board shall reach decisions on appointment, extension of the term of office or removal from office of the Executive Director on the basis of a two-thirds majority of its members with voting rights. 7. The Management Board may, acting on a proposal from the Commission which takes into account the assessment referred to in paragraph 5, extend once the term of office of the Executive Director for no more than five years. 8. The Management Board shall inform the European Parliament about its intention to extend the Executive Director’s term of office. Within three months before any such extension, the Executive Director shall, if invited, make a statement before the relevant committee of the European Parliament and answer Members’ questions. 9. An Executive Director whose term of office has been extended may not participate in another selection procedure for the same post. 10. The Executive Director may be removed from office only by decision of the Management Board, acting on a proposal from the Commission. Article 34 Seconded national experts and other staff 1. The Agency may make use of seconded national experts or other staff not employed by the Agency. The Staff Regulations and the Conditions of Employment of Other Servants shall not apply to such staff. 2. The Management Board shall adopt a decision laying down rules on the secondment to the agency of national experts. EN 57 EN CHAPTER V GENERAL PROVISIONS Article 35 Legal status of the Agency 1. The Agency shall be a body of the Union and shall have legal personality. 2. In each Member State, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It may, in particular, acquire or dispose of movable and immovable property and may be a party to legal proceedings, or both. 3. The Agency shall be represented by its Executive Director. Article 36 Liability of the Agency 1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question. 2. The Court of Justice of the European Union shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Agency. 3. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. 4. The Court of Justice of the European Union shall have jurisdiction in any dispute relating to compensation for such damage. 5. The personal liability of its servants towards the Agency shall be governed by the relevant conditions applying to the staff of the Agency. Article 37 Language arrangements 1. Council Regulation No 1 shall apply to the Agency41.The Member States and the other bodies appointed by them may address the Agency and receive a reply in the official language of the institutions of the Union of their choice. 2. The translation services required for the functioning of the Agency shall be provided by the Translation Centre for the Bodies of the European Union. 41 Regulation No 1 determining the languages to be used by the European Atomic Energy Community (OJ 17, 6.10.1958, p. 401). EN 58 EN Article 38 Protection of personal data 1. The processing of personal data by the Agency shall be subject to Regulation EC) No 45/2001 of the European Parliament and of the Council42. 2. The Management Board shall adopt implementing measures referred to in Article 24(8) of Regulation (EC) No 45/2001. The Management Board may adopt additional measures necessary for the application of Regulation (EC) No 45/2001 by the Agency. Article 39 Cooperation with third countries and international organisations 1. In so far as is necessary in order to achieve the objectives set out in this Regulation, the Agency may cooperate with the competent authorities of third countries or with international organisations or both. To this end, the Agency may, subject to prior approval by the Commission, establish working arrangements with the authorities of third countries and international organisations. These arrangements shall not create legal obligations incumbent on the Union and its Member States. 2. The Agency shall be open to the participation of third countries that have entered into agreements with the Union to this effect. Under the relevant provisions of these agreements, arrangements shall be made specifying in particular the nature, extent and manner in which those countries will participate in the Agency’s work, including provisions relating to participation in the initiatives undertaken by the Agency, financial contributions and staff. As regards staff matters, those arrangements shall, in any event, comply with the Staff Regulations. 3. The Management Board shall adopt a strategy for relations with third countries or international organisations concerning matters for which the Agency is competent. The Commission shall ensure that the agency operates within its mandate and the existing institutional framework by concluding an appropriate working arrangement with the agency's Executive Director. Article 40 Security rules on the protection of classified and sensitive non-classified information In consultation with the Commission, the Agency shall adopt its security rules applying the security principles contained in the Commission’s security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443 and 2015/444. This shall cover, inter alia, provisions for the exchange, processing and storage of such information. Article 41 Headquarters Agreement and operating conditions 1. The necessary arrangements concerning the accommodation to be provided for the Agency in the host Member State and the facilities to be made available by that 42 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1). EN 59 EN Member State together with the specific rules applicable in the host Member State to the Executive Director, members of the Management Board, Agency staff and members of their families shall be laid down in a Headquarters Agreement between the Agency and Member State where the seat is located, concluded after obtaining the approval of the Management Board and no later than [2 years after the entry into force of this Regulation]. 2. The Agency’s host Member State shall provide the best possible conditions to ensure the proper functioning of the Agency, including the accessibility of the location, the existence of adequate education facilities for the children of staff members, appropriate access to the labour market, social security and medical care for both children and spouses. Article 42 Administrative control The operations of the Agency shall be supervised by the Ombudsman in accordance with Article 228 TFEU. EN 60 EN TITLE III CYBERSECURITY CERTIFICATION FRAMEWORK Article 43 European cybersecurity certification schemes A European cybersecurity certification scheme shall attest that the ICT products and services that have been certified in accordance with such scheme comply with specified requirements as regards their ability to resist at a given level of assurance, actions that aim to compromise the availability, authenticity, integrity or confidentiality of stored or transmitted or processed data or the functions or services offered by, or accessible via, those products, processes, services and systems. Article 44 Preparation and adoption of a European Cybersecurity Certification Scheme 1. Following a request from the Commission, ENISA shall prepare a candidate European cybersecurity certification scheme which meets the requirements set out in Articles 45, 46 and 47 of this Regulation. Member States or the European Cybersecurity Certification Group (the 'Group') established under Article 53 may propose the preparation of a candidate European cybersecurity certification scheme to the Commission. 2. When preparing candidate schemes referred to in paragraph 1 of this Article, ENISA shall consult all relevant stakeholders and closely cooperate with the Group. The Group shall provide ENISA with the assistance and expert advice required by ENISA in relation to the preparation of the candidate scheme, including by providing opinions where necessary. 3. ENISA shall transmit the candidate European cybersecurity certification scheme prepared in accordance with paragraph 2 of this Article to the Commission. 4. The Commission, based on the candidate scheme proposed by ENISA, may adopt implementing acts, in accordance with Article 55(1), providing for European cybersecurity certification schemes for ICT products and services meeting the requirements of Articles 45, 46 and 47 of this Regulation. 5. ENISA shall maintain a dedicated website providing information on, and publicity of, European cybersecurity certification schemes. Article 45 Security objectives of European cybersecurity certification schemes A European cybersecurity certification scheme shall be so designed to take into account, as applicable, the following security objectives: (a) protect data stored, transmitted or otherwise processed against accidental or unauthorised storage, processing, access or disclosure; (b) protect data stored, transmitted or otherwise processed against accidental or unauthorised destruction, accidental loss or alteration; EN 61 EN (c) ensure that authorised persons, programmes or machines can access exclusively the data, services or functions to which their access rights refer; (d) record which data, functions or services have been communicated, at what times and by whom; (e) ensure that it is possible to check which data, services or functions have been accessed or used, at what times and by whom; (f) restore the availability and access to data, services and functions in a timely manner in the event of physical or technical incident; (g) ensure that ICT products and services are provided with up to date software that does not contain known vulnerabilities, and are provided mechanisms for secure software updates. Article 46 Assurance levels of European cybersecurity certification schemes 1. A European cybersecurity certification scheme may specify one or more of the following assurance levels: basic, substantial and/or high, for ICT products and services issued under that scheme. 2. The assurance levels basic, substantial and high shall meet the following criteria respectively: (a) assurance level basic shall refer to a certificate issued in the context of a European cybersecurity certification scheme, which provides a limited degree of confidence in the claimed or asserted cybersecurity qualities of an ICT product or service, and is characterised with reference to technical specifications, standards and procedures related thereto, including technical controls, the purpose of which is to decrease the risk of cybersecurity incidents; (b) assurance level substantial shall refer to a certificate issued in the context of a European cybersecurity certification scheme, which provides a substantial degree of confidence in the claimed or asserted cybersecurity qualities of an ICT product or service, and is characterised with reference to technical specifications, standards and procedures related thereto, including technical controls, the purpose of which is to decrease substantially the risk of cybersecurity incidents; (c) assurance level high shall refer to a certificate issued in the context of a European cybersecurity certification scheme, which provides a higher degree of confidence in the claimed or asserted cybersecurity qualities of an ICT product or service than certificates with the assurance level substantial, and is characterised with reference to technical specifications, standards and procedures related thereto, including technical controls, the purpose of which is to prevent cybersecurity incidents. Article 47 Elements of European cybersecurity certification schemes 1. A European cybersecurity certification scheme shall include the following elements: EN 62 EN (a) subject-matter and scope of the certification, including the type or categories of ICT products and services covered; (b) detailed specification of the cybersecurity requirements against which the specific ICT products and services are evaluated, for example by reference to Union or international standards or technical specifications; (c) where applicable, one or more assurance levels; (d) specific evaluation criteria and methods used, including types of evaluation, in order to demonstrate that the specific objectives referred to in Article 45 are achieved; (e) information to be supplied to the conformity assessment bodies by an applicant which is necessary for certification; (f) where the scheme provides for marks or labels, the conditions under which such marks or labels may be used; (g) where surveillance is part of the scheme, the rules for monitoring compliance with the requirements of the certificates, including mechanisms to demonstrate the continued compliance with the specified cybersecurity requirements; (h) conditions for granting, maintaining, continuing, extending and reducing the scope of certification; (i) rules concerning the consequences of non-conformity of certified ICT products and services with the certification requirements; (j) rules concerning how previously undetected cybersecurity vulnerabilities in ICT products and services are to be reported and dealt with; (k) rules concerning the retention of records by conformity assessment bodies; (l) identification of national cybersecurity certification schemes covering the same type or categories of ICT products and services; (m) the content of the issued certificate. 2. The specified requirements of the scheme shall not contradict any applicable legal requirements, in particular requirements emanating from harmonised Union legislation. 3. Where a specific Union act so provides, certification under a European cybersecurity certification scheme may be used to demonstrate the presumption of conformity with requirements of that act. 4. In the absence of harmonised Union legislation, Member State law may also provide that a European cybersecurity certification scheme may be used for establishing the presumption of conformity with legal requirements. Article 48 Cybersecurity certification 1. ICT products and services that have been certified under a European cybersecurity certification scheme adopted pursuant to Article 44 shall be presumed to be compliant with the requirements of such scheme. 2. The certification shall be voluntary, unless otherwise specified in Union law. EN 63 EN 3. A European cybersecurity certificate pursuant to this Article shall be issued by the conformity assessment bodies referred to in Article 51 on the basis of criteria included in the European cybersecurity certification scheme, adopted pursuant to Article 44. 4. By the way of derogation from paragraph 3, in duly justified cases a particular European cybersecurity scheme may provide that a European cybersecurity certificate resulting from that scheme can only be issued by a public body. Such public body shall be one of the following: (a) a national certification supervisory authority referred to in Article 50(1); (b) a body that is accredited as conformity assessment body pursuant to Article 51(1) or (c) a body established under laws, statutory instruments, or other official administrative procedures of a Member State concerned and meeting the requirements for bodies certifying products, processes and services further to ISO/IEC 17065:2012. 5. The natural or legal person which submits its ICT products or services to the certification mechanism shall provide the conformity assessment body referred to in Article 51 with all information necessary to conduct the certification procedure. 6. Certificates shall be issued for a maximum period of three years and may be renewed, under the same conditions, provided that the relevant requirements continue to be met. 7. A European cybersecurity certificate issued pursuant to this Article shall be recognised in all Member States. Article 49 National cybersecurity certification schemes and certificates 1. Without prejudice to paragraph 3, national cybersecurity certification schemes and the related procedures for the ICT products and services covered by a European cybersecurity certification scheme shall cease to produce effects from the date established in the implementing act adopted pursuant Article 44(4). Existing national cybersecurity certification schemes and the related procedures for the ICT products and services not covered by a European cybersecurity certification scheme shall continue to exist. 2. Member States shall not introduce new national cybersecurity certification schemes for ICT products and services covered by a European cybersecurity certification scheme in force. 3. Existing certificates issued under national cybersecurity certification schemes shall remain valid until their expiry date. Article 50 National certification supervisory authorities 1. Each Member State shall appoint a national certification supervisory authority. 2. Each Member State shall inform the Commission of the identity of the authority appointed. EN 64 EN 3. Each national certification supervisory authority shall, in its organisation, funding decisions, legal structure and decision-making, be independent of the entities they supervise. 4. Member States shall ensure that national certification supervisory authorities have adequate resources to exercise their powers and to carry out, in an effective and efficient manner, the tasks assigned to them. 5. For the effective implementation of the regulation, it is appropriate that these authorities participate in the European Cybersecurity Certification Group established pursuant to Article 53 in an active, effective, efficient and secure manner. 6. National certification supervisory authorities shall: (a) monitor and enforce the application of the provisions under this Title at national level and supervise compliance of the certificates that have been issued by conformity assessment bodies established in their respective territories with the requirements set out in this Title and in the corresponding European cybersecurity certification scheme; (b) monitor and supervise the activities of conformity assessment bodies for the purpose of this Regulation, including in relation to the notification of conformity assessment bodies and the related tasks set out in Article 52 of this Regulation; (c) handle complaints lodged by natural or legal persons in relation to certificates issued by conformity assessment bodies established in their territories, investigate, to the extent appropriate, the subject matter of the complaint, and inform the complainant of the progress and the outcome of the investigation within a reasonable time period; (d) cooperate with other national certification supervisory authorities or other public authorities, including by sharing information on possible non-compliance of ICT products and services with the requirements of this Regulation or specific European cybersecurity certification schemes; (e) monitor relevant developments in the field of cybersecurity certification. 7. Each national certification supervisory authority shall have at least the following powers: (a) to request conformity assessment bodies and European cybersecurity certificate holders to provide any information it requires for the performance of its task; (b) to carry out investigations, in the form of audits, of conformity assessment bodies and European cybersecurity certificates' holders, for the purpose of verifying compliance with the provisions under Title III; (c) to take appropriate measures, in accordance with national law, in order to ensure that conformity assessment bodies or certificate holders comply with this Regulation or with a European cybersecurity certification scheme; (d) to obtain access to any premises of conformity assessment bodies and European cybersecurity certificates' holders for the purpose of carrying out investigations in accordance with Union or Member State procedural law; EN 65 EN (e) to withdraw, in accordance with national law, certificates that are not compliant with this Regulation or a European cybersecurity certification scheme; (f) to impose penalties, as provided for in Article 54, in accordance with national law, and to require the immediate cessation of the breaches of obligations set out in this Regulation. 8. National certification supervisory authorities shall cooperate amongst each other and the Commission and, in particular, exchange information, experiences and good practices as regards cybersecurity certification and technical issues concerning cybersecurity of ICT products and services. Article 51 Conformity assessment bodies 1. The conformity assessment bodies shall be accredited by the national accreditation body named pursuant to Regulation (EC) No 765/2008 only when they meet the requirements set out in the Annex to this Regulation. 2. Accreditation shall be issued for a maximum of five years and may be renewed on the same conditions provided that the conformity assessment body meets the requirements set out in this Article. Accreditation bodies shall revoke an accreditation of a conformity assessment body pursuant to paragraph 1 of this Article where the conditions for the accreditation are not, or are no longer, met or where actions taken by a conformity assessment body infringe this Regulation. Article 52 Notification 1. For each European cybersecurity certification scheme adopted pursuant Article 44, national certification supervisory authorities shall notify the Commission of the accredited conformity assessment bodies accredited to issue certificates at specified assurance levels as referred to in Article 46 and, without undue delay, of any subsequent changes thereto. 2. One year after the entry into force of a European cybersecurity certification scheme, the Commission shall publish a list of notified conformity assessment bodies in the Official Journal. 3. If the Commission receives a notification after the expiry of the period referred to in paragraph 2, it shall publish in the Official Journal of the European Union the amendments to the list referred to in paragraph 2 within two months from the date of receipt of that notification. 4. A national certification supervisory authority may submit to the Commission a request to remove a conformity assessment body notified by that national certification supervisory authority from the list referred to in paragraph 2 of this Article. The Commission shall publish in the Official Journal of the European Union the corresponding amendments to the list within one month from the date of receipt of the national certification supervisory authority’s request. EN 66 EN 5. The Commission may, by means of implementing acts, define the circumstances, formats and procedures of notifications referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2). Article 53 European Cybersecurity Certification Group 1. The European Cybersecurity Certification Group (the 'Group') shall be established. 2. The Group shall be composed of national certification supervisory authorities. The authorities shall be represented by the heads or by other high level representatives of national certification supervisory authorities. 3. The Group shall have the following tasks: (a) to advise and assist the Commission in its work to ensure a consistent implementation and application of the present Title, in particular regarding cybersecurity certification policy issues, coordination of policy approaches, and the preparation of European cybersecurity certification schemes; (b) to assist, advise and cooperate with ENISA in relation to the preparation of a candidate scheme in accordance with Article 44 of this Regulation; (c) to propose to the Commission that it requests the Agency to prepare a candidate European cybersecurity certification scheme in accordance with Article 44 of this Regulation; (d) to adopt opinions addressed to the Commission relating to the maintenance and review of existing European cybersecurity certifications schemes; (e) to examine the relevant developments in the field of cybersecurity certification and exchange good practices on cybersecurity certification schemes; (f) to facilitate the cooperation between national certification supervisory authorities under this Title through the exchange of information, in particular by establishing methods for the efficient exchange of information relating to all issues concerning cybersecurity certification. 4. The Commission shall chair the Group and provide the secretariat to it, with the assistance of ENISA as provided for in Article 8(a). Article 54 Penalties Member States shall lay down the rules on penalties applicable to infringements of this Title and European cybersecurity certification schemes, and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall [by …/without delay] notify the Commission of those rules and of those measures and shall notify it of any subsequent amendment affecting them. EN 67 EN TITLE IV FINAL PROVISIONS Article 55 Committee procedure 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. 2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply. Article 56 Evaluation and review 1. Not later than five years after the date referred to in Article 58, and every five years thereafter, the Commission shall assess the impact, effectiveness and efficiency of the Agency and its working practices and the possible need to modify the mandate of the Agency and the financial implications of any such modification. The evaluation shall take into account any feedback made to the Agency in response to its activities. Where the Commission considers that the continuation of the Agency is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that this Regulation be amended with regard to the provisions related to the Agency. 2. The evaluation shall also assess the impact, effectiveness and efficiency of the provisions of Title III with regard to the objectives of ensuring an adequate level of cybersecurity of ICT products and services in the Union and improving the functioning of the internal market. 3. The Commission shall forward the evaluation report together with its conclusions to the European Parliament, the Council and the Management Board. The findings of the evaluation report shall be made public. Article 57 Repeal and succession 1. Regulation (EC) No 526/2013 is repealed with effect from [….]. 2. References to Regulation (EC) No 526/2013 and to ENISA shall be construed as references to this Regulation and to the Agency. 3. The Agency succeeds the Agency that was established by Regulation (EC) No 526/2013 as regards all ownership, agreements, legal obligations, employment contracts, financial commitments and liabilities. All existing decisions of the Management Board and Executive Board remain valid, providing they are not in conflict with the provisions of this Regulation. 4. The Agency shall be established for an indefinite period of time starting from […] EN 68 EN 5. The Executive Director appointed pursuant to Article 24(4) of Regulation (EC) No 526/2013 shall be the Executive Director of the Agency for the remaining part of his term of office. 6. The Members and their alternates of the Management Board appointed pursuant to Article 6 of Regulation (EC) No 526/2013 shall be the Members and their alternates of the Management Board of the Agency for the remaining part of their term of office. Article 58 1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. 2. This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President EN 69 EN LEGISLATIVE FINANCIAL STATEMENT 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE 1.1 Title of the proposal/initiative Proposal for a Regulation of the European Parliament and of the Council on ENISA, the 'EU cybersecurity agency' and repealing Regulation (EU) 526/2013, and on Information and Communication Technology security certification (''Cybersecurity Act/Regulation'') 1.2 Policy area(s) concerned Policy area: 09 - Communications networks, content and technology Activity: 09.02 digital single market 1.3 Nature of the proposal/initiative  The proposal/initiative relates to a new action (Title III – Certification)  The proposal/initiative relates to a new action following a pilot project/preparatory action43 The proposal/initiative relates to the extension of an existing action (Title II – ENISA's mandate)  The proposal/initiative relates to an action redirected towards a new action 1.4 Objective(s) 1.4.1 The Commission's multiannual ***strategic*** objective(s) targeted by the proposal/initiative 1. Increase the resilience of the Member States, businesses and the EU as a whole 2. Ensure the proper functioning of the EU internal market for ICT products and services 3. Increase the global competitiveness of the EU companies operating in the ICT field. 4. Approximate the laws, regulations and administrative provisions of the Member States which require cybersecurity 1.4.2 Specific objective(s) With the general objectives in mind, in the broader context of the reviewed Cybersecurity Strategy, the instrument, by delineating the scope and mandate of ENISA and establishing European certification framework for ICT products and services, intends to achieve the following specific objectives: 1. Increase capabilities and preparedness of Member States and businesses 2. Improve cooperation and coordination across Member States and EU, institutions, agencies and bodies. 3. Increase EU level capabilities to complement the action of Member States, in particular in the case of cross-border cyber crises. 4. Increase awareness of citizens and businesses on cybersecurity issues. 5. Strengthen trust in the digital single market and in digital innovation through increasing the overall transparency of cybersecurity assurance44 of ICT products and services. 43 As referred to in Article 54(2)(a) or (b) of the Financial Regulation. EN 70 EN ENISA will contribute to achieving the above objectives through: Enhanced policy making support – provide guidance and advice to the Commission and the Member States to update and develop a holistic normative framework in the field of cybersecurity as well as sector-specific policy and law initiatives where cybersecurity matters are involved; contribute to the work of the Cooperation Group (art. 11 of Directive (EU) 2016/1148) by providing expertise and assistance; support policy development and implementation in the area of electronic identity and trust services; promote exchange of best practices among competent authorities; Enhanced capacity building support - provide support to Member States, the Union institutions, bodies, offices and agencies to develop and improve the prevention, detection, analysis as well as the capacity to respond to cybersecurity problems and incidents; assist Member States, upon their request, in developing national CSIRTs, national cybersecurity strategies; assist Union institutions in developing and reviewing of Union's cybersecurity strategies; providing cybersecurity trainings; assisting Member States through the Cooperation Group in exchanging best practices; facilitating the establishment of sectoral Information Sharing and Analysis Centres (ISACs). Operational cooperation and crisis management support – support cooperation among competent public bodies and between stakeholders through establishing systematic cooperation with Union institutions, bodies, offices and agencies dealing with cybersecurity, cybercrime and the protection of privacy and personal data; providing the secretariat of the CSIRTs Network (art. 12(2) of Directive (EU) 2016/1148) as well as contribute to the operational cooperation within the Network by providing, in cooperation with CERT-EU, support to Member States, at their request; organise regular cybersecurity exercises; contribute to developing a cooperative response to the large scale cross-border cybersecurity incidents and crises; conduct, in cooperation with CSIRTs Network ex-post technical enquiries of significant incidents and issue follow-up recommendations; Market related tasks (standardisation, certification) - perform a number of functions specifically supporting the internal market: cybersecurity 'market observatory', by analysing relevant trends in the cybersecurity market to better match demand and supply; support and promote the development and implementation of the Union policy on cybersecurity certification of ICT products and services through preparing candidate European cybersecurity certification schemes for ICT products and services, providing the secretariat to the Union Cybersecurity Certification Group, providing guidelines and good practices concerning security requirements of ICT products and services in cooperation with national certification supervisory authorities and the industry; Enhanced knowledge, information and awareness raising support – provide assistance and deliver advice to the Commission and the Member States to reach a high level of knowledge, throughout the Union, on issues related to NIS and its application to the industry stakeholders. This assumes also pooling, organizing and making available to the public, through a dedicated portal, information on security of network and information systems [or cybersecurity]. Another important element are awareness raising activities and outreach campaigns targeted at the general public about cybersecurity risks. Enhanced research and innovation support - provide advice on research needs and priority-setting in cybersecurity area; 44 Transparency of cybersecurity assurance means providing users with sufficient information on cybersecurity properties which enables users to objectively determine the level of security of a given ICT product, service or process. EN 71 EN International cooperation support – support Union's efforts to cooperate with third countries and with international organisations to promote international cooperation on cybersecurity. CERTIFICATION Certification framework will contribute to achieving the objectives by increasing the overall transparency of cybersecurity assurance45 of ICT products and services and thereby strengthening trust in the digital single market and in digital innovation. This should also help avoid fragmentation of certification schemes in the EU and related security requirement and evaluation criteria across Member States and sectors; 1.4.3 Expected result(s) and impact Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted. A reinforced ENISA (supporting capabilities, prevention, cooperation and awareness at EU level, and therefore designed to increase overall EU cyber resilience), as well as supporting the EU certification framework of ICT products and services is expected to bring the following impacts (non-exhaustive list): Overall impact: - Overall positive impact on the internal market thanks to reduced market fragmentation and building trust in digital technologies through better cooperation, more harmonised approaches to EU cybersecurity policies and increased capabilities at EU level. This should result in a positive economic impact by helping to reduce the costs of cybersecurity/cybercrime incidents, for which the estimated economic impact in the Union stands at 0.41% of EU GDP (i.e around EUR 55 billion). Specific results: Improved cybersecurity capabilities and preparedness of Member States and businesses - Improved cybersecurity capabilities and preparedness of Member States (thanks to long-term ***strategic*** analysis of cyber threats and incidents, guidance and reports, brokerage of expertise and good practices, training and training materials availability, reinforced CyberEurope exercises) - Improved capabilities of private actors thanks to the support to the establishment of Information Sharing and Analysis Centres (ISACs) in various sectors. - Improved EU and Member States' cybersecurity preparedness thanks to the availability of a well-rehearsed and agreed plans in case of large scale cross-border cybersecurity incident tested in CyberEurope exercises; Improved cooperation and coordination across Member States and EU institutions, agencies and bodies - Improved cooperation both within and between public and private sectors; - Improved consistency of approach to the NIS Directive implementation across borders and sectors 45 Transparency of cybersecurity assurance means providing users with sufficient information on cybersecurity properties which enables users to objectively determine the level of security of a given ICT product, service or process. EN 72 EN - Improved cooperation in the field of certification thanks to an institutional framework enabling the development of European cybersecurity certification schemes and the development of a common policy in the field. Increased EU level capabilities to complement the action of Member States - Improved 'EU operational capacity' to complement the action of Member States and support them, upon request and in relation to limited and pre-identified services; These is expected to have a positive impact on the success of incident prevention, detection and response both at Member State and Union level; Increased awareness of citizens and businesses on cybersecurity issues - Improved general awareness of citizens and business on cybersecurity issues - Improved ability to make informed purchase decisions related to ICT products and services thanks to cybersecurity certification Strengthened trust in the digital single market and in digital innovation through increased transparency of cybersecurity assurance of ICT products and services - Increased transparency of cybersecurity assurance46 of ICT products and services thanks to simplification of procedures for security certification through an EU-wide framework - Improved level of assurance of the security proprieties of ICT products and services - Increased uptake of security certification incentivised by simplified procedures, reduced costs, and perspective of EU-wide business opportunities not hampered by market fragmentation - Improved competitiveness within EU cybersecurity market due to reduced costs and administrative burden for SMEs and eliminating potential market-entry barriers caused by numerous national certification systems Other - No significant environmental impact is expected for any of the objectives. - With regard to the EU budget, efficiency gains can be expected by increased cooperation and coordination of the activities between EU institutions, agencies and bodies. 1.4.4 Indicators of results and impact Specify the indicators for monitoring implementation of the proposal/initiative. (a) Objective: Increasing capabilities and preparedness of Member States and businesses:  Number of trainings organised by ENISA  ***Geographical*** coverage (number of countries and areas) of the direct assistance provided by ENISA  Level of preparedness reached by Member States in terms of CSIRT maturity 46 Transparency of cybersecurity assurance means providing users with sufficient information on cybersecurity properties which enables users to objectively determine the level of security of a given ICT product, service or process. EN 73 EN and supervision of cybersecurity related regulatory measures  Number of EU-wide good practices for critical infrastructures provided by ENISA  Number of EU-wide good practices for SMEs provided by ENISA  Publication of annual ***strategic*** analysis of cyber threats and incidents to identify emerging trends by ENISA  Regular contribution of ENISA to the work of cybersecurity working groups of the European Standardisation Organisations (ESOs). Objective: Improving cooperation and coordination across Member States and EU, institutions, agencies and bodies:  Number of Member States having made use of ENISA recommendations and opinions in their policy making process  Number of EU institutions, agencies and bodies having made use of ENISA recommendations and opinions in their policy making process  Regular implementation of CSIRTs Network work programme and well-functioning on the CSIRTs Network IT infrastructure and communication channels  Number of technical reports made available to and used by the Cooperation Group  Consistent approach to the NIS Directive implementation across borders and sectors  Number of regulatory compliance assessments performed by ENISA  Number of ISACS in place in different sectors, in particular for critical infrastructures  Establishment and regular running of information platform disseminating cybersecurity information deriving from the EU institutions, agencies and bodies  Regular contribution to the preparation of EU research and innovation work programmes  Cooperation agreement between ENISA, EC3 and CERT-EU in place  Number of certification schemes included and developed under the Framework Objective: Increasing EU level capabilities to complement the action of Member States, in particular in the case of cross-border cyber crises:  Publication of annual ***strategic*** analysis of cyber threats and incidents to identify emerging trends by ENISA  Publication of aggregated information of incident reported under NIS Directive by ENISA  Number of pan-European exercises coordinated by the Agency and number of Member States and organisations involved.  Number of requests to support emergency response by Member States to ENISA and performed by the Agency  Number of analyses of vulnerabilities, artefacts and incidents performed by ENISA in cooperation with CERT-EU. EN 74 EN  Availability of EU-wide situational reports based on information made available to ENISA by Member States and other entities in case of large scale cross-border cyber incident. Objective: Increasing awareness of citizens and businesses on cybersecurity issues:  Regular running of EU-wide and national awareness raising campaigns and regular update of the topics according to the emerging learning needs.  Increase of cyber awareness among EU citizens  Regular running of cybersecurity awareness quiz and increase over the time of the percentage of correct responses.  Regular publication of cybersecurity and cyber hygiene good practices targeted to employees and organisations. Objective: Strengthening trust in the digital single market and in digital innovation through increasing the overall transparency of cybersecurity assurance47 of ICT products and services:  Number of schemes that adhere to the EU framework  Reduced cost of obtaining a certificate for ICT security.  Number of conformity assessment bodies specialized in ICT certification, across Member States  Set-up of the European Cybersecurity Certification Group and regular organisation of meetings  Guidelines for certification according to the EU framework in place  Regular publication of analyses of the main trends in the EU cybersecurity market  Number of certified ICT products and services according to the rules of the European ICT security certification framework  Increased number of end-users who are aware of security features of ICT products and services (b) 1.4.5 Requirement(s) to be met in the short or long term In view of the regulatory requirements and fast evolving cybersecurity threat landscape, ENISA's mandate needs to be reviewed to lay down a renewed set of tasks and functions, with a view to effectively and efficiently supporting Member States, EU institutions and other stakeholders' efforts to ensure a secure cyberspace in the European Union. The suggested scope of the mandate is delineated, strengthening those areas where the agency has shown clear added value and adding those new areas where support is needed in view of the new policy priorities and instruments, in particular the NIS Directive, the review of the EU Cybersecurity Strategy, the EU Cybersecurity Blueprint for cyber crisis cooperation and ICT security certification. The new proposed mandate seeks to give the Agency stronger and more central role, in particular by also supporting Member States 47 Transparency of cybersecurity assurance means providing users with sufficient information on cybersecurity properties which enables users to objectively determine the level of security of a given ICT product, service or process. EN 75 EN more actively to counter particular threats (operational capacity) and by becoming a centre of expertise supporting Member States and the Commission on cybersecurity certification. At the same time the proposals establishes a European Cybersecurity Certification Framework for ICT products and services and specifies the essential functions and tasks of ENISA in the field of cybersecurity certification. The Framework lays down common provisions and procedures enabling the creation of EU-wide cybersecurity certification schemes for specific ICT products/services or cybersecurity risks. The creation of European cybersecurity certification schemes in accordance with the Framework will allow certificates issued under those schemes to be valid and recognised across all Member States and to address the current market fragmentation. 1.4.6 Added value of Union involvement Cybersecurity is a truly global issue, which is cross-border by nature and is becoming increasingly cross-sector due to the interdependencies between networks and information systems. The number, complexity and scale of cybersecurity incidents and their impact on economy and society are growing over time and they are expected to further increase in parallel to technological developments, for example the proliferation of the internet of things. This implies that the need for increased common effort from Member States, EU institutions, private stakeholders to face cybersecurity threats cannot expected to decrease in the future. Since its establishment in 2004, ENISA has aimed to foster cooperation between Member States and the NIS stakeholders, including supporting public-private cooperation. This support to cooperation included the technical work to provide an EU-wide picture of the threat landscape, the set-up of expert groups and the organisation of pan-European cyber incident and crisis management exercises for public and private sectors exercises (in particular 'Cyber Europe'). The NIS Directive entrusted ENISA with additional tasks, including the role of the Secretariat of the CSIRTs Network for operational cooperation between Member States. The added value of acting at EU level, in particular to enhance cooperation between Member States but also between NIS communities has been recognised by the 2016 Council Conclusions48 and it also clearly emerges from the 2017 evaluation of ENISA, which shows that Agency's added value lies primarily in its ability to enhance cooperation among these stakeholders. There is no other actor at EU level that supports the cooperation of the same variety of stakeholders on NIS. ENISA's added value in bringing cybersecurity communities and stakeholders together is also valid in the field of certification. The rise of cybercrime and security threats has resulted in the emergence of national initiatives setting high-level cybersecurity and certification requirements for ICT components used in traditional infrastructure. Although important, these initiatives bear the risk of creating fragmentation of the single market and barriers for interoperability. An ICT vendor might need to undergo several certification processes to be able to sell in several Member States.The ineffectiveness/inefficiency of the current certification schemes is unlikely to be solved in the absence of EU intervention. In the absence of action, the market fragmentation is very likely to increase in the short-medium term (next 5-10 years) with the emergence of new certification schemes. The lack of coordination and interoperability across such schemes is an element 48 Council Conclusions on Strengthening Europe's Cyber Resilience System and Fostering a Competitive and Innovative Cybersecurity Industry - 15 November 2016. EN 76 EN which decreases the potential of the digital single market. This proves the added value of establishing a European Cybersecurity Certification Framework for ICT products and services putting the right conditions in place for effectively addressing the problem related to the co-existence of multiple certification procedures in various Member States, reducing certification costs and thus making certification in the EU overall more attractive from a commercial and competitive perspective. 1.4.7 Lessons learned from similar experiences in the past In accordance with the ENISA legal base, the Commission has carried out an evaluation of the Agency, which included an independent study as well as a public consultation. The evaluation came to a conclusion that ENISA's objectives remain relevant today. In a context of technological developments and evolving threats and of significant need for increased network and information security (NIS) in the EU, there is a need for technical expertise on the evolution of network and information security issues. Capacities need to be built in the Member States to understand and respond to threats, and stakeholders need to cooperate across thematic fields and across institutions. The agency has been successfully contributing to increased NIS in Europe by offering capacity building in 28 Member States, enhancing cooperation between Member States and NIS stakeholders; provision of expertise, community building and support to policy. While ENISA managed to make an impact, at least to some extent, in the vast field of NIS but it has not fully succeeded in developing a strong brand name and gaining sufficient visibility to become recognised as 'the' centre of expertise in Europe. The explanation for this lies with the broad mandate of ENISA, which was not met with proportionally big resources. Furthermore, ENISA remains the only EU agency with a fixed-term mandate which limits its ability to develop a long term vision and support its stakeholders in a sustainable manner. This is also in contrast with the provisions of the NIS Directive, which entrust ENISA with tasks with no end date. As far as cybersecurity certification for ICT products and services is concerned no European Framework exists at the moment. However, the rise of cybercrime and security threats has resulted in the emergence of national initiatives, which create the risk of fragmentation of the single market. 1.4.8 Compatibility and possible synergy with other appropriate instruments The initiative is highly coherent with the existing policies, in particular in the area of the internal market. Indeed, it is designed according to the overall approach to cybersecurity, as defined by the review of the Digital Single Market Strategy, in order to complement a comprehensive set of measures, such as the review of the EU Cybersecurity Strategy, the blueprint for cyber crisis cooperation and the initiatives to fight cybercrime. It would ensure alignment with and build on the provisions of the existing cybersecurity legislation, in particular the NIS Directive, in order to pursue further the cyber resilience of the EU through enhanced capabilities, cooperation, risk management and cyber awareness. The suggested certification measures should address the potential fragmentation caused by existing and emerging national certification schemes, therefore contributing to the development of the digital single market. The initiative also supports and complements the implementation of the NIS Directive by providing the undertakings subject to the Directive with a tool to demonstrate compliance with the NIS requirements in the whole Union. EN 77 EN The European ICT cybersecurity certification framework as proposed, is without prejudice with the General Data Protection Regulation(GDPR)49 and in particular with the relevant provisions on regarding certification50 as they apply to the security of the processing of personal data. Last but not least, as much as possible the schemes proposed in the future European framework should rely on international standards as a way to avoid creating trade barriers and ensure coherence with international initiatives. 49 Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) 50 Such as Articles 42 (Certification) and 43 (Certification Bodies) as well as Articles 57, 58, and 70 regarding respectively the relevant tasks and powers of the independent supervisory authorities and the tasks of the European Data Protection Board. EN 78 EN 1.5 Duration and financial impact  Proposal/initiative of limited duration –  Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY –  Financial impact from YYYY to YYYY  Proposal/initiative of unlimited duration – Implementation with a start-up period from 2019 to 2020, – followed by full-scale operation. 1.6 Management mode(s) planned51  Direct management by the Commission (Title III – Certification) –  executive agencies  Shared management with the Member States  Indirect management by entrusting budget implementation tasks to:  international organisations and their agencies (to be specified); the EIB and the European Investment Fund;  bodies referred to in Articles 208 and 209 (Title II – ENISA)  public law bodies;  bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;  bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;  persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act. Comments The Regulation Covers: - Title II of the proposed Regulation reviews the mandate of the European Union Agency for Network and Information Security (ENISA) giving it an important role in certification while - Title III establishes a framework for the creation of European cybersecurity certification schemes of ICT products and services, in which ENISA plays a crucial role. 51 Details of management modes and references to the Financial Regulation may be found on the BudgWeb site:   [*https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx*](https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx) EN 79 EN 2. MANAGEMENT MEASURES 2.1 Monitoring and reporting rules Specify frequency and conditions. Monitoring will start right after the adoption of the legal instrument and it will focus on its application. The Commission will organise meetings with ENISA, Member States representatives (e.g group of experts) and the relevant stakeholders in particular to facilitate the implementation of the rules concerning certification such as the establishment of the Board. The first evaluation should take place 5 years after the entry into force of the legal instrument, provided sufficient data is available. An explicit evaluation and review clause [Art XXX], by which the Commission will conduct an independent evaluation, is included in the legal instrument. The Commission will subsequently report to the European Parliament and the Council on its evaluation accompanied where appropriate by a proposal for its review, in order to measure the impact of the Regulation and its added value. Further evaluations should take place every five years. The Commission Better Regulation methodology on evaluation will be applied. These evaluations will be conducted with the help of targeted, expert discussions, studies and wide stakeholders consultations. ENISA's Executive Director should present to the Management Board an ex-post evaluation of ENISA's activities every two years. The Agency should also prepare a follow-up action plan regarding the conclusions of retrospective evaluations and report on progress every two yearsto the Commission. The Management Board should be responsible to vigilante on the adequate follow-up of such conclusions. Alleged instances of maladministration in the activities of the Agency may be subject to inquiries by the European Ombudsman in accordance with the provisions of Article 228 of the Treaty. The data sources for planned monitoring would mostly be ENISA, the European Cyber-Certification Group, the Cooperation Group, the CSIRTs Network and the Member States' authorities. Besides the data deriving by the reports (including the annual activity reports) of ENISA, the European Cyber-Certification Group, the Cooperation Group and the CSIRTs Network, specific data gathering tools will be used when needed (for example surveys to national authorities, Eurobarometer and reports from Cybersecurity Month campaign and the pan-European exercises). 2.2 Management and control system 2.2.1 Risk(s) identified The risks identified are limited: a Union agency exists already and its mandate will be delineated, strengthening those areas where the Agency has shown clear added value and adding those new areas where support is needed in view of the new policy priorities and instruments, in particular the NIS Directive, the review of the EU Cybersecurity Strategy, the upcoming EU Cybersecurity Blueprint for cyber crisis cooperation and ICT security certification. EN 80 EN The proposal therefore details Agency's functions and leads to efficiency gains. The increase of operational competences and tasks does not represent a real risk as they would be complementing the action of Member States and supporting them, upon request and in relation to limited and pre-identified services. Furthermore the proposed model of the agency, as per the Common Approach, ensures that there is a sufficient control in place to make sure that ENISA works towards its objectives. The operational and financial risks of the proposed changes seem to be limited. At the same time, it is necessary to ensure adequate financial resources in order for ENISA to fulfil the tasks entrusted by the new mandate, including in the field of certification. 2.2.2 Control method(s) envisaged The agency's accounts will be submitted for approval of the Court of Auditors and subject to the discharge procedure and audits are envisaged. Also the operations of the agency are subject to the supervision of the Ombudsman in accordance with the provisions of Article 228 of the Treaty. See also point 2.1 and point 2.2.1 above 2.3 Measures to prevent fraud and irregularities Specify existing or envisaged prevention and protection measures. The ENISA’s prevention and protection measures would apply, specifically: - Payments for any service or studies requested are checked by the agency’s staff prior to payment, taking into account any contractual obligations, economic principles and good financial or management practice. Anti-fraud provisions (supervision, reporting requirements, etc.) will be included in all agreements and contracts concluded between the agency and recipients of any payments. - In order to combat fraud, corruption and other unlawful activities the provisions of Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-fraud Office (OLAF) shall apply without restriction. - The agency shall accede, within six months form the day of entry into force of this regulation, to the Inter-institutional Agreement of 25 May 1999 between the European Parliament and the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-fraud Office (OLAF) and shall issue, without delay, the appropriate provisions applicable to all the employees of the agency. EN 81 EN 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE 3.1 Heading(s) of the multiannual financial framework and expenditure budget line(s) affected  Existing budget lines In order of multiannual financial framework headings and budget lines. Heading of multiannual financial framework Budget line Type of expenditure Contribution Diff./Non-diff.52 from EFTA countries53 from candidate countries54 from third countries within the meaning of Article 21(2)(b) of the Financial Regulation 1a Competitiveness for growth and employment 09.0203 ENISA and Information and communication Technology security certification Diff YES NO NO NO 5 Administrative expenditure] 09.0101 Expenditure related to staff in active employment of Communications networks, content and technology 09.0102 Expenditure related to external staff in active employment of Communications networks, content and Non-diff. NO NO NO NO 52 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations. 53 EFTA: European Free Trade Association. 54 Candidate countries and, where applicable, potential candidates from the Western Balkans. EN 82 EN technology 09.010211 Other management expenditure 3.2 Estimated impact on expenditure 3.2.1 Summary of estimated impact on expenditure EUR million (to three decimal places) Heading of multiannual financial framework 1a Competitiveness for growth and employment ENISA Baseline 2017 (31/12/2016) 2019 (from 01.07.2019) 2020 2021 2022 TOTAL Title 1: Staff Expenditure (including also expenditure related to staff recruitment, training, socio-medical infrastructure and external services) Commitments (1) 6.387 9.899 12.082 13.349 13.894 49.224 Payments (2) 6.387 9.899 12.082 13.349 13.894 49.224 Title 2: Infrastructure & operating expenditure Commitments (1a) 1.770 1.957 2.232 2.461 2.565 9.215 Payments (2a) 1.770 1.957 2.232 2.461 2.565 9.215 Title 3: Operational Expenditure Commitments (3a) 3.086 4.694 6.332 6.438 6.564 24.028 Payments (3b) 3.086 4.694 6.332 6.438 6.564 24.028 TOTAL appropriations for ENISA Commitments =1+1a +3a 11.244 16.550 20.646 22.248 23.023 82.467 Payments =2+2a +3b 11.244 16.550 20.646 22.248 23.023 82.467 EN 83 EN Heading of multiannual financial framework 5 ‘Administrative expenditure’ EUR million (to three decimal places) 2019 (from 01.07.2019) 2020 2021 2022 TOTAL DG: CNECT  Human Resources 0.216 0.846 0.846 0.846 2.754  Other administrative expenditure 0.102 0.235 0.238 0.242 0.817 TOTAL DG CNECT Appropriations 0.318 1.081 1.084 1.088 3.571 The staff costs were calculated according to the planned recruitment date (employment is envisaged starting from 01.07.2019). The resources outlook beyond 2020 is indicative and without prejudice to the Commission proposals for the post-2020 multiannual financial framework TOTAL appropriations under HEADING 5 of the multiannual financial framework (Total commitments = Total payments) 0.318 1.081 1.084 1.088 3.571 EUR million (to three decimal places) 2019 2020 2021 2022 TOTAL TOTAL appropriations Commitments 16.868 21.727 23.332 24.11 86.038 EN 84 EN under HEADINGS 1 to 5 of the multiannual financial framework Payments 16.868 21.727 23.332 24.11 86.038 EN 85 EN 3.2.2 Estimated impact on Agency's appropriations –  The proposal/initiative does not require the use of operational appropriations –  The proposal/initiative requires the use of operational appropriations, as explained below: Commitment appropriations in EUR million (to three decimal places) Indicate objectives and outputs55  2019 2020 2021 2022 TOTAL Increasing capabilities and preparedness of Member States and businesses 1.408 1.900 1.931 1.969 7.208 Improving cooperation and coordination across Member States and EU institutions, agencies and bodies. 0.939 1.266 1.288 1.313 4.806 Increasing EU level capabilities to complement the action of Member States, in particular in the case of cross-border cyber crises. 0.704 0.950 0.965 0.985 3.604 Increasing awareness of citizens and businesses on cybersecurity issues. 0.704 0.950 0.965 0.985 3.604 Strengthening trust in the digital single market and in digital innovation through increasing the overall transparency of cybersecurity assurance of ICT products and services. 0.939 1.266 1.288 1.313 4.806 TOTAL COST 4,694 6.332 6.437 6.565 24.028 55 This table outlines only operational expenditure as per Title 3. EN 86 EN 3.2.3 Estimated impact on Agency's human resources 3.2.3.1 Summary –  The proposal/initiative does not require the use of appropriations of an administrative nature –  The proposal/initiative requires the use of appropriations of an administrative nature, as explained below: EUR million (to three decimal places) Q3/4 2019 2020 2021 2022 Temporary Officials (AD Grades) 4.242 5.695 6.381 6.709 Temporary Officials (AST grades) 1.601 1.998 2.217 2.217 Contract Agents 2.041 2.041 2.041 2.041 Seconded National Experts 0.306 0.447 0.656 0.796 TOTAL 8.190 10.181 11.295 11.763 The staff costs were calculated according to the planned recruitment date (for current ENISA staff full employment was assumed as from 01.01.2019). For the new staff progressive employment was envisaged starting from 01.07.2019 and achieving full employment in 2022. The resources outlook beyond 2020 is indicative and without prejudice to the Commission proposals for the post-2020 multiannual financial framework. Estimated impact on the staff (additional FTE) – establishment plan Function group and grade 2017 Current ENISA Q3/Q4.2019 2020 2021 2022 AD16 AD15 1 AD14 AD13 AD12 3 3 AD11 AD10 5 AD9 10 2 AD8 15 4 2 1 AD7 3 3 2 AD6 3 3 AD5 AD Total 34 9 8 6 3 EN 87 EN AST11 AST10 AST9 AST8 AST7 2 1 1 1 AST6 5 2 1 AST5 5 AST4 2 AST3 AST2 AST1 AST Total 14 3 2 1 AST/SC 6 AST/SC 5 AST/SC 4 AST/SC 3 AST/SC 2 AST/SC 1 AST/SC Total GRAND TOTAL 48 12 10 7 3 The tasks for additional AD/AST staff to achieve the objectives of the instrument as described in section 1.4.2: Tasks AD AST SNE Total Policy and capacity building 8 1 9 Operational cooperation 8 1 7 16 Certification (market related tasks) 9 3 2 14 Knowledge, information and awareness 1 1 2 TOTAL 26 6 9 41 Description of tasks to be carried out: Tasks Additional resources required EU policy development and implementation & Capacity building Tasks would include assisting the Cooperation Group, supporting consistent NIS implementation across borders, regular reporting on the state of implementation of the EU legal framework; advising and coordinating sectorial cybersecurity initiatives including in energy, transport (e.g aviation/ road/ maritime/ connected vehicles), health, finance, providing support to the establishment of Information Sharing and Analysis Centres (ISACs) in various sectors. EN 88 EN Operational cooperation and crisis management The tasks would include: Providing Secretariat to the CSIRT Network by ensuring, among others, the well-functioning of the CSIRTs Network IT infrastructure and communication channels. Ensure structured cooperation with CERT-EU, EC3 and other relevant EU bodies. Organising Cyber Europe Exercises56 -tasks related to scaling up the exercise from a biennial to annual event and making sure the exercises look at incident from beginning to end. Technical assistance - tasks would include structured cooperation with CERT-EU to provide technical assistance in case of significant incidents and to support incident analysis. This would include providing to Member States assistance to handle incidents and analyse of vulnerabilities, artefacts and incidents. Facilitate cooperation between individual Member States in dealing with emergency response by analysing and aggregating national situational reports based on information made available to the Agency by Member States and other entities. Blueprint for coordinated response to large-scale cross-border cyber incidents - the Agency will contribute to develop a cooperative response, at Union and Member States level, to large-scale cross-border incidents or crises related to the cybersecurity through a series of tasks from contributing to establish a situational awareness at Union level to testing the cooperation plans for incidents. Ex post technical enquiries on incidents - conduct or contribute to ex-post technical enquiries on incidents in cooperation with the CSIRTs Network with a view issuing recommendations and reinforcing capabilities in form of public reports to better prevent future incidents. Market related tasks The tasks would include actively supporting the 56 Cyber Europe is the largest and most comprehensive EU cyber-security exercise to date involving more than 700 cyber-security professionals from all 28 Member States. It is held every second year. The evaluation of ENISA and the 2013 EU Cybersecurity Strategy point to the fact that many stakeholders advocate scaling up Cyber Europe to an annual event given the fast evolving nature of cyber threats. This is, however, not feasible at the moment in view of the limited resources of the Agency. EN 89 EN (standardisation, certification) work undertaken within the Certification Framework, including providing technical expertise to prepare candidate European cybersecurity certification schemes. The tasks will also include support to Union policy development and implementation on standardisation, certification and Market Observatory- this will require facilitating the take-up of risk-management standards of electronic products, networks and services and advise operators of essential services and digital service providers on technical security requirements. The tasks will also include providing analysis of the main trends in the cybersecurity market. Knowledge and information, awareness raising: With a view of ensuring easier access to better structured information on cybersecurity risks and potential remedies, the proposal confers to the Agency a new task of developing and maintaining the 'information hub' of the Union. The tasks would include pooling, organising and making available to the public, through a dedicated portal, information on security of network and information systems, in particular cybersecurity, provided by the EU institutions, agencies and bodies. The tasks would also include supporting ENISA's activities in the field of awareness raising to allow the Agency to scale up the effort. EN 90 EN 3.2.3.2 Estimated requirements of human resources for the parent DG –  The proposal/initiative does not require the use of human resources. –  The proposal/initiative requires the use of human resources, as explained below: Estimate to be expressed in full amounts (or at most to one decimal place) Additional Staff Baseline 2017 Q3/4 2019 2020 2021 2020  Establishment plan posts (officials and temporary staff) 09 01 01 01 (Headquarters and Commission’s Representation Offices) 1 2 3  External staff (in Full Time Equivalent unit: FTE)57 09 01 02 01 (AC, END, INT from the ‘global envelope’) 1 2 TOTAL 4 3 Description of tasks to be carried out: Officials and temporary staff Represent the Commission in the Management Board of the agency. Draw up Commission opinion on the ENISA single programming document and monitor its implementation. Supervise the preparation of the agency’s budget and monitor its implementation. Assist the agency in developping its actitvities in line with the Union policies including by participating in relevant meetings. Supervise the implementation of the framework for European cybersecurity certification schemes of ICT products and services. Maintain contacts with Member States and other relevant stakeholders in relation to certification efforts. Cooperate with ENISA regarding candidate schemes. Preapre candidate European cybersecurity schemes. External staff As above 57 AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT = agency staff; JED = Junior Experts in Delegations. EN 91 EN 3.2.4 Compatibility with the current multiannual financial framework –  The proposal/initiative is compatible the current multiannual financial framework. –  The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework. The proposal will entail reprogramming of article 09 02 03 due to the revision of the ENISA's mandate, which confers the agency with new tasks related, among others, to the NIS Directive implementation and the European Cybersecurity Certification Framework. The corresponding amounts: Year Envisaged Request 2019 10.739 16.550 2020 10.954 20.646 2021 N/A 22.248\* 2022 N/A 23.023\* \* This is an estimate. EU funding after 2020 will be examined in the context of a Commission-wide debate on all proposals for the post-2020 period. This means that once the Commission has made its proposal for the next multi-annual financial framework, the Commission will present an amended legislative financial statement taking into account the conclusions of the impact assessment58. –  The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework59. 3.2.5 Third-party contributions –  The proposal/initiative does not provide for co-financing by third parties. –  The proposal/initiative provides for the co-financing estimated below: Year 2019 Year 2020 Year 2021 Year 2022 EFTA p.m.60 p.m p.m p.m 58 Link to the page with impact assessment 59 See Articles 11 and 17 of Council Regulation (EU, Euratom) No 1311/2013 laying down the multiannual financial framework for the years 2014-2020. 60 The exact amount for the subsequent years will be known when the EFTA’s proportionality factor will be fixed for the year concerned. EN 92 EN 3.3 Estimated impact on revenue –  The proposal/initiative has no financial impact on revenue. –  The proposal/initiative has the following financial impact: –  on own resources –  on miscellaneous

**Load-Date:** November 8, 2017

**End of Document**



[***FEDERAL REGISTER: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Pages 56336 - 56527 [FR DOC # 2017-25068]***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5R2J-NC51-F0YC-N49J-00000-00&context=1516831)

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**Body**

Washington: Office of the Federal Register has issued the following notice:

Department of Health and Human Services ----------------------------------------------------------------------- Centers for Medicare & Medicaid Services ----------------------------------------------------------------------- 42 CFR Parts 405, 417, 422, et al. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program; Proposed Rule Federal Register / Vol. 82 , No. 227 / Tuesday, November 28, 2017 / Proposed Rules [[Page 56336]] ----------------------------------------------------------------------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services 42 CFR Parts 405, 417, 422, 423, and 498 [CMS-4182-P] RIN 0938-AT08 Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for- Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule. ----------------------------------------------------------------------- SUMMARY: This proposed rule would revise the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act; improve program quality, accessibility, and affordability; improve the CMS customer experience; address program integrity policies related to payments based on prescriber, provider and supplier status in Medicare Advantage, Medicare cost plan, Medicare Part D and the PACE programs; provide a proposed update to the official Medicare Part D electronic prescribing standards; and clarify program requirements and certain technical changes regarding treatment of Medicare Part A and Part B appeal rights related to premiums adjustments. DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m on January 16, 2018. ADDRESSES: In commenting, please refer to file code CMS-4182-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed): 1. Electronically. You may submit electronic comments on this regulation to [*http://www.regulations.gov*](http://www.regulations.gov) Follow the ``Submit a comment'' instructions. 2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4182-P, P.O Box 8013, Baltimore, MD 21244-8013. Please allow sufficient time for mailed comments to be received before the close of the comment period. 3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4182-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850. 4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC--Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp- in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.) b. For delivery in Baltimore, MD--Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850. If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period. For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section. FOR FURTHER INFORMATION CONTACT: Theresa Wachter, (410) 786-1157, Part C Issues. Marie Manteuffel, (410) 786-3447, Part D Issues. Kristy Nishimoto, (206) 615-2367, Beneficiary Enrollment and Appeals Issues. Raghav Aggarwal, (410) 786-0097, Part C and D Payment Issues. Vernisha Robinson-Savoy, (267) 970-2395, Part C and D Compliance Issues. Frank Whelan, (410) 786-1302, Preclusion List Issues. Shelly Winston, (410) 786-3694, Part D E-Prescribing Program. SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received:   [*http://www.regulations.gov*](http://www.regulations.gov) Follow the search instructions on that Web site to view public comments. Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m to 4 p.m To schedule an appointment to view public comments, phone 1-800-743-3951. Table of Contents I. Executive Summary A. Purpose B. Summary of the Major Provisions 1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions 2. Updating the Part D E-Prescribing Standards (Sec. 423.160) 3. Revisions to Timing and Method of Disclosure Requirements 4. Preclusion List a. Part D b. Part C C. Summary of Costs and Benefits II. Provisions of the Proposed Regulations A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability 1. 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Conclusion Acronyms ACA Affordable Care Act ACS American Community Survey AEP Annual Election Period ANDA Abbreviated New Drug Application ANOC Annual Notice of Change AMA American Medical Association AO Accrediting Organization ASPE Office of the Assistant Secretary for Planning and Evaluation AWP Any Willing Pharmacy CAI Categorical Adjustment Index CARA Comprehensive Addiction and Recovery Act CCIP Chronic Care Improvement Program CMS Centers for Medicare & Medicaid Services CPT Current Procedural Terminology DAB Departmental Appeals Board DE Dual Eligible DIR Direct or Indirect Remuneration DME Durable Medical Equipment DSMO Designated Standards Maintenance Organization D-SNP Dual-Eligible Special Needs Plan EDM Enhanced Disease Management EHR Electronic Health Record EOC Evidence of Coverage EP Eligible Professionals FFS Fee-for-Service ePA Electronic Prior Authorization eRx Electronic Prescription (e-prescribing) FDA Food and Drug Administration FIDE Fully Integrated Dual Eligible FMV Fair Market Value FPL Federal Poverty Level HPMS Health Plan Management System ICD-10 ICD-10-CM IRE Independent Review Entity LIS Low Income Subsidy LPPO Local Preferred Provider Organization LTC Long Term Care MA Medicare Advantage MADP Medicare Advantage Disenrollment Period MA-PD Medicare Advantage Prescription Drug MAO Medicare Advantage Organizations MIPPA Medicare Improvements for Patients and Providers Act MLR Medical Loss Ratio MOOP Maximum Out-of-Pocket NCPDP National Council of Prescription Drug Programs NCQA National Committee for Quality Assurance NDC National Drug Code NSO National Standard Organization OIG Office of Inspector General OEP Open Enrollment Period OMHA Office of Medicare Hearings and Appeals OOPC Out-of-Pocket Cost PA Prior Authorization PBM Pharmacy Benefit Manager PBP Plan Benefit Package PDP Prescription Drug Plan PHSA Public Health Service Act [[Page 56339]] PIP Physician Incentive Plan PQA Pharmacy Quality Alliance PSO Provider Sponsored Organization PSP Provider Specific Plan QBP Quality Bonus Payment QI Quality Improvement QIA Quality Improvement Activities QIP Quality Improvement Project REMS Risk Evaluation and Mitigation Strategies RFI Request for Information RHC Rural Health Center RI Rewards and Incentives RPPO Regional Preferred Provider Organization RRB Railroad Retirement Board SE Standard Error SEP Special Enrollment/Election Period SES Socio-Economic Status SNP Special Needs Plan SSA Social Security Administration TMP Timeliness Monitoring Project I. Executive Summary A. Purpose The primary purpose of this proposed rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act. The proposed changes are necessary to--(1) Support Innovative Approaches to Improving Quality, Accessibility, and Affordability; (2) Improve the CMS Customer Experience; and (3) Implement Other Changes. In addition, this rule proposes technical changes related to treatment of Part A and Part B premium adjustments and updates the Script standard used for Part D electronic prescribing. While the Part D program has high satisfaction among users, we continually evaluate program policies and regulations to remain responsive to current trends and newer technologies. Specifically, this regulation meets the Administration's priorities to reduce burden and provide the regulatory framework to develop MA and Part D products that better meet the individual beneficiary's healthcare needs. Additionally, this regulation includes a number of provisions that will help address the opioid epidemic and mitigate the impact of increasing drug prices in the Part D program. B. Summary of the Major Provisions 1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions This proposed regulatory provision would implement statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, which amended the Social Security Act and includes new authority for Medicare Part D drug management programs, effective on or after January 1, 2019. Through this provision, CMS proposes a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or ``at-risk beneficiaries.'' CMS proposes that, under such programs, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are ``frequently abused drugs'' to a selected prescriber(s) and/or network pharmacy(ies). CMS also proposes to limit the use of the special enrollment period (SEP) for dually- or other low income subsidy (LIS)-eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such a drug management program. Finally, this provision proposes to codify the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) by integrating this current policy with our proposals for implementing the drug management program provisions. The current policy involves Part D prescription drug benefit plans engaging in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Through the adoption of this policy, from 2011 through 2016, there was a 61 percent decrease (over 17,800 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers.\1\ Thus, this proposal expands upon an existing, innovative, successful approach to reduce opioid overutilization in the Part D program by improving quality of care through coordination while maintaining access to necessary pain medications. --------------------------------------------------------------------------- \1\ CY 2018 Final Parts C&D Call Letter, April 3, 2017. --------------------------------------------------------------------------- 2. Updating the Part D E-Prescribing Standards (Sec. 423.160) This provision proposes an update to the electronic standards to be used by Medicare Part D prescription drug plans. This includes the proposed adoption of the NDPDP SCRIPT Standard Version 2017071, and retirement of the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals. These changes would become effective January 1, 2019. The NCPDP SCRIPT standards are used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans. Although e-prescribing is optional for physicians and pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit e- prescriptions and related communications electronically must utilize the adopted standards. The proposed updated NCPDP SCRIPT standards have been requested by the industry and could provide a number of efficiencies which the industry and CMS supports. In order to facilitate this change, we propose to update Sec. 423.160, and also make a number of conforming technical changes to other sections of part 423. In addition, we are proposing to correct a typographical error that occurred in the regulatory text listing the applicability dates of the standards by changing the reference in Sec. 423.160(b)(1)(iv) to reference (b)(2)(iii) instead of (b)(2)(ii) to correctly cite to the present use of the currently adopted NCPDP SCRIPT Standard Version 10. 3. Revisions to Timing and Method of Disclosure Requirements We are proposing to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC). Additionally, we are proposing to change the timeframe for delivery of the EOC in particular to the first day of the Annual Election Period (AEP) rather than fifteen days prior to that date. Allowing plans to provide the EOC electronically would alleviate plan burden related to printing and mailing, and simultaneously would reduce the number of paper documents that beneficiaries receive from plans. This would allow beneficiaries to focus on materials, like the Annual Notice of Change (ANOC), that drive decision making. Changing the date by which plans must provide the EOC to members would allow plans more time to finalize the formatting and ensure the accuracy of the information, as well as further distance it from the ANOC, which must still be delivered 15 days prior to the AEP. We see this proposed change as an overall reduction of impact that our regulations have on plans and beneficiaries. In aggregate, we estimate a savings (to plans for not producing [[Page 56340]] and mailing hard-copy EOCs) of approximately $51 million. 4. Preclusion List a. Part D This proposed rule would rescind the current provisions in Sec. 423.120(c)(6) that require physicians and eligible professionals (as defined in section 1848(k)(3)(B) of the Act) to enroll in or validly opt-out of Medicare in order for a Part D drug prescribed by the physician or eligible professional to be covered. As a replacement, we propose that a Part D plan sponsor must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the ``preclusion list,'' which would be defined in Sec. 423.100 and would consist of certain prescribers who are currently revoked from the Medicare program under Sec. 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. We recognize, however, the need to minimize interruptions to Part D beneficiaries' access to needed medications. Therefore, we also propose to prohibit plan sponsors from rejecting claims or denying beneficiary requests for reimbursement for a drug on the basis of the prescriber's inclusion on the preclusion list, unless the sponsor has first covered a 90-day provisional supply of the drug and provide individualized written notice to the beneficiary that the drug is being covered on a provisional basis. b. Part C This proposed rule would rescind the current provisions in Sec. 422.222 stating that providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act must be enrolled in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. As a replacement, we propose that an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the ``preclusion list.'' The preclusion list, which would be defined in Sec. 422.2, would consist of certain individuals and entities that are currently revoked from the Medicare program under Sec. 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. C. Summary of Costs and Benefits ------------------------------------------------------------------------ Provision Savings ------------------------------------------------------------------------ Implementation of the Besides the benefits of preventing opioid Comprehensive Addiction and dependency in beneficiaries we estimate Recovery Act of 2016. a net savings in 2019 of $13 million to the Trust Fund because of reduced scripts, modestly increasing to a savings of $14 million in 2023. The cost to industry is estimated at about $2.8 million per year. Revisions to Timing and We estimate 67% of the current 47.8 Method of Disclosure million beneficiaries will prefer use of Requirements. the internet vs. hard copies. This wi

ll result in savings of $55 million in 2019 and growing due to inflation to $67 million in 2023. ------------------------------------------------------------------------ II. Provisions of the Proposed Regulations A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability 1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions a. Medicare Part D Drug Management Programs The Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, amended the Social Security Act and includes new authority for the establishment of drug management programs in Medicare Part D, effective on or after January 1, 2019. In accordance with section 704(g)(3) of CARA and revised section 1860D- 4(c) of the Act, CMS must establish through notice and comment rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at-risk for prescription drug abuse, or ``at-risk beneficiaries.'' Under such a Part D drug management program, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are ``frequently abused drugs'' to a selected prescriber(s) and/or network pharmacy(ies). While such programs, commonly referred to as ``lock-in programs,'' have been a feature of many state Medicaid programs for some time, prior to the enactment of CARA, there was no statutory authority to allow Part D plan sponsors to require beneficiaries to obtain controlled substances from a certain pharmacy or prescriber in the Medicare Part D program. In summary, this proposed rule would implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) (``current policy''). As explained in more detail later in this section, this integration would mean that Part D sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of opioids beginning 2019 through a point-of-sale (POS) claim edit and/or by requiring the beneficiary to obtain opioids from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary would have to meet clinical guidelines that factor in that the beneficiary is taking a high-risk dose of opioids over a sustained time period and that the beneficiary is obtaining them from multiple prescribers and multiple pharmacies. This proposed rule would also implement a limitation on the use of the special enrollment period (SEP) for low income subsidy (LIS)-eligible beneficiaries who are identified as potential at-risk beneficiaries. b. Stakeholder Input Informing This Notice of Proposed Rulemaking Section 704(g)(2) of CARA required us to convene stakeholders to provide input on specific topics so that we could take such input into account in promulgating regulations governing Part D drug management programs. Stakeholders include Medicare beneficiaries with Part A or Part B, advocacy groups representing Medicare beneficiaries, physicians, pharmacists, and other clinicians (particularly other lawful prescribers of controlled [[Page 56341]] substances), retail pharmacies, Part D plan sponsors and their delegated entities (such as pharmacy benefit managers), and biopharmaceutical manufacturers. We hosted a Listening Session on the CARA drug management program provisions via a public conference call on November 14, 2016 that was announced in the October 26, 2016 Federal Register (81 FR 74388). We sought stakeholder input on specific topics enumerated in sections 704(a)(1) and 704(g)(2)(B) of the CARA and other related topics of concern to the stakeholders. In developing this proposed rule, we considered the stakeholders' comments provided during the Listening Session, as well as written comments submitted afterward, including those submitted in response to the Request for Information associated with the publication of the Plan Year 2018 Medicare Parts C&D Final Call Letter. We refer to this input in this preamble using the terms ``stakeholders,'' ``commenters'' and ``comments.'' c. Integration of CARA and the Current Part D Opioid DUR Policy and OMS As noted in section II.A.1 of this proposed rule previously, we are proposing to implement the CARA Part D drug management program provisions by integrating them with our current policy that is not currently codified, but would be under this proposal. In using the term ``current policy'', we refer to the aspect of our current Part D opioid overutilization policy that is based on retrospective DUR.\2\ Specifically, we are proposing a regulatory framework for Part D plan sponsors to voluntarily adopt drug management programs through which they address potential overutilization of frequently abused drugs identified retrospectively through the application of clinical guidelines/criteria that identify potential at-risk beneficiaries and conduct case management which incorporates clinical contact and prescriber verification that a beneficiary is an at-risk beneficiary. If deemed necessary, a sponsor could limit at-risk beneficiaries' access to coverage for such drugs through pharmacy lock-in, prescriber lock-in, and/or a beneficiary-specific point-of-sale (POS) claim edit. Finally, sponsors would report to CMS the status and results of their case management to OMS and any beneficiary coverage limitations they have implemented to MARx, CMS' system for payment and enrollment transactions. While plan sponsors would have the option to implement a drug management program, our proposal codifies a framework that would place requirements upon such programs. We foresee that all plan sponsors will implement such drug management programs based on our experience that all plan sponsors' are complying with the current policy as laid out in guidance, the fact that our proposal largely incorporates the CARA drug management provisions into existing CMS and sponsor operations, and especially, in light of the national opioid epidemic and the declaration that the opioid crisis is a nationwide Public Health Emergency. --------------------------------------------------------------------------- \2\ Please refer to the CMS Web site, ``Improving Drug Utilization Review Controls in Part D'' at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) which contains CMS communications regarding the current policy. --------------------------------------------------------------------------- Because we propose to integrate the CARA Part D drug management program provisions with the current policy and codify them both, we describe the current policy in section II.A.1.c (1) of this proposed rule, noting where our proposal incorporates changes to the current policy in order to comply with CARA and achieve operational consistency. Where we do not note a change, our intent is to codify the current policy, and we seek specific comment as to whether we have overlooked any feature of the current policy that should be codified. CMS communications regarding the current policy can be found at the CMS Web site, ``Improving Drug Utilization Review Controls in Part D'' at   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) Then we set forth our proposal for codification of the regulatory framework for drug management programs in section II.A.1.c (2) of this proposed rule, which includes provisions specific to lock-in, which is not a feature of the current policy. (1) Current Part D Opioid DUR Policy and OMS CMS is actively engaged in addressing the opioid epidemic and committed to implementing effective tools in Medicare Part D. We will work across all stakeholder, beneficiary and advocacy groups, health plans, and other federal partners to help address this devastating epidemic. CMS has worked with plan sponsors and other stakeholders to implement Medicare Part D opioid overutilization policies with multiple initiatives to address opioid overutilization in Medicare Part D through a medication safety approach. These initiatives include better formulary and utilization management; real-time safety alerts at the pharmacy aimed at coordinated care; retrospective identification of high risk opioid overutilizers who may need case management; and regular actionable patient safety reports based on quality metrics to sponsors. The goal of the current policy and OMS is to reduce opioid overutilization in Part D. In conjunction with related Part D opioid overutilization policies that address prospective opioid use, the current policy has played a key role in reducing high risk opioid overutilization in the Part D program by 61 percent (representing over 17,800 beneficiaries) from 2011 (pre-policy pilot) through 2016, even as the number of beneficiaries enrolled in Part D increased overall during this period from 31.5 million to 43.6 million enrollees, or a 38 percent increase.\3\ --------------------------------------------------------------------------- \3\ Final CY 2018 Parts C&D Call Letter, April 3, 2017. --------------------------------------------------------------------------- The purpose of the current policy is to provide Part D plan sponsors with specific guidance about compliance with Sec. 423.153(b)(2) as to opioid overutilization, which requires a Part D plan sponsor to have a reasonable and appropriate drug utilization management program that maintains policies and systems to assist in preventing overutilization of prescribed medications. We adopted the current policy on January 1, 2013, and it has evolved over time in scope in several ways with stakeholder feedback and support, including through the addition of the OMS in July 2013, primarily via the annual Parts C&D Call Letter process. The current policy has two aspects. First, in the CY 2013 final Call Letter and subsequent supplemental guidance, we provided guidance about our expectations for Part D plan sponsors to retrospectively identify beneficiaries who are at high risk for potential opioid overutilization and provide appropriate case management aimed at coordinated care.\4\ More specifically, we currently expect Part D plan sponsors' Pharmacy and Therapeutics (P&T) committees to establish criteria consistent with CMS guidance to retrospectively identify potential opioid overutilizers at high risk for an adverse event enrolled in their plans who may warrant case management because they are receiving opioid prescriptions from multiple prescribers and pharmacies. Enrollees [[Page 56342]] with cancer or in hospice are excluded from the current policy, because the benefit of their high opioid use may outweigh the risk associated with such use. This exclusion was supported by stakeholder feedback on the current policy. --------------------------------------------------------------------------- \4\ An excerpt from the Final 2013 Call Letter, the supplemental guidance, and additional information about the policy and OMS are available on the CMS Web page, ``Improving Drug Utilization Controls in Part D'' at   [*https://www.cms.gov/Medicare/Prescription-Drug/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug/PrescriptionDrugCovContra/RxUtilization.html) --------------------------------------------------------------------------- Once such enrollees are identified through retrospective prescription drug claims review, we expect the Part D plan sponsors to diligently assess each case, and if warranted, have their clinical staff conduct case management with the beneficiary's opioid prescribers until the case is resolved. According to the supplemental guidance,\5\ case management entails: --------------------------------------------------------------------------- \5\ September 6, 2012 HPMS memo, ``Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D.'' ---------------------------------------------------------------------------  The personnel communicating with prescribers have appropriate credentials.      Written inquiries to the prescribers of the opioid medications about the appropriateness, medical necessity and safety of the apparent high dosage for their patient.      Attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period from the issuance of the written inquiry notification, if necessary.      The clinician-to-clinician communication includes information about the existence of multiple prescribers and the beneficiary's total opioid utilization, and the plan's clinician elicits the information necessary to identify any complicating factors in the beneficiary's treatment that are relevant to the case management effort.      After discussion or communication about the appropriate level of opioid use, the consensus reached by the prescribers is implemented by the sponsor, with a beneficiary-specific opioid POS claim edit, as deemed appropriate by the prescribers, to prevent further Part D coverage of an unsafe level of drug.      In cases of non-responsive prescribers, the sponsor may also implement a beneficiary-specific opioid POS claim edit to prevent further coverage of an unsafe level of drug and to encourage the prescribers to participate in case management.     Thus, we expect case management to confirm that the beneficiary's opioid use is medically necessary or resolve an overutilization issue.     As part of the current policy, and because the Food and Drug Administration (FDA)-approved labeling for opioids generally does not include maximum daily doses, CMS developed specific criteria to identify beneficiaries at high risk through retrospective review of their opioid use in order to assist Part D sponsors in identifying such beneficiaries. These criteria incorporate a morphine milligram equivalent (MME) \6\ approach, which is a method to uniformly calculate the total daily dosage of opioids across all of a patient's opioid prescription drug claims. Beginning with plan year 2018, we adjusted these criteria to align with the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline) \7\ issued in March 2016 in terms of using 90 MME as a threshold to identify beneficiaries who appear to be at high risk due to their opioid use. In its guideline, after considering information from relevant studies and experts, the CDC identifies 50 MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME. Our criteria, which we will discuss more fully later in the preamble, also incorporate a multiple prescriber and pharmacy count to focus on beneficiaries who appear to be not only overutilizing opioids but who also are at increased risk due to potential coordination of care issues, such that the providers who are prescribing or dispensing opioids to these beneficiaries may not know that other providers are also doing so. ---------------------------------------------------------------------------

    \6\ Please note that CMS will use the term ``MME'' going forward instead of morphine equivalent dose (MED), which CMS has used to date. CMS used the term MED in a manner that was equivalent to MME. We will update CMS documents that currently refer to MED as soon as practicable.     \7\ Please see [*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*](https://www.cdc.gov/drugoverdose/prescribing/guideline.html) ---------------------------------------------------------------------------

    The second aspect of the current policy came into place in July 2013, when CMS launched the OMS as a tool to monitor Part D plan sponsors' effectiveness in complying with Sec.  423.153(b)(2) to address opioid overutilization. Through the OMS, CMS sends sponsors quarterly reports about their Part D enrollees who meet the criteria for being at high risk of opioid overutilization. Then, we expect sponsors to address each case through the case management process previously described and respond to CMS through the OMS using standardized responses. In addition, we expect sponsors to provide information to their regional CMS representatives and the MARx system about beneficiary-specific opioid POS claim edits that they intend to or have implemented.\8\ ---------------------------------------------------------------------------

    \8\ Please refer to the CMS Web site, ``Improving Drug Utilization Review Controls in Part D'' at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) which contains CMS communications regarding the current policy. ---------------------------------------------------------------------------

    Because case management is very resource intensive for sponsors and PBMs, we have limited the scope of the current policy in terms of the number of beneficiaries identified by OMS, and when expanding that number, we have made changes incrementally through annual Parts C&D Call Letter process. (2) Proposed Requirements for Part D Drug Management Programs (Sec. Sec.  423.100 and 423.153)     We first propose several definitions for terms we propose to use in establishing requirements for Part D drug management programs. (i) Definitions (Sec.  423.100) (A) Definition of ``Potential At-Risk Beneficiary'' and ``At-Risk Beneficiary'' (Sec.  423.100)     Section 1860D-4(c)(5)(C) of the Act contains a definition for ``at- risk beneficiary'' that we propose to codify at Sec.  423.100 In addition, although the section 1860D-4(c)(5) of the Act does not explicitly define a ``potential at-risk beneficiary,'' it contemplates a beneficiary who is potentially at-risk. Accordingly, we propose to define these two terms at Sec.  423.100 as follows: Potential at-risk beneficiary means a Part D eligible individual--(1) Who is identified using clinical guidelines (as defined in Sec.  423.100); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. At-risk beneficiary means a Part D eligible individual--(1) who is--(i) Identified using clinical guidelines (as defined in Sec.  423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program in accordance with the requirements of Sec.  423.153(f); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most

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recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. The distinction between a ``potential at-risk beneficiary'' and an ``at- risk beneficiary'' is important for a few reasons that we will explain later in this preamble. Also, we added the phrase, ``and the new plan has adopted the identification'' to both definitions for cases where a beneficiary has been identified as a potential at-risk or at-risk beneficiary by the immediately prior plan to indicate that the beneficiary's status in the subsequent plan is not automatic. (B) Definition of ``Frequently Abused Drug'', ``Clinical Guidelines'', ``Program Size'', and ``Exempted Beneficiary'' (Sec.  423.100)     Because we use these terms in the proposed definitions of ``potential at-risk beneficiary'' and ``at-risk beneficiary,'' we propose to define ``frequently abused drug,'' ``clinical guidelines'', ``program size'', and ``exempted beneficiary'' at Sec.  423.100 as follows:  Frequently Abused Drug     Section 1860D-4(c)(5)(G) of the Act defines ``frequently abused drug'' as a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted. Consistent with the statutory definition, we propose to define ``Frequently abused drug'' at Sec.  423.100 to mean a controlled substance under the federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account the following factors: (1) The drug's schedule designation by the Drug Enforcement Administration; (2) Government or professional guidelines that address that a drug is frequently abused or misused; and (3) An analysis of Medicare or other drug utilization or scientific data. This definition is intended to provide enough specificity for stakeholders to know how the Secretary will determine a frequently abused drug, while preserving flexibility to update which drugs CMS considers to be frequently abused drugs based on relevant factors, such as actions by the Drug Enforcement Administration and/or trends observed in Medicare or scientific data.     We plan to publish and update a list of frequently abused drugs for purposes of Part D drug management programs. We propose that future designations of frequently abused drugs by the Secretary primarily be included in the annual Parts C&D Call Letter or in similar guidance, which would be subject to public comment, if necessary to address midyear entries to the drug market or evolving government or professional guidelines. This approach would be consistent with our approach under the current policy and necessary for Part D drug management programs to be responsive to changing public health issues over time.     While this is the approach we propose for future designations of frequently abused drugs, we are including a discussion of the designation for plan year 2019 in this preamble. For plan year 2019, consistent with current policy, we propose that opioids are frequently abused drugs. Our proposal to designate opioids as frequently abused drugs illustrates how the proposed definition could work in practice:     First, the Secretary determines opioids are frequently abused or diverted, because they are controlled substances, and drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are so considered precisely because they have abuse potential. The Drug Enforcement Administration (DEA) divides controlled substances into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. Most prescription opioids are Schedule II, where the DEA places substances with a high potential for abuse with use potentially leading to severe psychological or physical dependence.\9\ A few opioids are Schedule III or IV, where the DEA places substances that have a potential for abuse. ---------------------------------------------------------------------------

    \9\ The abuse rate is a determinate factor in the DEA's scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes-- Schedule II, Schedule III, etc., so does the abuse potential-- Schedule V drugs represents the least potential for abuse. See DEA Web site about Drug Scheduling: [*https://www.dea.gov/druginfo/ds.shtml*](https://www.dea.gov/druginfo/ds.shtml) ---------------------------------------------------------------------------

    Second, on October 26, 2017, the President directed that executive agencies use all appropriate emergency authorities and other relevant authorities to address drug addiction and opioid abuse, and the Acting Secretary of Health and Human Services declared a nationwide Public Health Emergency to address the opioid crisis.\10\ In addition, the CDC has declared opioid overuse a national epidemic, both of which are relevant factors.\11\ More than 33,000 people died from opioid overuse in 2015, which is the highest number per year on record. From 2000 to 2015, more than half a million people died from drug overdoses, and 91 Americans die every day from an opioid overdose. Nearly half of all opioid overdose deaths involve a prescription opioid. Given that opioids, including prescription opioids, are the main driver of drug overdose deaths in the U.S , it is reasonable for the Secretary to conclude that opioids are frequently abused and misused. ---------------------------------------------------------------------------

    \10\ See White House Web site [*https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies*](https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies), and the HHS Web site   [*https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html*](https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html)     \11\ See CDC Web site   [*https://www.cdc.gov/drugoverdose/index.html*](https://www.cdc.gov/drugoverdose/index.html) for all statistics in this paragraph. ---------------------------------------------------------------------------

    Third, government or professional guidelines support determining that opioids are frequently abused or misused. Consistent with current policy, we propose to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables. The CDC MME Conversion Factor file \12\ does not include all formulations of buprenorphine for MAT so that access is not limited, and injectables are not included due to low claim volume. Therefore, CMS cannot determine the MME. CMS will consider revisions to the CDC MME Conversion Factor file when updating the list of opioids designated as frequently abused drugs in future guidance. ---------------------------------------------------------------------------

    \12\ See [*https://www.cdc.gov/drugoverdose/resources/data.html*](https://www.cdc.gov/drugoverdose/resources/data.html) ---------------------------------------------------------------------------

    Fourth, an analysis of Medicare data supports designating opioids as ``frequently abused drugs,'' at least initially. Over 727,000 Part D beneficiaries had an average MME of at least 90 mg during the 6-month period from July 1, 2015 to December 31, 2015 (``90 mg MME + users''), a number which excludes beneficiaries with cancer or in hospice, whom we propose to exempt from drug management programs, as we discuss later. As noted earlier, the CDC recommends prescribers generally avoid increasing the daily opioid dosage to 90 MME. Given that so many beneficiaries have an average MME above this threshold, it is reasonable that the Secretary consider this data to be a relevant factor in determining that opioids are frequently abused or diverted.     Most stakeholders recommended designating opioids as frequently abused drugs. In this regard, we note

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that our current policy applies only to opioids and that we are integrating the drug management provisions of CARA with our current policy. Therefore, designating opioids as frequently abused drugs, at least in the initial implementation of drug management programs, would have the added benefit of allowing CMS and stakeholders to gain experience with the use of lock-in in the Part D program, before potentially designating other controlled substances as frequently abused drugs.     Some commenters expressed support for including other or all controlled substances, such as benzodiazepines, sedatives, and certain muscle relaxants as frequently abused drugs; however, we are not persuaded. Opioids are unique in that there is generally no maximum dose for them in the FDA labeling. Also, in the proposed Contract Year 2016 Parts C&D Call Letter, we solicited feedback on expanding the current policy to other drugs, and the comments were mixed. A few commenters suggested that we expand the current policy to benzodiazepines and muscle relaxants when used with opioids. In respond to the feedback, we did not expand the current policy beyond the opioid class but indicated that we would investigate. Subsequently, the CDC Guideline was published and it specifically recommends that clinicians avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible due to increased risk for overdose. Therefore, we added a concurrent benzodiazepine-opioid flag to OMS in October 2016 to alert Part D sponsors that concurrent use may be an issue that should be addressed during case management, and we will continue to do so.\13\ ---------------------------------------------------------------------------

    \13\ Please refer to the memo, ``Medicare Part D Overutilization Monitoring System (OMS) Update: Addition of the Concurrent Opioid- Benzodiazepine Use Flag'' dated October 21, 2016. ---------------------------------------------------------------------------

    Other than conveying the concurrent benzodiazepine use information to sponsors, we have not expanded the current policy to address non- opioid medications. However, we have stated that if a sponsor chooses to implement the current policy for non-opioid medications, we would expect the sponsor to employ the same level of diligence and documentation with respect to non-opioid medications that we expect for opioid medications.\14\ We have taken this approach to the current policy so that we could focus on the opioid epidemic and also due to the difficulty in establishing overuse guidelines for non-opioid controlled substances. For this reason our proposal would not identify benzodiazepines as frequently abused drugs. However, we solicit additional comment on our proposed approach to frequently abused drugs. Also, we propose that, if finalized, this rule would supersede our current policy, and sponsors would no longer be allowed to implement the current policy for non-opioid medications. We seek feedback on allowing sponsors to continue to implement the current policy for non- opioid medications with respect to beneficiary-specific claim edits. ---------------------------------------------------------------------------

    \14\ See ``Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D,'' dated September 6, 2012. ---------------------------------------------------------------------------

 Clinical Guidelines and Program Size     Section 1860D-4(c)(5)(C)(i)(I) of the Act requires at-risk beneficiaries to be identified using clinical guidelines that indicate misuse or abuse of frequently abused drugs and that are developed in consultation with stakeholders. We propose to include a definition of ``clinical guidelines'' that cross references standards that we are proposing at Sec.  423.153(f) for how the guidelines would be established and updated. Specifically, we propose to define clinical guidelines for purposes of a Part D drug management program as criteria to identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs, and that are developed in accordance with the proposed standards in Sec.  423.153(f)(16) and published in guidance annually.     We also propose to add Sec.  423.153(f)(16) to state that potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or the Part D sponsor using clinical guidelines that: (1) Are developed with stakeholder consultation; (2) Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs, or any combination of these factors; (3) Are derived from expert opinion and an analysis of Medicare data; and (4) Include a program size estimate. This proposed approach to developing and updating the clinical guidelines is intended to provide enough specificity for stakeholders to know how CMS would determine the guidelines by identifying the standards we would apply in determining them.     This proposed approach indicates that the program size would be determined as part of the process to develop the clinical guidelines--a process into which stakeholders would provide input. Section 1860D- 4(c)(5)(C)(iii) of the Act states that the Secretary shall establish policies, including the guidelines and exemptions, to ensure that the population of enrollees in drug management programs could be effectively managed by plans. We propose to define ``program size'' in Sec.  423.100 to mean the estimated population of potential at-risk beneficiaries in drug management programs (described in Sec.   423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.     This proposed approach to developing and updating the clinical guidelines would also be flexible enough to allow for updates to the guidelines outside of the regulatory process to address trends in Medicare with respect to the misuse and/or diversion of frequently abused drugs. We have determined this approach is appropriate to enable CMS to assist Part D drug management programs in being responsive to public health issues over time. This approach would also be consistent with how the OMS criteria have been established over time through the annual Medicare Parts C&D Call Letter process, which we plan to continue except for 2019.     For plan year 2019, we propose the clinical guidelines in this preamble to be the OMS criteria established for plan year 2018, which meet the proposed standards for the clinical guidelines for the following reasons: First, as described earlier, the OMS criteria incorporate a 90 MME threshold cited in a CDC Guideline, which was developed by experts as the level that prescribers should avoid reaching with their patients. This threshold does not function as a prescribing limit for the Part D program; rather, it identifies potentially risky and dangerous levels of opioid prescribing in terms of misuse or abuse. Second, the OMS criteria also incorporate a multiple prescriber and pharmacy count. A high MED level combined with multiple prescribers and/or pharmacies may also indicate the abuse or misuse of opioids due to the possible lack of care coordination among the providers for the patient. Third, the OMS criteria have been revised over time based on analysis of Medicare data and with stakeholder input via the annual Parts C&D Call Letter process. Indeed, many stakeholders recommended the use of the CDC Guideline as part of the clinical guidelines the Secretary must develop, with some noting that they would need to be used in a way that accounts for use of multiple providers, which the OMS criteria do. Fourth, these criteria are familiar to Part D sponsors--they will already have experience with them by

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2019, and they were established with an estimate of program size.     Several stakeholders in their comments referred to various criteria used in state Medicaid lock-in programs to identify beneficiaries appropriate for lock-in, without suggesting that any particular ones be adopted. Other commenters suggested CMS consider other guidelines, such as the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use and the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline on Opioid Therapy for Chronic Pain. However, these guidelines are similar to or moving toward an MME methodology which we currently use or address a more narrow population than persons who may be abusing or misusing frequently abused drugs, and they do not directly address situations involving multiple opioid providers. The VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain is similar to the scope of the CDC Guideline. The ASAM Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use was developed specifically for the evaluation and treatment of opioid use disorder and for the management of opioid overdose, which would not be applicable here because it serves a different purpose. Therefore, we do not see a reason to adopt these guidelines instead of the 2018 OMS criteria.     The clinical guidelines for use in drug management programs we are proposing for 2019 are: Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies OR 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. We note that we have described alternative clinical guidelines that we considered in the Regulatory Impact Analysis section of this rule. Stakeholders are invited to comment on those alternatives and any others which would involve identifying more or fewer potential at-risk beneficiaries.     We propose that under the proposed clinical guidelines, prescribers associated with the same single Tax Identification Number (TIN) be counted as a single prescriber. This is consistent with the current policy under which we have found that such prescribers are typically in the same group practice that is coordinating the care of the patients served by it. Thus, it is appropriate to count such prescribers as one, so as not to identify beneficiaries who are not at-risk.     In this regard, in applying the OMS criteria, CMS counts prescribers with the same TIN as one prescriber, unless any of the prescribers are associated with multiple TINs. For example, under the criteria we have proposed, a beneficiary who meets the 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 3 independent opioid prescribers (1 group practice + 3 prescribers = 4 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies, would still meet the criteria, which is appropriate. However, a beneficiary who meets that 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 1 independent opioid prescriber (1 group practice + 1 prescriber = 2 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies would not meet the criteria, which is also appropriate at this time given program size concerns.     Section 1860D-4(c)(5)(D) of the Act specifies that for purposes of limiting access to coverage of frequently abused drugs to those obtained from a selected pharmacy, if the pharmacy has multiple locations that share real-time electronic data, all such locations of the pharmacy collectively are treated as one pharmacy. Given this provision, as well as our proposal to treat multiple prescribers from the same group practice as one prescriber under the clinical guidelines, we propose that where a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines.     Because not all Part D plans' data systems may be able to account for group practice prescribers as we described above, or chain pharmacies through data analysis alone, or may not be able to fully account for them, we request information on sponsors' systems capabilities in this regard. Also, if a plan sponsor does not have the systems capability to automatically determine when a prescriber is part of a group or a pharmacy is part of a chain, the plan sponsor would have to make these determinations during case management, as they do with respect to group practices under the current policy. If through such case management, the Part D plan finds that the multiple prescribers who prescribed frequently abused drugs for the beneficiary are members of the same group practice, the Part D plan would treat those prescribers as one prescriber for purposes of identification of the beneficiary as a potential at-risk beneficiary. Similarly, if through such case management, the Part D plan finds that multiple locations of a pharmacy used by the beneficiary share real-time electronic data, the Part D plan would treat those locations as one pharmacy for purposes of identification of the beneficiary as a potential at-risk beneficiary. Both of these scenarios may result in a Part D sponsor no longer conducting case management for a beneficiary because the beneficiary does not meet the clinical guidelines. We also note that group practices and chain pharmacies are important to consider for purposes of the selection of a prescriber(s) and pharmacy(ies) in cases when a Part D plan limits a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s), which we discuss in more detail later in this preamble.     Under the current policy, sponsors must use 90 MME as a ``floor'' for their own criteria to identify beneficiaries who may be overutilizing opioids, but they may vary the prescriber and pharmacy count. This means sponsors may review beneficiaries who do not meet the OMS criteria but meet the sponsors' internal criteria for review, or they may not review beneficiaries who meet the OMS criteria but do not meet the sponsors' internal criteria for review. However, under our proposal to adopt the 2018 OMS criteria as the 2019 clinical guidelines for Part D drug management programs, we also propose to mostly eliminate this feature of the current policy. Under our proposal, Part D plan sponsors would not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs, except that we propose to continue to permit plan sponsors to apply the criteria more frequently than CMS would apply them through OMS in 2018, which can result in sponsors identifying beneficiaries earlier. This is because CMS evaluates enrollees quarterly using a 6-month look back period, whereas sponsors may evaluate enrollees more frequently (for example, monthly).     While several commenters stated that Part D plan sponsors should have flexibility in developing their own criteria for identifying at- risk beneficiaries in their plans, a more conservative and uniform approach is warranted for the initial implementation of Part D drug management programs. While we already have experience with how frequently Part D plan sponsors use beneficiary-specific opioid POS claim edits to prevent opioid overutilization, we wish to learn how sponsors will use

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lock-in as a tool to address this issue before adopting clinical guidelines that might include parameters for permissible variations of the criteria. We plan to monitor compliance of drug management programs as we monitor compliance with the current policy through various CMS data sources, such as OMS, MARx, beneficiary complaints and appeals.     Also, we note that despite sponsors' additional identification of some beneficiaries currently, in practice, we have found that CMS identifies the vast majority of beneficiaries who are reviewed by Part D sponsors through OMS. CMS identifies over 80 percent of the cases reviewed through OMS, and about 20 percent are identified by sponsors based on their internal criteria. We understand that most of the beneficiaries representing the 20 percent were reported to OMS due to the sponsors averaging the MME calculations across all opioid prescriptions, which has subsequently been changed in the 2018 OMS criteria. The 2018 OMS criteria also have a lower MME threshold and account for additional beneficiaries who receive their opioids from many prescribers regardless of the number of pharmacies, which will result in the identification of more beneficiaries through OMS. Thus, our proposal would not substantially change the current practice. Furthermore, in approximately 39 percent of current OMS cases, sponsors respond that the case does not meet the sponsor's internal criteria for review.\15\ We found that the original OMS criteria generated false positives that some sponsors' internal criteria did not because these sponsors used a shorter look back period or were able to group prescribers within the same practice or chain pharmacies. These best practices have also been incorporated into the revised 2018 OMS criteria, which are the basis of the proposed 2019 clinical guidelines. Thus, while our proposal will prevent sponsors from voluntarily reviewing more potential at-risk beneficiaries than CMS identifies through OMS, it will likely require sponsors to review more beneficiaries than they currently do. ---------------------------------------------------------------------------

    \15\ We noted in the final CY Parts C&D Call Letter, for the January 2014 OMS reports, 67 percent of the potential opioid overutilization responses were that the beneficiary did not meet the sponsor's internal criteria. We explained the reasons for this figure and the actions we took to reduce it. ---------------------------------------------------------------------------

    Table 1 shows that in 2015 approximately 33,000 beneficiaries would have met the proposed 2019 clinical guidelines, which is approximately 0.08 percent of the 42 million beneficiaries enrolled in Part D in 2015. We think this population would constitute a manageable program size because this is the estimated OMS population we finalized during the Plan Year 2018 Parts C&D Call Letter process. Moreover, we have no evidence to suggest that this program size will be problematic for sponsors.     In addition, current Medicaid lock-in programs support the notion that this program size would be manageable by Part D plan sponsors. In 2015, an average 0.37 percent of Medicaid recipients were locked-in and the percentage of recipient's locked-in by state programs ranged from 0.01 percent to 1.8 percent.\16\ ---------------------------------------------------------------------------

    \16\ Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug-Fee-For-Service Programs (December 2016), pg. 26. ---------------------------------------------------------------------------

    To derive this estimated population of potential at-risk beneficiaries, we analyzed prescription drug event data (PDE) from 2015,\17\ using the CDC opioid drug list and MME conversion factors, and applying the criteria we proposed earlier as the clinical guidelines. This estimate is over-inclusive because we did not exclude beneficiaries in long-term care (LTC) facilities who would be exempted from drug management programs, as we discuss later in this section. However, based on similar analyses we have conducted, this exclusion would not result in a noteworthy reduction to our estimate. Also, we were unable to count all locations of a pharmacy that has multiple locations that share real-time electronic data as one, which is a topic we discussed earlier and will return to later. Thus, there likely are beneficiaries counted in our estimate who would not be identified as potential at-risk beneficiaries because they are in an LTC facility or only use multiple locations of a retail chain pharmacy that share real- time electronic data. ---------------------------------------------------------------------------

    \17\ Unique count of beneficiaries who met the criteria in any 6 month measurement period (January 2015-June 2015; April 2015- September 2015; or July 2015-December 2015).

      Table 1--Clinical Guidelines or Identifying Potential At-Risk                               Beneficiaries ------------------------------------------------------------------------             Criteria applied                 Impact to Part D program ------------------------------------------------------------------------ [gteqt]90 mg MED and either:             33,053 beneficiaries in 2015                                           (76.3% were LIS).     4+ opioid prescribers AND 4+ opioid  Represents 0.08% of 41,835,016      dispensing pharmacies.               Part D beneficiaries in 2015. OR                                       LTC beneficiaries included in                                           estimate but are exempt.     6+ opioid prescribers (regardless    Prescribers associated with the      of the number of opioid dispensing   same single Tax Identification      pharmacies).                         Numbers (TIN) are counted as a                                           single prescriber. ------------------------------------------------------------------------

    We note that the alternatives for clinical guidelines that we considered, which are described in the Regulatory Impact Analysis (RIA) section of this rule, also include estimated population of potential at-risk beneficiaries for each alternative. Most of the options include a 90 MME threshold with varying prescriber and pharmacy counts and range from identifying 33,053 to 319,133 beneficiaries. Again, stakeholders are invited to comment on these alternatives. We are particularly interested in receiving comments on whether CMS should adjust the clinical guidelines so that more or fewer potential at-risk beneficiaries are identified, and if more are identified, whether the additional number would result in a manageable program size for plan sponsors (or too few beneficiaries to be meaningful).  Exempted Beneficiary     Section 1860D-4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. Consistent with this, we propose that an exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents

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through a contract with a single pharmacy; or (3) Has a cancer diagnosis.     While the first two exceptions are required under CARA, we propose to exercise the authority in section 1860D-4(c)(5)(C)(ii)(III) of the Act to treat a beneficiary who has a cancer diagnosis as an exempted individual for two reasons. First, many commenters recommended that the Secretary exempt beneficiaries who have a cancer diagnosis, because a Part D drug management program should not be able to interfere administratively with their pain control regimen in the form of additional notices from their prescription drug benefit plans and limitations on their access to coverage for frequently abused drugs. We agree with these commenters. Second, exempting beneficiaries with a cancer diagnosis would be consistent with current policy. Under the current policy, which has been developed through stakeholder feedback, beneficiaries with cancer are excluded because the benefit of their opioid use may outweigh the risk associated with their opioid use. Also, as noted previously, some commenters requested that implementation of the drug management program provisions of CARA be as consistent as possible with the current policy for operational ease. We also agree with these commenters.     Some commenters recommended against exempting beneficiaries with cancer diagnoses, stating that there is no standard clinical reason why a beneficiary with cancer should be receiving opioids from multiple prescribers and/or multiple pharmacies, and that such situations warrant further review. While we understand the concern of these commenters, we maintain that beneficiaries who have a cancer diagnosis should be exempted for the reasons stated just above. Moreover, our experience with this exemption under the current policy suggests that the exemption is workable and appropriate. We understand beneficiaries with cancer diagnoses are identifiable by Part D plan sponsors either through recorded diagnoses, their drug regimens or case management, and no major concerns have been expressed about this exemption under our current policy, including from standalone Part D plan sponsors who may not have access to their enrollees' medical records.     A few commenters suggested exempting beneficiaries who are receiving palliative and end-of-life care, since not all patients receiving this type of care are necessarily enrolled in hospice or reside in an LTC facility. Two commenters suggested exempting beneficiaries in assisted living. Other commenters suggested exempting beneficiaries in various other health care facilities, such as group homes and adult day care centers, where medication is supervised. Other commenters suggested exempting beneficiaries with debilitating disorders or receiving medication-assisted treatment for substance abuse disorders.     We have not proposed to exempt these additional categories of beneficiaries but we seek specific comment on whether to do so and our rationale. First, we have not exempted these other beneficiaries under the current policy, and we thus do not think it is necessary to exempt them from drug management programs. Second, unlike with cancer diagnoses, we are not able to determine administratively through CMS data who these beneficiaries are to exempt them from OMS reporting. Consequently, it could be burdensome for Part D sponsors to attempt to exempt these beneficiaries, by definition, from their drug management programs. Third, it is important to remember that the proposed clinical guidelines would only identify potential at-risk beneficiaries in the Part D program who are receiving potentially unsafe doses of opioids from multiple prescribers and/or multiple pharmacies who typically do not know about each other in terms of providing services to the beneficiary. Thus, it is likely that a plan would discover during case management that a potential at-risk beneficiary is receiving palliative and end-of-life care during case management. Absent a compelling reason, we would expect the plan not to seek to implement a limit on such beneficiary's access to coverage of opioids under the current policy nor a drug management program, as it would seem to outweigh the medication risk in such circumstances. Moreover, in cases where a prescriber is cooperating with case management, we would not expect the prescriber to agree to such a limitation, again, absent a compelling reason. With respect to beneficiaries receiving medication-assisted treatment for substance abuse for opioid use disorder, we decline to propose to treat these individuals as exempted individuals. It is these beneficiaries who are among the most likely to benefit from a drug management program. (ii) Requirements of Drug Management Programs (Sec. Sec.  423.153, 423.153(f))     As noted previously, we are proposing to codify a regulatory framework under which Part D plan sponsors may adopt drug management programs to address overutilization of frequently abused drugs. Therefore, we propose to amend Sec.  423.153(a) by adding this sentence at the end: ``A Part D plan sponsor may establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section,'' in accordance with our authority under revised section 1860D-4(c)(5)(A) of the Act.     We also propose to revise Sec.  423.153 by adding a new paragraph (f) about drug management programs for which the introductory sentence would read: ``(f) Drug Management Programs. A drug management program must meet all the following requirements.'' Thus, the requirements that a Part D plan sponsor must meet to operate a drug management program would be codified in various provisions under subsection Sec.   423.153(f). (iii) Written Policies and Procedures (Sec.  423.153(f)(1))     We propose to require Part D sponsors document their programs in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate, which is consistent with the current policy. Also consistent with the current policy, we would require these policies and procedures to address the appropriate credentials of the personnel conducting case management and the necessary and appropriate contents of files for case management. We additionally propose to require sponsors to monitor information about incoming enrollees who would meet the definition of a potential at-risk and an at-risk beneficiary in proposed Sec.  423.100 and respond to requests from other sponsors for information about potential at-risk and at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. We discuss potential at-risk and at- risk beneficiaries who are identified as such in their most recent Part D plan later in this preamble.     To codify these requirements, we propose that section Sec.   423.153(f)(1) read as follows: (1) Written policies and procedures. A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. The policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following: (i) The appropriate credentials of the personnel conducting case management required under

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paragraph (f)(2); (ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2); and (iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary and a potential at-risk beneficiary in Sec.  423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at- risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. Thus, Part D sponsors would have flexibility--as they do today under the current policy--to adopt specific policies and procedures for their drug management programs, as long as they are consistent with the requirements of Sec.  423.153, as finalized. (iv) Case Management/Clinical Contact/Prescriber Verification (Sec.   423.153(f)(2))     As discussed earlier, case management is a key feature of the current policy, under which we currently expect Part D plan sponsors' clinical staff to diligently engage in case management with the relevant opioid prescribers to coordinate care with respect to each beneficiary reported by OMS until the case is resolved (unless the beneficiary does not meet the sponsor's internal criteria). We propose that the second requirement for drug management programs in a new Sec.   423.153(f)(2) reflect the current policy with some adjustment to the current policy to require all beneficiaries reported by OMS to be reviewed by sponsors.     Our proposal for a new Sec.  423.153(f)(2) also meets the requirements of section 1860D-4I(5)(C) of the Act. This section of the Act requires that, with respect to each at-risk beneficiary, the sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions. Further, our proposal meets the requirements of Section 1860D-4(c)(5)(B)(i)(II) of the Act, which requires that a Part D sponsor first verify with the beneficiary's providers that the beneficiary is an at-risk beneficiary, if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs.     Specifically, we propose that a new Sec.  423.153(f)(2) read as follows: Case Management/Clinical Contact/Prescriber Verification. (i) General Rule. The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Proposed Sec.  423.153(f)(2)(i) would further state that, except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following: (A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at-risk beneficiary; (B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary; and (C) In cases where the prescribers have not responded to the inquiry described in (i)(B), make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.     Given the ``Except as provided in paragraph (f)(2)(ii) of this section'', we propose to add paragraph (ii) to Sec.  423.153(f)(2) that would read: (ii) Exception for identification by prior plan. If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan, and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is still clinically adequate and up to date. This proposal is to avoid unnecessary burden on health care providers when additional case management outreach is not necessary. This is consistent with the current policy under which sponsors are expected to enter information into MARx about pending, implemented and terminated beneficiary- specific POS claim edits, which is transferred to the next sponsor, if applicable. Pending and implemented POS claim edits are actions that sponsors enter into MARx after case management. We discuss potential at-risk and at-risk beneficiaries who change plans again later in this preamble.     The information that the plan sends to the prescribers and elicits from them is intended to assist a Part D sponsor to understand why the beneficiary meets the clinical guidelines and if a plan intervention is warranted for the safety of the beneficiary. Also, sponsors use this information to choose standardized responses in OMS and provide information to MARx about plan interventions that were referenced earlier. We will address required reporting to OMS and MARx by sponsors again later.     We note that, currently, OMS standardized responses generally fall into four categories: First, in approximately 18 percent of cases, the enrollee's opioid use is medically necessary. Second, approximately 38 percent of cases are resolved without a beneficiary-specific POS opioid claim edit, for example, when the sponsor takes a ``wait and see'' approach to observe if the prescribers adjust their management of, and the opioid prescriptions they are writing for, their patient due to the written information they received from the sponsor about their patient. Third, a small subset of cases--on average 1.3 percent--need a beneficiary-specific opioid POS claim edit to resolve the beneficiary's opioid overutilization issue. From 2013 through of July 4, 2017, CMS received 4,617 contract-beneficiary-level opioid POS claim edit notifications through MARx for 3,961 unique beneficiaries. Fourth, as previously mentioned, approximately 39 percent of cases do not meet the sponsor's internal criteria for review. We expect adjustment to these percentages under our proposal, particularly since we anticipate that plans will no longer be able to respond that a case does not meet its internal criteria for review. In addition, the revised 2018 OMS criteria which are the basis of the proposed 2019 clinical guidelines should reduce ``false positives'' which may have been reported through OMS but not identified through sponsors' internal criteria due to a shorter look back period and ability to group prescribers within the same practice.     We also note that under the current policy, sponsors are expected to make ``at least three (3) attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period (for example, a 10 business day period) from the issuance of the written inquiry notification.'' If the prescribers are unresponsive to case management, under our current policy, a sponsor may also implement a beneficiary-specific POS claim edit for opioids as a last resort to encourage prescriber engagement with case management.     By contrast, our proposed Sec.  423.153(f)(2) uses the terms ``reasonable attempts'' and ``reasonable period'' rather than a specific number of attempts or a specific timeframe for plan to call prescribers. The reason for this proposed adjustment to our policy is because our current policy also states that ``[s]ponsors are not required to

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automatically contact prescribers telephonically,'' but those that ``employ a wait-and-see approach'' should understand that ``we expect sponsors to address the most egregious cases of opioid overutilization without unreasonable delay, and that we do not believe that all such cases can be addressed through a prescriber letter campaign.'' Our guidance further states that, ``to the extent that some cases can be addressed through written communication to prescribers only, we would acknowledge the benefit of not aggravating prescribers with unnecessary telephonic communications.'' Finally, our guidance states that, ``[s]ponsors must determine for themselves the usefulness of attempting to call or contact all opioid prescribers when there are many, particularly when they are emergency room physicians.'' \18\ ---------------------------------------------------------------------------

    \18\ See ``Supplemental Guidance Relating to Improving Drug Utilization Review Controls in Part D'', September 6, 2012 (pp. 5, 19-20) at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) ---------------------------------------------------------------------------

    Given the competing priorities of sponsors' diligently addressing opioid overutilization in the Part D program through case management, which may necessitate telephone calls to the prescribers, while being cognizant of the need to be judicious in contacting prescribers telephonically in order to not unnecessarily disrupt their practices, we wish to leave flexibility in the regulation text for sponsors to balance these priorities on a case-by-case basis in their drug management programs, particularly since this flexibility exists under the current policy. We note however, that we propose a 3 attempts/10 business days requirement for sponsors to conclude that a prescriber is unresponsive to case management in Sec.  423.153(f)(4) discussed later in this section. (v) Limitations on Access to Coverage for Frequently Abused Drugs (Sec.  423.153(f)(3))     As described earlier, under the current policy, Part D sponsors may implement a beneficiary-specific opioid POS claim edit to prevent continued overutilization of opioids, with prescriber agreement or in the case of an unresponsive prescriber during case management. If a sponsor implements a POS claim edit, the sponsor thereafter does not cover opioids for the beneficiary in excess of the edit, absent a subsequent determination, including a successful appeal.     As noted earlier, revised section 1860D-4(c)(5)(A) of the Act provides additional tools commonly known as ``lock-in'', for Part D plans to limit an at-risk beneficiary's access to coverage for frequently abused drugs. Prescriber lock-in would limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers, and pharmacy lock-in would restrict an at-risk beneficiary's access to coverage for frequently abused drugs to those that are dispensed to the beneficiary by one or more network pharmacies.     If the sponsor uses a lock-in tool(s), the sponsor must generally cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) and/or prescriber(s), as applicable, absent a subsequent determination, including a successful appeal. Pursuant to section 1860D-4(c)(5)(D)(i)(II) of the Act, a sponsor would also have to cover frequently abused drugs from a non- selected pharmacy or prescriber, if such coverage were necessary in order to provide reasonable access. We discuss selection of pharmacies and prescribers and reasonable access later.     We propose to describe all the tools that would be available to sponsors to limit an at-risk beneficiary's access to coverage for frequently abused drugs through a drug management program in Sec.   423.153(f)(3) as follows: Limitation on Access to Coverage for Frequently Abused Drugs. Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following: (i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary; or (ii) In accordance with paragraphs (f)(10) and (f)(11) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are (A) Prescribed for the beneficiary by one or more prescribers; (B) Dispensed to the beneficiary by one or more network pharmacies; or (C) Specified in both paragraphs (3)(ii)(B)(1) and (2) of this paragraph. Paragraph (iii)(A) would state that if the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal. Paragraph (iii)(B) would state that if the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) and/or prescriber(s), or both, as applicable, (1) in accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal, and (2) except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section. (vi) Requirements for Limiting Access to Coverage for Frequently Abused Drugs (Sec.  423.153(f)(4))     We propose that before a Part D plan sponsor could limit the access of at-risk beneficiary to coverage for frequently abused drugs, the sponsor must first take certain actions, consistent with current policy. We propose that a sponsor must first conduct the case management discussed earlier, which includes clinical contact to determine whether prescribed medications are appropriate for the potential at-risk beneficiary's medical conditions and prescriber verification that the beneficiary is an at-risk beneficiary. We also propose that the sponsor must first obtain the agreement of the prescribers of frequently abused drugs with the limitation, unless the prescribers were not responsive to the required case management, in light of the risk to the beneficiary's health. We further propose that the sponsor must first provide notice to the beneficiary in accordance with section 1860D-4(c)(5)(B)(i)(I) of the Act.     We propose to require the additional step of prescriber agreement, which is consistent with the current policy as discussed earlier, because a prescriber may verify that the beneficiary is an at-risk beneficiary but may not view a limitation on the beneficiary's access to coverage for frequently abused drugs as appropriate. Given the additional information the prescribers would have from the Part D sponsor through case management about the beneficiary's utilization of frequently abused drugs, the prescribers' professional opinion may be that an adjustment to their prescribing for, and care of, the beneficiary is all that is needed to safely manage the beneficiary's use of frequently abused drugs going forward. We invite stakeholders to comment on not requiring prescriber agreement to implement pharmacy lock-in. We could foresee a case in which the prescriber is responsive, but does not agree with pharmacy lock-in.     We also propose language that would provide an exception to the case management requirement in Sec.  423.153(f)(2) when an at-risk

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beneficiary was identified as an at-risk beneficiary by the beneficiary's most recent prior prescription drug benefit plan. We discuss such cases more later in this section. Given the foregoing, we propose to add a paragraph (f)(4) to Sec.  423.153 that reads: Requirements for Limiting Access to Coverage for Frequently Abused Drugs. (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following: (A) Conducted the case management required by paragraph (f)(2) of this section and updated it, if necessary; (B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate; and (C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section. We would also state in subsection (ii) that if the sponsor complied with the requirement of paragraph (f)(2)(i)(C) of this section, and the prescribers were not responsive after 3 attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section. Finally, we would state in a subsection (iii) that if the beneficiary meets paragraph (2) of the definition of a potential at- risk beneficiary or an at-risk beneficiary, and the sponsor has obtained the applicable case management information from the sponsor of the beneficiary's most recent plan and updated it as appropriate, the sponsor has met the case management requirement in paragraph (f)(2)(i). (vii) Beneficiary Notices and Limitation of Special Enrollment Period (Sec. Sec.  423.153(f)(5), 423.153(f)(6), 423.38) (A) Initial Notice to Beneficiary and Sponsor Intent To Implement Limitation on Access to Coverage for Frequently Abused Drugs (Sec.   423.153(f)(5))     The notices referred to in proposed Sec.  423.153(f)(4)(i)(C) are the initial and second notice that section 1860D-4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to send to potential at-risk and at- risk beneficiaries regarding their drug management programs. We remind Part D sponsors that under Section 504 of the Rehabilitation Act of 1973, effective communications requirements would apply to both these notices. We first discuss the initial notice.     We propose in Sec.  423.153(f)(5) that if a Part D plan sponsor intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs, the sponsor would be required to provide an initial written notice to the potential at-risk beneficiary. We also propose that the language be approved by the Secretary and be in a readable and understandable form that contains the language required by section 1860D-4(c)(5)(B)(ii) of the Act to which we propose to add detail in the regulation text. Finally, we propose that the sponsor be required to make reasonable efforts to provide the prescriber(s) of frequently abused drugs with a copy of the notice.     We propose that Sec.  423.153(f)(5)(i) read as follows: Initial Notice to Beneficiary. A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary. Paragraph (f)(5)(ii) would require that the notice use language approved by the Secretary and be in a readable and understandable form that provides the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary; (2) A description of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits); (3) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at Sec.  423.580 et seq.; (4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under Sec.   423.153(f)(3)(ii); (5) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including an explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program, the timeframe for the sponsor's decision, and if applicable, any limitation on the availability of the special enrollment period described in Sec.   423.38; (6) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(4); (7) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program; and (8) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     We propose to require at Sec.  423.153(f)(5)(iii) that the Part D plan sponsor make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i).     The content of the initial notice we propose in Sec.  423.153(f)(5) closely follows the content required by section 1860D-4(c)(5)(B)(ii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (f)(5)(ii)(C)(2)--which would require a description of public health resources that are designed to address prescription drug abuse--we propose to require that the notice contain information on how to access such services. We also included a reference in proposed paragraph (ii)(C)(4) to the fact that a beneficiary would have 30 days to provide information to the sponsor, which is a timeframe we discuss later in this preamble. We propose an additional requirement in paragraph (ii)(C)(5) that the sponsor include the limitation the sponsors intends to place on the beneficiary's access to coverage for frequently abused drugs, the timeframe for the sponsor's decision, and, if applicable, any limitation on the availability of the SEP. Finally, we proposed a requirement in paragraph (ii)(C)(8) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.     We note that our proposed implementation of the statutory requirements for the initial notice would permit the notice also to be used when the sponsor intends to implement a beneficiary-specific POS claim edit for frequently abused drugs. This is consistent with our current policy and would streamline beneficiary notices about opioids since we propose frequently abused drugs to consist of opioids for 2019.

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    Although section 1860D-4(c)(5) is silent as to the sequence of the steps of clinical contact, prescriber verification, and the initial notice, we propose to implement these requirements such that they would occur in the following order: First, the plan sponsor would conduct the case management which encompasses clinical contact and prescriber verification required by Sec.  423.153(f)(2) and prescriber agreement required by Sec.  423.153(f)(4), and second would, as applicable, indicate the sponsor's intent to limit the beneficiary's access to frequently abused drugs by providing the initial notice. In our view, a sponsor cannot reasonably intend to limit the beneficiary's access unless it has first undertaken case management to make clinical contact and obtain prescriber verification and agreement. Further, under our proposal, although the proposed regulatory text of (f)(4)(i) states that the sponsor must verify with the prescriber(s) that the beneficiary is an at-risk beneficiary in accordance with the applicable statutory language, the beneficiary would still be a potential at-risk beneficiary from the sponsor's perspective when the sponsor provides the beneficiary the initial notice. This is because the sponsor has yet to solicit information from the beneficiary about his or her use of frequently abused drugs, and such information may have a bearing on whether a sponsor identifies a potential at-risk beneficiary as an at- risk beneficiary.     Moreover, we believe that in general, a sponsor should not send a potential at-risk beneficiary an initial notice until after the sponsor has been in contact with the beneficiary's prescribers of frequently abused drugs, so as to avoid unnecessarily alarming the beneficiary, considering that a sponsor may learn from the prescribers that the beneficiary's use of the drugs is medically necessary, or that the beneficiary is an exempted beneficiary. This proposed approach is also consistent with our current policy and stakeholder comments. Therefore, under this approach, a sponsor would provide an initial notice to a potential at-risk beneficiary if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, and the sponsor would provide a second notice to an at-risk beneficiary when it actually limits the beneficiary's access to coverage for frequently abused drugs. Alternatively, the sponsor would provide an alternate second notice if it decides not to limit the beneficiary's access to coverage for frequently abused drugs. We discuss the second notice and alternate second notice later in this preamble.     We intend to develop language for the initial notice. Therefore, the proposed regulatory text states that the notice must use language approved by the Secretary. (B) Limitation on the Special Enrollment Period for LIS Beneficiaries With an At-Risk Status (Sec.  423.38)     In addition to providing relevant information to a potential at- risk beneficiary, we propose that the initial notice will notify dually- and other low income subsidy (LIS)-eligible beneficiaries, that they will be unable to use the special enrollment period (SEP) for LIS beneficiaries due to their at-risk status. (Hereafter, this SEP is referred to as the ``duals' SEP''). Section 1860D-1(b)(3)(D) of the Act requires the Secretary to establish a Part D SEP for full-benefit dually eligible (FBDE) beneficiaries. This SEP, codified at Sec.   423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries (75 FR 19720) so that all LIS-eligible beneficiaries were treated uniformly. The duals' SEP currently allows such individuals to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans) throughout the year, unlike other Part D enrollees who generally may make enrollment changes only during the annual election period (AEP). Individuals using this SEP can enroll in either a stand-alone Part D prescription drug plan (PDP) or a Medicare Advantage plan with prescription drug coverage.     Section 704(a)(3) of CARA gives the Secretary the discretion to limit the SEP for FBDE beneficiaries outlined in section 1860D- 1(b)(3)(D) of the Act. This limitation is related to, but distinct from, other changes to the duals' SEP proposed in section III.A.11 of this proposed rule (as discussed later). A limitation under a sponsor's drug management program can only be effective as long as the individual is enrolled in that plan or another plan that also has a drug management program. Therefore, this proposed SEP limitation would be an important tool to reduce the opportunities for LIS-eligible beneficiaries designated as at-risk to switch plans. If an individual is determined to be an at-risk beneficiary, and is permitted to change plans using the duals' SEP, he or she could avoid the drug management program by leaving the plan before the program can be started or by enrolling in a PDP that does not have a drug management program. This would allow the beneficiary to circumvent the lock-in program and not receive the care coordination such a program provides. Even if an-risk beneficiary joined another plan that had a drug management program in place, there would be challenges in terms of preventing a gap managing their potential or actual overutilization of frequently abused drugs due to timing of information sharing between the plans and possible difference in provider networks.     Accordingly, we are proposing to revise Sec.  423.38(c)(4), so that it is not available to potential at-risk beneficiaries or at-risk beneficiaries. Once an individual is identified as a potential at-risk beneficiary and the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, the sponsor would provide an initial notice to the beneficiary and the duals' SEP would no longer be available to the otherwise eligible individual. This means that he or she would be unable to use the duals' SEP to enroll in a different plan or disenroll from the current Part D plan. The limitation would be effective as of the date the Part D plan sponsor identifies an individual to be potentially at-risk. Limiting the duals' SEP concurrent with the plan's identification of a potential at-risk beneficiary would reduce the opportunities for such beneficiaries to use the interval between receipt of the initial notice and application of the limitation (for example, pharmacy or prescriber lock-in, beneficiary-specific POS claim edit) as an opportunity to change plans before the restriction takes effect.     Based on the 2015 data in CMS' OMS, more than 76 percent of all beneficiaries estimated to be potential at-risk beneficiaries are LIS- eligible individuals. Based on this data, without an SEP limitation at the initial point of identification, the notification of a potential drug management program may prompt these individuals to switch plans immediately after receiving the initial notice. In effect, under the current regulations, if unchanged, the dually- or other LIS-eligible individual, could keep changing plans and avoid being subject to any drug management program.     We propose that, consistent with the timeframes discussed in proposed paragraph Sec.  423.153(f)(7), if the Part D plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 90 days from the initial notice, the ``potentially at-risk'' designation and the duals' SEP limitation would expire. If the sponsor determines that the potential at-risk beneficiary is an at- risk beneficiary, the

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duals' SEP would not be available to that beneficiary until the date the beneficiary's at-risk status is terminated based on a subsequent determination, including a successful appeal, or at the end of a 12- month period calculated from the effective date the sponsor provided the beneficiary in the second notice as proposed at Sec.  423.153(f)(6) whichever is sooner.     As discussed in section III.A.11 of this proposed rule, we are also proposing to revise Sec.  423.38(c)(4) to make the SEP for FBDE or other subsidy-eligible individuals available only in certain circumstances. As further explained in section III.A.11, we also are proposing to establish a new SEP at Sec.  423.38(c)(9) to permit any beneficiary to make an enrollment change when he or she has a gain, loss, or change in Medicaid or LIS eligibility.     We propose not to limit the availability of this new SEP to potential at-risk and at-risk beneficiaries. In situations where an individual is designated as a potential at-risk beneficiary or an at- risk beneficiary and later determined to be dually-eligible for Medicaid or otherwise eligible for LIS, that beneficiary should be afforded the ability to receive the subsidy benefit to the fullest extent for which he or she qualifies and therefore should be able to change to a plan that is more affordable, or that is within the premium benchmark amount if desired. Likewise, if an individual with an ``at- risk'' designation loses dual-eligibility or LIS status, or has a change in the level of extra help, he or she would be afforded an opportunity to elect a different Part D plan, as discussed in section III.A.11 of this proposed rule. This is also a life changing event that may have a financial impact on the individual, and could necessitate an individual making a plan change in order to continue coverage.     We note that auto- and facilitated enrollment of LIS eligible individuals and plan annual reassignment processes would still apply to dual- and other LIS-eligible individuals who were identified as an at- risk beneficiary in their previous plan. This is consistent with CMS's obligation and general approach to ensure Part D coverage for LIS- eligible beneficiaries and to protect the individual's access to prescription drugs. Furthermore, we note that the proposed enrollment limitations for Medicaid or other LIS-eligible individuals designated as at-risk beneficiaries would not apply to other Part D enrollment periods, including the AEP or other SEPs. As discussed previously, we propose that the ability to use the duals' SEP, as outlined in section III.A.11 of this proposed rule, would not be permissible once the individual is enrolled in a plan that has identified him or her as a potential at-risk beneficiary or at-risk beneficiary, for a dual or other LIS-eligible who meets the definition of at-risk beneficiary or potential at-risk beneficiary under proposed Sec.  423.100 (C) Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs by Sponsor (Sec.  423.153(f)(6))     As previously noted, section 1860D-4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to provide a second written notice to at-risk beneficiaries when they limit their access to coverage for frequently abused drugs. Also, as with the initial notice, our proposed implementation of this statutory requirement for the second notice would permit the second notice to be used when the sponsor implements a beneficiary-specific POS claim edit for frequently abused drugs.     We propose to codify this requirement in Sec.  423.153(f)(6)(i). Specifically, we propose to require the sponsor to provide the second notice when it determines that the beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs. We further propose to require the second notice to include the effective and end date of the limitation. Thus, this second notice would function as a written confirmation of the limitation the sponsor is implementing with respect to the beneficiary, and the timeframe of that limitation.     We also propose that the second notice, like the initial notice, contain language required by section 1860D-4(c)(5)(B)(iii) of the Act to which we propose to add detail in the regulation text. We also propose that the second notice, like the initial notice, be approved by the Secretary and be in a readable and understandable form, as well as contain other content that CMS determines is necessary for the beneficiary to understand the information required in this notice. Finally, in Sec.  423.153(f)(6)(iii), we propose that the sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice, as we proposed with the initial notice.     Proposed Sec.  423.153(f)(6)(i) would read as follows: Second notice. Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary. Paragraph (f)(6)(ii) would require that the second notice use language approved by the Secretary and be in a readable and understandable form that contains the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary; (2) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including the limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and, if applicable, any limitation on the availability of the special enrollment period described in Sec.  423.38 et seq.; (3) The prescriber(s) and/or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor; (4) An explanation of the beneficiary's right to a redetermination under Sec.  423.580 et seq., including a description of both the standard and expedited redetermination processes, with the beneficiary's right to, and conditions for, obtaining an expedited redetermination; (5) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs; (6) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(5) of this section; and (7) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     The content of the second notice we propose in Sec.  423.153(f)(6) closely follows the content required by section 1860D-4(c)(5)(B)(iii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (2), we have proposed language that would require a sponsor to include the limitation the sponsors is placing on the beneficiary's access to coverage for frequently abused drugs, the effective and end date of the limitation, and if applicable, any limitation on the availability of the SEP. We propose an additional requirement in paragraph (6) that the sponsor include instructions how the beneficiary

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may submit information to the sponsor in response to the request described in paragraph (4). Finally, we proposed a requirement in paragraph (7) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.     We note that under our current policy, plan sponsors send only one notice to the beneficiary if they intend to implement a beneficiary- specific POS opioid claim edit, which generally provides the beneficiary with a 30-day advance written notice and opportunity to provide additional information, as well as to request a coverage determination if the beneficiary disagrees with the edit. If our proposal is finalized, the implementation of a beneficiary-specific POS claim edit or a limitation on the at-risk beneficiary's coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) would be an at-risk determination (a type of initial determination that would confer appeal rights). Also, the sponsor would generally be required to send two notices--the first signaling the sponsor's intent to implement a POS claim edit or limitation (both referred to generally as a ``limitation''), and the second upon implementation of such limitation. Under our proposal, the requirement to send two notices would not apply in certain cases involving at-risk beneficiaries who are identified as such and provided a second notice by their immediately prior plan's drug management program. (D) Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur (Sec.  423.153(f)(7))     We propose that if a sponsor does not implement the limitation on the potential at-risk beneficiary's access to coverage of frequently abused drugs it described in the initial notice, then the sponsor would be required to provide the beneficiary with an alternate second notice. Although not explicitly required by the statute, we believe this notice is consistent with the intent of the statute and is necessary to avoid beneficiary confusion and minimize unnecessary appeals. We propose generally that in such an alternate notice, the sponsor must notify the beneficiary that the sponsor no longer considers the beneficiary to be a potential at-risk beneficiary upon making such determination; will not place the beneficiary in its drug management program; will not limit the beneficiary's access to coverage for frequently abused drugs; and if applicable, that the SEP limitation no longer applies.     Specifically, we propose that Sec.  423.153(f)(7)(i) would read: Alternate second notice. (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary. Paragraph (f)(7)(ii) would require that the notice use language approved by the Secretary in a readable and understandable form containing the following information: (1) The sponsor has determined that the beneficiary is not an at-risk beneficiary; (2) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs; (3) If applicable, the SEP limitation no longer applies; (4) Clear instructions that explain how the beneficiary may contact the sponsor; and (5) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.     Again, as with the initial and second notices, we propose in a paragraph (f)(7)(iii) that the Part D sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(7)(i). Also, as with the initial and second notices, we propose in paragraph (ii) that the notice use language approved by the Secretary and be in a readable and understandable form; in paragraph (ii)(C)(4) that the notice contain clear instructions that explain how the beneficiary may contact the sponsor; and in paragraph (ii)(C)(5), that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the notice. (E) Timing of Notices (Sec.  423.153(f)(8))     Section 1860D-4(c)(5)(B)(iv) of the Act requires a Part D sponsor to provide the second notice to the beneficiary on a date that is not less than 30 days after the sponsor provided the initial notice to the beneficiary. We interpret the purpose of this requirement to be that the beneficiary should have ample time to provide information to the sponsor that may alter the sponsor's intended action that is contained in the initial notice to the beneficiary, or to provide the sponsor with the beneficiary's pharmacy and/or prescriber preferences, if the sponsor's intent is to limit the beneficiary's access to coverage for frequently abused drugs from selected a pharmacy(ies) and/or prescriber(s).     In addition, we propose to impose a deadline by when a sponsor must provide the second notice or alternate second notice to the beneficiary, although not specifically required by CARA. Such a requirement should provide the sponsor with sufficient time to complete the administrative steps necessary to execute the action the sponsor intends to take that was explained in the initial notice to the beneficiary, while acknowledging that the sponsor would have already met in the case management, clinical contact and prescriber verification requirement.     In the case of an alternate second notice, the timeframe should provide the beneficiary with definitive notice that the sponsor has not identified the beneficiary as an at-risk beneficiary and that there will be no limitation on his/her access to coverage for frequently abused drugs. Accordingly, we propose that the sponsor would be required to send either the second notice or the alternate second notice, as applicable, when it makes its determination or no later than 90 calendar days after the date on the initial notice, whichever comes sooner.     Specifically, we propose to include at Sec.  423.153(f)(8) the following: Timing of Notices. (i) Subject to paragraph (ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days and not more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice described in paragraph (f)(5) of this section. We intend this proposed timeframe for the sponsor to provide either the second notice or the alternate second notice, as applicable, to be reasonable for both Part D sponsors and the relevant beneficiaries and important to ensuring clear, timely and reasonable communication between the parties.     Section 1860D-4(c)(5)(B)(iv)(II) of the Act explicitly provides for an exception to the required timeframe for issuing a second notice. Specifically, the statute permits the Secretary to identify through rulemaking concerns regarding the health or safety of a beneficiary or significant drug diversion activities that would necessitate that a Part D sponsor provide the second written notice to the beneficiary before the 30 day time period normally required has elapsed. For this reason, we included the language, ``subject to paragraph (ii),'' at the beginning of proposed Sec.  423.153(f)(8)(i).

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    We note that the proposed definition of at-risk beneficiary would include beneficiaries for whom a gaining Part D plan sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon enrollment. This proposed definition is based on the language in section 1860-D-4(c)(5)(C)(i)(II) of the Act.     Given that this provision allows an at-risk identification to carry forward to the next plan, we believe it is appropriate to propose to permit a gaining plan to provide the second notice to an at-risk beneficiary so identified by the most recent prior plan sooner than would otherwise be required. For the same reasons, we believe that it would be appropriate to permit the gaining plan to even send the beneficiary a combined initial and second notice, under certain circumstances. However, because the content of the initial notice would not be appropriate for an at-risk beneficiary, and because such beneficiary would have already received an initial notice from his or her immediately prior plan sponsor, the content of this combined notice should only consist of the required content for the second notice so as not to confuse the beneficiary. Thus, our interpretation of section 1860D-4(c)(5)(B)(iv)(II) of the Act in conjunction with section 1860D- 4(c)(5)(C)(i)(II) of the Act is that a gaining Part D sponsor may send the second notice immediately to a beneficiary for whom the sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment. This is consistent with our current policy under which a gaining sponsor may immediately implement a beneficiary-specific opioid POS claim edit, if the gaining sponsor is notified that the beneficiary was subject to such an edit in the immediately prior plan and such edit had not been terminated.\19\ ---------------------------------------------------------------------------

    \19\ See ``Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,'' August 25, 2014. ---------------------------------------------------------------------------

    We propose that sending a second notice to an at-risk beneficiary so identified in the most recent plan would be permissible only if the new sponsor is implementing a beneficiary-specific POS claim edit for a frequently abused drug, or if the sponsor is implementing a limitation on access to coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) and has the same location of pharmacy(ies) and/or the same prescriber(s) in its provider network, as applicable, that the beneficiary used to obtain frequently abused drugs in the most recent plan. Otherwise, we propose that the new sponsor would be required to provide the initial notice to the at-risk beneficiary, even though the initial notice is generally intended for potential at-risk beneficiaries, and could not provide the second notice until at least 30 days had passed. This is because even though there would also be a concern for the at-risk beneficiary's health and safety in this latter case as well, this concern would be outweighed by the fact that the beneficiary had not been afforded a chance to submit his or her preference for a pharmacy(ies) and/or prescriber(s), as applicable, from which he or she would have to obtain frequently abused drugs to obtain coverage under the new plan's drug management program.     We propose to codify this policy by adding a paragraph (ii) to Sec.  423.153(f)(8), as noted earlier, to read as follows: Immediately upon the beneficiary's enrollment in the gaining plan, the gaining plan sponsor may provide a second notice described in paragraph (f)(6) to a beneficiary for whom the gaining sponsor received notice that the beneficiary was identified as an at-risk beneficiary by his or her most recent prior plan and such identification had not been terminated in accordance with Sec.  423.153(f)(14), if the sponsor is implementing either of the following: (A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i); or (B) A limitation on access to coverage as described in paragraph(f)(3)(ii), if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under (f)(9).     Some stakeholders commented that sponsors should be allowed to expedite the second notice in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court. However, given the importance of a beneficiary having advance notice of a pending limit on his or her access to coverage for frequently abused drugs and sufficient time to respond and/or prepare, we believe exceptions to the timing of the notices should be very narrow. Therefore, we have only included a proposal for an exception to shorten the 30 day timeframe between the initial and second notice that is based on a beneficiary's status as an at-risk beneficiary in an immediately preceding plan. We note that is a status the drug management provisions of CARA explicitly requires to be shared with the next plan sponsor, if a beneficiary changes plans, which means there would be a concrete data point for this proposed exception to the timing of the notices. We discuss such sharing of information later in the preamble. (viii) Provisions Specific to Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers (Sec. Sec.  423.153(f)(4), 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423,153(f)(13))     Some of the drug management program provisions in CARA are only relevant to ``lock-in''. We propose several regulatory provisions to implement these provisions, as follows: (A) Special Requirement To Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s) (Sec.  423.153(f)(4))     We believe prescriber lock-in should be a tool of last resort to manage at-risk beneficiaries' use of frequently abused drugs, meaning when a different approach has not been successful, whether that was a ``wait and see'' approach or the implementation of a beneficiary specific POS claim edit or a pharmacy lock-in. Limiting an at-risk beneficiary's access to coverage for frequently abused drugs from only selected prescribers impacts the beneficiary's relationship with his or her health care providers and may impose burden upon prescribers in terms of prescribing frequently abused drugs.     As a result, we propose that a sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary. We propose that this date be the date of the first OMS report that identified the beneficiary, so long as the beneficiary was also reported in the most recent OMS report that the sponsor received. This is because limiting the beneficiary's access to coverage of frequently abused drugs from a selected prescriber would only be necessary if the beneficiary continues to meet the clinical guidelines despite any existing

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intervention or limitation. We discuss OMS reports in more detail later.     We expect that the 6-month waiting period will provide the sponsor additional time to assess whether case management or another tool, such as a beneficiary-specific POS claim edit or pharmacy lock-in has failed to resolve the beneficiary's overutilization of frequently abused drugs. Sponsors have indicated in comments on the current policy that the case management process can take 3 to 6 months. Also, sponsors would need time to determine whether the beneficiary still meets the clinical guidelines and is thus continuing to be reported by OMS. Therefore, the time period we propose was chosen to account for time needed for the case management process and to align with the 6 month measurement period of the proposed clinical guidelines.     We seek comment on whether this 6-month waiting period would reduce provider burden sufficiently to outweigh the additional case management, clinical contact and prescriber verification that providers may experience if a sponsor believes a beneficiary's access to coverage of frequently abused drugs should be limited to a selected prescriber(s). Comments should include the additional operational considerations for sponsors to implement this proposal.     Given our proposal, we propose adding a paragraph (iv) to Sec.   423.153(f)(4) that would state: (f)(4)(iv) A Part D sponsor must not limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers under Sec.  423.153(f)(3)(ii)(A) unless--(A) At least 6 months has passed from the date the beneficiary was first identified as a potential at-risk beneficiary from the date of the applicable CMS identification report; and (B) The beneficiary meets the clinical guidelines and was reported by the most recent CMS identification report.     We note that in conducting the case management required under Sec.   423.153(f)(4)(i)(A) in anticipation of implementing a prescriber lock- in, the sponsor would be expected to update any case management it had already conducted. Also, even if a sponsor had already obtained the prescriber's agreement to implement a limitation on the beneficiary's coverage of frequently abused drugs to a selected pharmacy to comply with Sec.  423.153(f)(4)(i)(B), for example, the sponsor would have to obtain the agreement of the prescriber who would be selected to implement a limitation on a beneficiary's coverage of frequently abused drugs to a selected prescriber. Finally, we note that even if a sponsor had already provided the beneficiary with the required notices to comply with Sec.  423.153(f)(4)(i)(C), the sponsor would have to provide them again in order to remain compliant, because the beneficiary would not have been notified about the specific limitation on his or her access to coverage for frequently abused drugs to a selected prescriber(s) and has an opportunity to select the prescriber(s).     We foresee a scenario in which a sponsor may wish to implement a limitation on a beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) when the sponsor's first round of case management, clinical contact and prescriber verification resulted only in sending the prescribers of frequently abused drugs a written report about the beneficiary's utilization of frequently abused drugs and taking a ``wait and see'' approach, which did not result in the prescribers' adjusting their prescriptions for frequently abused drugs for their patient. In such a scenario, assuming the patient still meets the clinical guidelines and continues to be reported by OMS, the sponsor would need to try another intervention to address the opioid overuse. Another scenario could be that the sponsor implemented a pharmacy lock-in, but after 6-months, the beneficiary still meets the clinical guidelines due to receiving frequently abused drugs from additional prescribers. (B) Selection of Pharmacies and Prescribers (Sec. Sec.  423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423.153(f)(13)) (1) Beneficiary Preferences (Sec.  423.153(f)(9))     Section 1860D-4(c)(5)(D) of the Act provides that, if a sponsor intends to impose, or imposes, a limit on a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) or prescriber(s), and the potential at-risk beneficiary or at-risk beneficiary submits preferences for a pharmacy(ies) or prescriber(s), the sponsor must select the pharmacy(ies) and prescriber(s) for the beneficiary based on such preferences, unless an exception applies, which we will address later in the preamble. We further propose that such pharmacy(ies) or prescriber(s) must be in-network, except if the at-risk beneficiary's plan is a stand-alone prescription drug benefit plan and the beneficiary's preference involves a prescriber. Because stand-alone Part D plans (PDPs) do not have provider networks, and thus no prescriber would be in-network, the plan sponsor must generally select the prescriber that the beneficiary prefers, unless an exception applies. We discuss exceptions in the next section of this preamble. In our view, it is essential that an at-risk beneficiary must generally select in-network pharmacies and prescribers so that the plan is in the best possible position to coordinate the beneficiary's care going forward in light of the demonstrated concerns with the beneficiary's utilization of frequently abused drugs.     Accordingly, we propose Sec.  423.153(f)(9) to read: Beneficiary preferences. Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following--(i) Review such preferences and (ii) If the beneficiary is--(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s) or (B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s). If the beneficiary submits preferences for a non-network pharmacy(ies), or in the case of a Medicare Advantage prescription drug benefit plan a non-network prescriber(s), or both, the sponsor does not have to select or change the selection for the beneficiary to a non-network pharmacy or prescriber except if necessary to provide reasonable access.     In a paragraph (iii), we propose that the sponsor must inform the beneficiary of the selection in the second notice, or if not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission. Thus, this section would require a Part D plan sponsor to honor an at-risk beneficiary's preferences for in-network prescribers and pharmacies from which to obtain frequently abused drugs, unless the plan was a stand-alone PDP and the selection involves a prescriber. In other words, a stand-alone PDP or MA-PD does not have to honor a beneficiary's selection of a non-network pharmacy, except as necessary

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to provide reasonable access, which we discuss later in this section. Also, under our proposal, the beneficiary could submit preferences at any time. Finally, the sponsor would be required to confirm the selection in writing either in the second notice, if feasible, or within 14 days of receipt of the beneficiary's submission. (2) Exception to Beneficiary Preferences (Sec.  423.153(f)(10))     Section 1860D-4(c)(5)(D)(iv) of the Act, provides for an exception to an at-risk beneficiary's preference of prescriber or pharmacy from which the beneficiary must obtain frequently abused drugs, if the beneficiary's allowable preference of prescriber or pharmacy would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary. Section 1860-D-4(c)(5)(D)(iv) of the Act requires the sponsor to provide the at-risk beneficiary with at least 30 days written notice and a rationale for not honoring his or her allowable preference for pharmacy or prescriber from which the beneficiary must obtain frequently abused drugs under the plan.     A few commenters asserted there should be limits to how many times beneficiaries can submit their preferences. Other commenters stated there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection.     We are not proposing to place a limit on how many times beneficiaries can submit their preferences, but we are open to additional comments on this topic. We agree with commenters who stated that there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection, but we note that because such a situation would often involve a network pharmacy or prescriber, we would expect that the sponsor would also take appropriate action with respect to the pharmacy or prescriber, such as termination from the network.     Given the foregoing, we propose to add the following: Sec.   423.153(f)(10) Exception to Beneficiary Preferences. (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy or beneficiary. (ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with (A) At least 30 days advance written notice of the change; and (B) A rationale for the change. (3) Reasonable Access (Sec. Sec.  423.100, 423.153(f)(11), 423.153(f)(12))     If a potential at-risk beneficiary or at-risk beneficiary does not submit pharmacy or prescriber preferences, section 1860-D-4(c)(5)(D)(i) of the Act provides that the Part D sponsor shall make the selection. Section 1860-D-4(c)(5)(D)(ii) of the Act further provides that, in making the selection, the sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time.     We propose to add the following at Sec.  423.153(f)(11): Reasonable access. In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure both of the following: (i) That the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, the beneficiary's predominant usage of a prescriber or pharmacy or both, impact on cost-sharing, and reasonable travel time; and (ii) reasonable access to frequently abused drugs in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.     Since the statute explicitly allows the beneficiary to submit preferences, we interpret the additional reference to beneficiary preference in the context of reasonable access to mean that a beneficiary allowable preference should prevail over a sponsor's evaluation of geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy impact on cost-sharing and reasonable travel time. In the absence of a beneficiary preference for pharmacy and/or prescriber, however, a Part D plan sponsor must take into account geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy, impact on cost-sharing and reasonable time travel in selecting a pharmacy and/or prescriber, as applicable, from which the at-risk beneficiary will have to obtain frequently abused drugs under the plan. Thus, absent a beneficiary's allowable preference, or the beneficiary's selection would contribute to prescription drug abuse or drug diversion, the sponsor must ensure reasonable access by choosing the network pharmacy or prescriber that the beneficiary uses most frequently to obtain frequently abused drugs, unless the plan is a stand-alone PDP and the selection involves a prescriber(s). In the latter case, the prescriber will not be a network provider, because such plans do not have provider networks. In urgent circumstances, we propose that reasonable access means the sponsor must have reasonable policies and procedures in place to ensure beneficiary access to coverage of frequently abused drugs without a delay that may seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function.     Determining reasonable access may be complicated when an enrollee has multiple addresses or his or her health care necessitates obtaining frequently abused drugs from more than one prescriber and/or more than one pharmacy. Section 1860D-4(c)(5) addresses this issue by requiring the Part D plan sponsor to select more than one prescriber to prescribe frequently abused drugs and more than one pharmacy to dispense them, as applicable, when it reasonably determines it is necessary to do so to provide the at-risk beneficiary with reasonable access.     Given the foregoing, we propose the following at Sec.   423.153(f)(12): Selection of Prescribers and Pharmacies. (i) A Part D plan sponsor must select, as applicable--(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP and the selection involves a prescriber(s), in which case, the prescriber need not be a network prescriber; and (B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary.     We also propose to address chain pharmacies and group practices by adding a paragraph (ii) that states: (ii) (A) For purposes of this subsection (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy; and (B) For purposes of this subsection (f)(12), in the case of a group practice, all prescribers of the group practice shall be treated as one prescriber.     We would interpret these provisions to mean that a sponsor would be required to select more than one prescriber of frequently abused drugs, if more than one prescriber has asserted

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during case management that multiple prescribers of frequently abused drugs are medically necessary for the at-risk beneficiary. We further propose that if no prescribers of frequently abused drugs were responsive during case management, and the beneficiary does not submit preferences, the sponsor would be required to select the pharmacy or prescriber that the beneficiary predominantly uses to obtain frequently abused drugs. (4) Confirmation of Pharmacy and Prescriber Selection (Sec.   423.153(f)(13))     Section 1860D-4(c)(5)(D)(v) of the Act requires that, before selecting a prescriber or pharmacy, a Part D plan sponsor must notify the prescriber and/or pharmacy that the at-risk beneficiary has been identified for inclusion in the drug management program which will limit the beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s) and that the prescriber and/or pharmacy has been selected as a designated prescriber and/or pharmacy for the at-risk beneficiary.     We propose that plan sponsors can obtain a network provider's confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries' selected prescriber or pharmacy, as applicable. In these cases, the network provider would agree to forgo providing specific confirmation if selected under a drug management program to serve an at-risk beneficiary. However, the contract between the sponsor and the network provider would need to specify how the sponsor will notify the provider of its selection. Absent a provision in the network contract, however, the sponsor would be required to receive confirmation from the prescriber(s) and/or pharmacy(ies) that the selection is accepted before conveying this information to the at-risk beneficiary. Otherwise, the plan would need to make another selection and seek confirmation.     We propose Sec.  423.153(f)(13) to read: Confirmation of Selections(s). (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is (are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs. (ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both that the selection is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the prescriber or pharmacy will be notified by the sponsor of its selection. (ix) Drug Management Program Appeals (Sec. Sec.  423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, 423.638, 423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126)     Section 1860D-4(c)(5)(E) of the Act specifies that the identification of an individual as an at-risk beneficiary for prescription drug abuse under a Part D drug management program, a coverage determination made under such a program, the selection of a prescriber or pharmacy, and information sharing for subsequent plan enrollments shall be subject to reconsideration and appeal under section 1860D-4(h) of the Act. This provision also permits the option of an automatic escalation to external review to the extent provided by the Secretary.     As discussed earlier in this preamble, we are proposing to integrate the lock-in provisions with existing Part D Opioid DUR Policy/OMS. Determinations made in accordance with any of those processes, proposed at Sec.  423.153(f), and discussed previously, are interrelated issues that we collectively refer to as an ``at-risk determination'' made under a drug management program. The at-risk determination includes prescriber and/or pharmacy selection for lock- in, beneficiary-specific POS claim edits for frequently abused drugs, and information sharing for subsequent plan enrollments. Given the concomitant nature of the at-risk determination and associated aspects of the drug management program applicable to an at-risk beneficiary, we expect that any dispute under a plan's drug management program will be adjudicated as a single case involving a review of all aspects of the drug management program for the at-risk beneficiary. While a beneficiary who is subject to a Part D plan sponsor's drug management program always retains the right to request a coverage determination under existing Sec.  423.566 for any Part D drug that the beneficiary believes may be covered by their plan, we believe that appeals of an at-risk determination made under proposed Sec.  423.153(f) should involve consideration of all relevant elements of that at-risk determination. For example, if a Part D plan determines that a beneficiary is at-risk, implements a beneficiary-specific claim edit on 2 drugs that beneficiary is taking and locks that beneficiary into a specific pharmacy, the affected beneficiary should not be expected to raise a dispute about the pharmacy selection and about one of the claim edits in distinct appeals.     We note that, while section 1860D-4(c)(5)(B)(ii)(III) of the Act requires the initial written notice to the beneficiary, which identifies him or her as potentially being at-risk, to include ``notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h),'' we interpret ``such identification'' to refer to any subsequent identification that the beneficiary is actually at-risk. Because CARA, at section 1860D- 4(c)(5)(E) of the Act, specifically provides for appeal rights under subsection (h) but does not refer to identification as a potential at- risk beneficiary, we believe this interpretation is consistent with the statutory intent. Furthermore, when a beneficiary is identified as being potentially at-risk, but has not yet been identified as at-risk, the plan is not taking any action to limit such beneficiary's access to frequently abused drugs; therefore, the situation is not ripe for appeal. While an LIS SEP under Sec.  423.38 would be restricted at the time the beneficiary is identified as potentially at-risk under proposed Sec.  423.100, the loss of such SEP is not appealable under section 1860D-4(h) of the Act.     As noted previously, section 1860D-4(c)(5)(E) of the Act specifically refers to the Part D benefit appeals provisions in section 1860D-4(h) of the Act, which require Part D plan sponsors to meet the requirements of paragraphs (4) and (5) of section 1852(g) of the Act for benefits in a manner similar to the manner such requirements apply to MA organizations. Section 1852(g)(4) of the Act specifically provides for independent review of ``reconsiderations that affirm denial of coverage, in whole or in part (emphasis added).'' We believe section 1860D-4(c)(5)(E) of the Act broader reference to ``reconsideration and appeal'' should be interpreted to mean that individuals have a right to a plan level appeal, consistent with the reconsideration provisions under section 1860D-4(g) of the Act, followed by the right to independent review if the plan level affirms the initial adverse decision. In other words, we believe the reference to ``reconsideration'' means that a Part D plan sponsor should conduct the initial

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level of appeal following an at-risk determination under the plan sponsor's drug management program, consistent with the existing Part D drug benefit appeals process, despite the absence of a specific reference to section 1860D-4(g) of the Act.     Part D enrollees, plan sponsors, and other stakeholders are already familiar with the Part D benefit appeals process. Resolving disputes that arise under a plan sponsor's drug management program within the existing Part D benefit appeals process would allow at-risk beneficiaries to be more familiar with, and more easily access, the appeals process instead of creating a new process specific to appeals related to a drug management program. Also, allowing a plan sponsor the opportunity to review information it used to make an at-risk determination under the drug management program (and any additional relevant information submitted as part of the appeal) would be efficient for both the individual and the Medicare program because it would potentially resolve the issues at a lower level of administrative review. Conversely, permitting review by the independent review entity (IRE) before a plan sponsor has an opportunity to review and resolve any errors or omissions that may have been made during the initial at- risk determination would likely result in an unnecessary increase in costs for plan sponsors as well as CMS' Part D IRE contract costs.     As noted previously, the Secretary has the discretion under CARA to provide for automatic escalation of drug management program appeals to external review. Under existing Part D benefit appeals procedures, there is no automatic escalation to external review for adverse appeal decisions; instead, the enrollee (or prescriber, on behalf of the enrollee) must request review by the Part D IRE. Under the existing Part D benefit appeals process, cases are auto-forwarded to the IRE only when the plan fails to issue a coverage determination within the applicable timeframe. During the stakeholder call and in subsequent written comments, most commenters opposed automatic escalation to the IRE, citing support for using the existing appeals process for reasons of administrative efficiency and better outcomes for at-risk beneficiaries. The majority of stakeholders supported following the existing Part D appeals process, and some commenters specifically supported permitting the plan to review its lock-in decision prior to the case being subject to IRE review. Stakeholders cited a variety of reasons for their ***opposition***, including increased costs to plans, the IRE, and the Part D program. Stakeholders cited administrative efficiency in using the existing appeal process that is familiar to enrollees, plans, and the IRE, while other commenters expressed support for automatic escalation to the IRE as a beneficiary protection.     We are proposing that at-risk determinations made under the processes at Sec.  423.153(f) be adjudicated under the existing Part D benefit appeals process and timeframes set forth in Subpart M. However, we are not proposing to revise the existing definition of a coverage determination. The types of decisions made under a drug management program align more closely with the regulatory provisions in Subpart D than with the provisions in Subpart M related to coverage or payment for a drug based on whether the drug is medically necessary for an enrollee. Therefore, we believe it is clearer to set forth the rules for at-risk determinations as part of Sec.  423.153 and cross reference Sec.  423.153(f) in relevant provisions in Subpart M and Subpart U. While a coverage determination made under a drug management program would be subject to the existing rules related to coverage determinations, the other types of initial determinations made under a drug management program (for example, a restriction on the at-risk beneficiary's access to coverage of frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers) would be subject to the processes set forth at proposed Sec.   423.153(f). Consistent with existing rules for redeterminations at Sec.  423.582, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the second written notice to make such request, unless the enrollee shows good cause for untimely filing under Sec.  423.582(c). As previously discussed for proposed Sec.  423.153(f)(6), the second written notice is sent to a beneficiary the plan has identified as an at-risk beneficiary and with respect to whom the sponsor limits his or her access to coverage of frequently abused drugs regarding the requirements of the sponsor's drug management programs.     Also consistent with the existing Part D benefit appeals process, we are proposing that at-risk beneficiaries (or an at-risk beneficiary's prescriber, on behalf of the at-risk beneficiary) must affirmatively request IRE review of adverse plan level appeal decisions made under a plan sponsor's drug management program. In other words, under this proposal, an adverse redetermination would not be automatically escalated to the Part D IRE, unless the plan sponsor fails to meet the redetermination adjudication timeframe. We are also proposing to amend the existing Subpart M rules at Sec.  423.584 and Sec.  423.600 related to obtaining an expedited redetermination and IRE reconsideration, respectively, to apply them to appeals of a determination made under a drug management program. The right to an expedited appeal of such a determination, which must be adjudicated as expeditiously as the at-risk beneficiary's health condition requires, would ensure that the rights of at-risk beneficiaries are protected with respect to access to medically necessary drugs. While we are not proposing to adopt auto-escalation, we believe our proposed approach ensures that an at-risk beneficiary has the right to obtain IRE review and higher levels of appeal (ALJ/attorney adjudicator, Council, and judicial review). Accordingly, we also are proposing to add the reference to an ``at-risk determination'' to the following regulatory provisions that govern ALJ and Council processes: Sec. Sec.  423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126     Finally, we are also proposing a change to Sec.  423.1970(b) to address the calculation of the amount in controversy (AIC) for an ALJ hearing in cases involving at-risk determinations made under a drug management program in accordance with proposed Sec.  423.153(f). Specifically, we propose that the projected value of the drugs subject to the drug management program be used to calculate the amount remaining in controversy. For example, if the beneficiary is disputing the lock-in to a specific pharmacy for frequently abused drugs and the beneficiary takes 3 medications that are subject to the plan's drug management program, the projected value of those 3 drugs would be used to calculate the AIC, including the value of any refills prescribed for the drug(s) in dispute during the plan year.     In addition to the proposed changes related to the implementation of drug management program appeals, we are also proposing to make technical changes to Sec.  423.562(a)(1)(ii) to remove the comma after ``includes'' and replace the reference to ``Sec. Sec.  423.128(b)(7) and (d)(1)(iii)'' with a reference to ``Sec. Sec.  423.128(b)(7) and (d)(1)(iv).'' (x) Termination of a Beneficiary's Potential At-Risk or At-Risk Status (Sec.  423.153(f)(14))     Section 1860-D-4(c)(5)(F) of the Act provides that the Secretary shall develop standards for the termination of the identification of an individual as an at-risk beneficiary, which shall be the

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earlier of the date the individual demonstrates that he or she is no longer likely to be an at-risk beneficiary in the absence of limitations, or the end of such maximum period as the Secretary may specify.     Most commenters recommended a maximum 12-month period for an at- risk beneficiary to be locked-in. We also note that a 12-month lock-in period is common in Medicaid lock-in programs.\20\ A few commenters stated that a physician should be able to determine that a beneficiary is no longer an at-risk beneficiary. One commenter was opposed to an arbitrary termination based on a time period. ---------------------------------------------------------------------------

    \20\ Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug Fee-For Service Program (December 2016). ---------------------------------------------------------------------------

    Given that most commenters recommended a 12-month period and such a period is common in Medicaid ``lock-in'' program, we propose a maximum 12-month period for both a lock-in period, and also for the duration of a beneficiary-specific POS claim edit for frequently abused drugs through the addition of the following language at Sec.  423.153(f)(14): Termination of Identification as an At-Risk Beneficiary. The identification of an at-risk beneficiary as such shall terminate as of the earlier of the following--     (i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary; or     (ii) The end of a 12 calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section.     Thus, we note that if a beneficiary continues to meet the clinical guidelines and, if the sponsor implements an additional, overlapping limitation on the at-risk beneficiary's access to coverage for frequently abused drugs, the beneficiary may experience a coverage limitation beyond 12-months. The same is true for at-risk beneficiaries who were identified as such in the most recent prescription drug plan in which they were enrolled and the sponsor of his or her subsequent plan immediately implements a limitation on coverage of frequently abused drugs.     Section 1860-D-4(c)(5)(F)(ii) of the Act states that nothing in CARA shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary after such termination on the basis of additional information on drug use occurring after the date of notice of such termination. Accordingly, we note that our proposed approach to termination of an at-risk determination would not prevent an at-risk beneficiary from being subsequently identified as a potential at-risk beneficiary or at-risk beneficiary on the basis of new information on drug use occurring after the date of such termination that causes the beneficiary to once again meet the clinical guidelines. (xi) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments (Sec.  423.153(f)(15))     In order for Part D sponsors to conduct the case management/ clinical contact/prescriber verification required by proposed Sec.   423.153(f)(2), CMS must identify potential at-risk beneficiaries to sponsors who are in the sponsors' Part D prescription drug benefit plans. In addition, new sponsors must have information about potential at-risk beneficiaries and at-risk beneficiaries who were so identified by their immediately prior plan and enroll in the new sponsor's plan and such identification had not terminated before the beneficiary disenrolled from the immediately prior plan. Finally, as discussed earlier, sponsors may identify potential at-risk beneficiaries by their own application of the clinical guidelines on a more frequent basis. It is important that CMS be aware of which Part D beneficiaries sponsors identify on their own, as well as which ones have been subjected to limitations on their access to coverage for frequently abused drugs under sponsors' drug management programs for Part D program administration and other purposes. This data disclosure process would be consistent with current policy, as described earlier in this preamble.     As we also discussed earlier, under the current policy, CMS provides quarterly reports to sponsors about beneficiaries enrolled in their plans who meet the OMS criteria. In turn, Part D sponsors are expected to provide responses to CMS through the OMS for each case identified within 30 days of receiving a report that reflects the status or outcome of their case management.\21\ At the same time, also within 30 days, sponsors are expected to report additional beneficiaries to OMS that they identify using their own opioid overutilization identification criteria.\22\ ---------------------------------------------------------------------------

    \21\ See ``Medicare Part D Overutilization Monitoring System,'' July 5, 2013.     \22\ See ``Medicare Part D Overutilization Monitoring System, January 17, 2014. ---------------------------------------------------------------------------

    Regarding data disclosures, section 1860D-4(c)(5)(H) of the Act provides that, in the case of potential at-risk beneficiaries and at- risk beneficiaries, the Secretary shall establish rules and procedures to require the Part D plan sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.     Sponsors also report information to CMS' MARx system about pending, implemented and terminated beneficiary-specific POS claim edit for opioids within 7 business days of the date on the applicable beneficiary notice or of the termination.\23\ The MARx system transfers information about pending and implemented claim edits to the gaining sponsor with the beneficiary's enrollment record if the beneficiary disenrolls and enrolls in the gaining sponsor's plan. If a gaining sponsor requests case management information from the losing sponsor about the beneficiary, we expect the losing sponsor to transfer the information to the gaining sponsor as soon as possible, but no later than 2 weeks from the date of the gaining sponsor's request.\24\ ---------------------------------------------------------------------------

    \23\ Final Parts C&D 2017 Call Letter, April 4, 2016.     \24\ See ``Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,'' August 25, 2014. ---------------------------------------------------------------------------

    Section 1860-D-4(c)(5)(I) of the Act requires that the Secretary establish procedures under which Part D sponsors must share information when at-risk beneficiaries or potential at-risk beneficiaries enrolled in one prescription drug plan subsequently disenroll and enroll in another prescription drug plan offered by the next sponsor (gaining sponsor). We plan to expand the scope of the reporting to MARx under the current policy to include the ability for sponsors to report similar information to MARx about all pending, implemented and terminated limitations on access to coverage of frequently abused drugs associated with their plans' drug management programs.     We propose to codify the data disclosure and information sharing process under the current policy, with the expansion just described, by adding the following requirement to Sec.  423.153: (f)(15) Data Disclosure. (i) CMS identifies each potential at-risk beneficiary to the sponsor of the prescription drug plan in which the beneficiary is enrolled. (ii) A Part D sponsor that operates a drug management program must disclose any

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data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner, specified by CMS. The data and information disclosures must do all of the following: (A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS; (B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries; (C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs; and (D) Transfer case management information upon request of a gaining sponsor as soon as possible but no later than 2 weeks from the gaining sponsor's request when: (1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and (2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment. (xii) Summary     Our proposal is intended to be responsive to stakeholder input that CMS focus on opioids; allow for flexibility to adjust the clinical guidelines and frequently abused drugs in the future; is reflective of the importance of the provider-patient relationship; protects beneficiary's rights and access, and allows for operational manageability and consistency with the current policy to the extent possible. This proposal, if finalized, should result in effective Part D drug management programs within a regulatory framework provided by CMS, and further reduce opioid overutilization in the Part D program. 2. Flexibility in the Medicare Advantage Uniformity Requirements     We have determined that providing access to services (or specific cost sharing for services or items) that is tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the Medicare Advantage (MA) regulations at Sec.   422.100(d). This regulatory requirement is a means to implement both section 1852(d) of the Act, which requires that benefits under the MA plan be available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. We have determined that these statutory provisions and the regulation at Sec.  422.100(d) mean that we have the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. For example, reduced cost sharing flexibility would allow an MA plan to offer diabetic enrollees zero cost sharing for endocrinologist visits. Similarly, with this flexibility, a MA plan may offer diabetic enrollees more frequent foot exams as a tailored, supplemental benefit. In addition, with this flexibility, a MA plan may offer diabetic enrollees a lower deductible. Under this example, non-diabetic enrollees would not have access to these diabetic-specific tailored cost-sharing or supplemental benefits; however, any enrollee that develops diabetes would then have access to these benefits.     Such flexibility under our new interpretation of the uniformity requirement is not without limits, however, as section 1852(b)(1)(A) of the Act prohibits an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health- status related factors. MA regulations (for example, Sec. Sec.   422.100(f)(2) and 422.110(a)) reiterate and implement this non- discrimination requirement. In interpreting these obligations to protect against discrimination, we have historically indicated that the purpose of the requirements is to protect high-acuity enrollees from adverse treatment on the basis of their higher cost health conditions (79 FR 29843; 76 FR 21432; and 74 FR 54634). As MA plans consider this new flexibility in meeting the uniformity requirement, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations.\25\ MA plans that exercise this flexibility must ensure that the cost sharing reductions and targeted supplemental benefits are for health care services that are medically related to each disease condition. CMS will be concerned about potential discrimination if an MA plan is targeting cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other higher-cost conditions. We will review benefit designs to make sure that the overall impact is non- discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations. ---------------------------------------------------------------------------

    \25\ Among these responsibilities and obligations are compliance with Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act. ---------------------------------------------------------------------------

    For example, an MA plan could identify enrollees diagnosed with specific diseases, such as diabetes, chronic heart failure, and COPD, as medically vulnerable and in need of certain services, which could be offered to these enrollees in the form of tailored supplemental benefits. In identifying eligible enrollees, the MA plan must use medical criteria that are objective and measurable, and the enrollee must be diagnosed by a plan provider or have their existing diagnosis certified or affirmed by a plan provider to assure equal application of the objective criteria necessary to provide equal treatment of similarly situated individuals.     For contract year 2019, we are considering issuing guidance clarifying the flexibility MA plans have to offer targeted supplemental benefits for their most medically vulnerable enrollees. A benefit package that offers differential access to enhanced services or benefits or reduced cost sharing or different deductibles based on objective criteria, and ensures equal treatment of similarly situated enrollees, for whom such services and benefits are useful, can be priced at a uniform premium consistent with the requirements for availability and accessibility throughout the service area for all enrollees in section 1852(d)(1)(A) of the Act and for uniform bids and premiums in section 1854(c) of the Act. We believe this flexibility will help MA plans better manage health care services for the most vulnerable enrollees. The benefit and cost sharing flexibility we have discussed here applies to Part C benefits but not Part D benefits. We are requesting comments and/or questions from stakeholders about the implementation of this flexibility. We note that CMS is currently testing value based insurance design (VBID) through the use of our demonstration authority under Section 1115A of the Act (42 U.S.C 1315a, added by Section 3021 of the Affordable Care Act), which will include some of the elements we have discussed

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previously. However, there are also features of the VBID demonstration that are unique to the demonstration test. We expect the VBID demonstration to provide CMS with insights into future VBID innovations for the MA program. 3. Segment Benefits Flexibility     In reviewing section 1854(h) of the Social Security Act and Medicare Advantage (MA) regulations governing plan segments, we have determined that the statute and existing regulations may be interpreted to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. Plans segments are county-level portions of a plan's overall service area which, under current CMS policy, are permitted to have different premiums and cost sharing amounts as long as these premiums and cost sharing amounts are uniform throughout the segment. We are proposing to revise our interpretation of the existing statute and regulations to allow MA plan segments to vary by benefits in addition to premium and cost sharing, consistent with the MA regulatory requirements defining segments at Sec.  422.262(c)(2). 4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (Sec. Sec.  422.100 and 422.101)     As provided at Sec.  422.100(f)(4) and (5) and Sec.  422.101(d)(2) and (3), all Medicare Advantage (MA) plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)), must establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS. CMS added Sec. Sec.  422.100(f)(4) and (f)(5), effective for coverage in 2011, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory) (75 FR 19709-11). Section 1858(b)(2) of the Act requires a limit on in-network out-of-pocket expenses for enrollees in Regional MA Plans. In addition, Local Preferred Provider Organization (LPPO) plans, under Sec.   422.100(f)(5), and Regional PPO (RPPO) plans, under section 1858(b)(2) of the Act and Sec.  422.101(d)(3), are required to have a ``catastrophic'' limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the annual limit which is also established by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services, excluding plan premium, must be included in each plan's Maximum Out-of-Pocket (MOOP) amount subject to these limits.     As discussed in the 2010 rulemaking (75 FR 19709), CMS affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. The percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7 percent in CY 2011 to 68.1 percent in CY 2017. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51 percent in CY 2011 to 21 percent in CY 2017.     As stated in the CY 2018 final Call Letter \26\ and in the 2010 final rule (75 FR 19710), CMS currently sets MOOP limits based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare Fee-for-Service (FFS) for local and regional MA plans. The mandatory MOOP amount represents approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, 5 percent of Medicare FFS beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments, and coinsurance. The voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs. The Office of the Actuary conducts an annual analysis to help CMS determine the MOOP limits. Since the MOOP requirements for local and regional MA plans were finalized in regulation, a strict application of the 95th and 85th percentile would have resulted in MOOP limits for local and regional MA plans fluctuating from year-to-year. Therefore, CMS has exercised discretion in order to maintain stable MOOP limits from year-to-year, when the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages year over year, and does not discourage the adoption of the lower voluntary MOOP amount because of fluctuations in the amount. CMS expects to change MOOP limits if a consistent pattern of increasing or decreasing costs emerges over time. ---------------------------------------------------------------------------

    \26\ The CY 2018 final Call Letter may be accessed at [*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html*](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html) ---------------------------------------------------------------------------

    As part of the annual Call Letter process, stakeholders have suggested changes to how CMS establishes MOOP limits. Some of the comments suggested CMS use Medicare FFS and MA encounter data to inform its decision-making. Other suggestions received have included increasing the voluntary MOOP limit, increasing the number of service categories that have higher cost sharing in return for a plan offering a lower MOOP limit, and considering three levels of MOOP and service category cost sharing to encourage plan offerings with lower MOOP limits.     CMS's goal is to establish future MOOP limits based on the most relevant and available data, or combination of data, that reflects beneficiary health care costs in the MA program and maintains benefit stability over time. Medicare FFS data currently represents the most relevant and available data at this time. CMS may consider future rulemaking regarding the use of MA encounter cost data to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. Under this current proposal to revise the regulations controlling MOOP limits, CMS might change its existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending in the future. CMS expects to establish future limits by striking the appropriate balance between limiting MOOP costs and potential changes in premium, benefits, and cost sharing with the goal of making sure beneficiaries can access affordable and sustainable benefit packages. While CMS intends to continue using the 85th and 95th percentiles of projected beneficiary out-of-pocket spending for the immediate future to set MA MOOP limits, CMS proposes to amend the regulation text in Sec. Sec.  422.100(f)(4) and (5) and 422.101(d)(2) and (d)(3) to incorporate authority to balance factors discussed previously. The flexibility provided by these proposed changes will permit CMS to annually adjust mandatory and voluntary MOOP limits based on changes in market conditions and to ensure the sustainability of the MA program and benefit options.     The proposed new authority permitting changes in data and methodology related to establishing MOOP limits would be exercised by CMS in advance of each plan year; CMS would use the annual Call Letter and other guidance documents to explain its application of this proposed regulatory standard and the data used to identify MOOP limits in advance of bid

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deadlines. This will provide MA organizations adequate time to comment and prepare for changes. In addition, CMS plans to transition any significant changes under this proposal over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.     CMS proposes to codify specific requirements because of the number of comments received in the past about MOOP changes. CMS proposes to amend Sec. Sec.  422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3) to clarify that CMS may use Medicare FFS data to establish annual MOOP limits. In addition, CMS would have authority to increase the voluntary MOOP limit to another percentile level of Medicare FFS, increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount, and implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits. This proposal includes authority to increase the number of service categories that have higher cost sharing in return for offering a lower (voluntary) MOOP amount and considering more than two levels of MOOP (with associated cost sharing limits) to encourage plan offerings with lower MOOP limits. Consistent with past practice, CMS will continue to publish annual limits and a description of how the regulation standard was applied (that is, the methodology used) in the annual Call Letter prior to bid submission so that MA plans can submit bids consistent with parameters that CMS has determined to meet the cost sharing limits requirements. CMS seeks comments and suggestions on the topics discussed in this section. 5. Cost Sharing Limits for Medicare Parts A and B Services (Sec. Sec.   417.454 and 422.100)     As provided at Sec. Sec.  417.454(e), 422.100(f)(6), and 422.100(j), MA plan cost sharing for Parts A and B services specified by CMS must not exceed certain levels. Section 422.100(f)(6) provides that cost sharing must not be discriminatory and CMS determines annually the level at which certain cost sharing becomes discriminatory. Sections 417.454(e) and 422.100(j), on the other hand, are based on how section 1852(a)(1)(B)(iii) and (iv) of the Act directs that cost sharing for certain services may not exceed cost sharing levels in Medicare Fee-for-Service (FFS); under the statute and the regulations, CMS may add to that list of services. CMS reviews cost sharing set by MA organizations using parameters based on Parts A and B services that are more likely to have a discriminatory impact on beneficiaries. The review parameters are currently based on Medicare FFS data and reflect a combination of patient utilization scenarios and length of stays or services used by average to sicker patients. CMS uses multiple utilization scenarios for some services (for example, inpatient care) to guard against MA organizations distributing benefit cost sharing amounts in a manner that is discriminatory. Review parameters are also established for frequently used professional services, such as primary and specialty care services.     CMS proposes here to amend Sec.  422.100(f)(6) to clarify that it may use Medicare FFS data to establish appropriate cost sharing limits. In addition, CMS intends to use MA utilization encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory; we solicit comment on whether to codify that use of MA encounter data for this purpose in Sec.  422.100(f)(6). This proposal is not related to a statutory change.     This proposal aims to allow CMS to use the most relevant and appropriate information in determining whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory. CMS intends to continue the practice of furnishing information to MA organizations about the methodology used to establish cost sharing limits and the thresholds CMS identifies as non-discriminatory through the annual Call Letter process or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows MA organizations to prepare plan bids consistent with parameters that CMS have determined to be non-discriminatory.     As specified in section 1852(a)(1)(B)(iv) of the Act, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. Although CMS has not established a specific service category cost sharing limit for all possible services, CMS has issued guidance that MA plans must pay at least 50 percent of the contracted (or Medicare allowable) rate and that cost sharing for services cannot exceed 50 percent of the total MA plan financial liability for the benefit in order for the cost sharing for such services to be considered non-discriminatory; CMS believes that cost sharing (service category deductibles, copayments or co- insurance) that fails to cover at least half the cost of a particular service or item acts to discriminate against those for whom those services and items are medically necessary and discourages enrollment by beneficiaries who need those services and items. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Medicare FFS service category cannot exceed 50 percent of the average contracted rate of that service under this guidance (Medicare Managed Care Manual, Chapter 4, Section 50.1). Some service categories may identify specific benefits for which a unique copayment would apply, while others include a variety of services with different levels of cost which may reasonably have a range of copayments based on groups of similar services, such as durable medical equipment or outpatient diagnostic and radiological services.     CMS affords MA plans that adopt a lower, voluntary MOOP limit greater flexibility in establishing Parts A and B cost sharing than is available to plans that adopt the higher, mandatory MOOP limit. As discussed in section III.A.5, CMS intends to continue to establish more than one set of Parts A and B service cost sharing thresholds for plans choosing to offer benefit designs with either a lower, voluntary MOOP limit or the higher, mandatory MOOP limit set under Sec. Sec.   422.100(f)(4) and (5) and 422.101(d)(2) and (3). Medicare FFS data currently represents the most relevant and available data at this time and is used to evaluate cost sharing for specific services as well in applying the standard currently at Sec.  422.100(f)(6) and in considering CMS's authority to add (by regulation) categories of services for which cost sharing may not exceed levels in Medicare FFS.     As noted with regard to setting MOOP limits under Sec. Sec.   422.100 and 422.101, CMS expects that MA encounter data will be more accurate and complete in the future and may consider future rulemaking regarding the use of MA encounter to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. For reasons discussed in section III.A.5, CMS proposes to amend Sec.  422.100(f)(6) to permit use of Medicare FFS to evaluate whether cost sharing for Part A and B services is discriminatory to set the evaluation limits announced each year in the Call Letter: in addition, we propose to use MA utilization encounter data as part of that evaluation process. As with the proposal to authorize use of this data for setting MOOP limits, CMS intends to use the Advance Notice/Call Letter process to communicate its

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application of the regulation and to transition any significant changes over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.     This proposal will allow CMS to use the most relevant and appropriate information in determining cost sharing standards and thresholds. For example, analyses of MA utilization encounter data can be used with Medicare FFS data to establish the appropriate utilization scenarios to determine MA plan cost sharing standards and thresholds. CMS seeks comments and suggestions on this proposal, particularly whether additional regulation text is needed to achieve CMS's goal of setting and announcing each year presumptively discriminatory levels of cost sharing. 6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (Sec. Sec.  422.254 and 422.256)     As provided at Sec. Sec.  422.254(a)(4) and 422.256(b)(4), CMS will only approve a bid submitted by a Medicare Advantage (MA) organization if its plan benefit package is substantially different from those of other plans offered by the organization in the area with respect to key plan characteristics such as premiums, cost sharing, or benefits offered. MA organizations may submit bids for multiple plans in the same area under the same contract only if those plans are substantially different from one another based on CMS's annual meaningful difference evaluation standards. CMS proposes to eliminate this meaningful difference requirement beginning with MA bid submissions for contract year (CY) 2019. Separate meaningful difference rules were concurrently adopted for MA and stand-alone prescription drug plans (PDPs), but this specific proposal is limited to the meaningful difference provision related to the MA program. This proposal is not related to a statutory change.     This proposal aims to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation. CMS will maintain requirements that prohibit plans from misleading beneficiaries in their communication materials, provide CMS the authority to disapprove a bid if a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare- eligible individuals, and allow CMS to non-renew a plan that fails to attract a sufficient number of enrollees over a sustained period of time (Sec. Sec.  422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects organizations to continue designing plan benefit packages that, within a service area, are different from one another with respect to key benefit design characteristics, so that any potential beneficiary confusion is minimized when comparing multiple plans offered by the organization. For example, beneficiaries may consider the following factors when they make their health care decisions: plan type, Part D coverage, differences in provider network, Part B and plan premiums, and unique populations served (for example, special needs plans, or SNPs). In addition, CMS intends to continue the practice of furnishing information to MA organizations about their bid evaluation methodology through the annual Call Letter process and/or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows CMS to articulate bid requirements and MA organizations to prepare bids that satisfy CMS requirements and standards prior to bid submission in June each year.     Research studies indicate that consumers, especially elderly consumers, may be challenged by a large number of plan choices that may: (1) Result in not making a choice, (2) create a bias to not change plans, and (3) impact MA enrollment growth.\27\ Beneficiaries indicate they want to make informed and effective decisions, but do not feel qualified. As a result, they seek help from Medicare Plan Finder (MPF), brokers or plan representatives, providers, and family members. Although challenged by choices, beneficiaries do not want their plan choices to be limited and understand key decision factors such as premiums, out-of-pocket cost sharing, Part D coverage, familiar providers, and company offering the plan.\28\ CMS continues to explore enhancements to MPF that will improve the customer experience; some examples of recent updates are provided below. ---------------------------------------------------------------------------

    \27\ McWilliams JM, Afendulis CC, McGuire TG, Landon BE. Complex Medicare advantage choices may overwhelm seniors--especially those with impaired decision making. Health Aff (Millwood). 2011;30(9):1786-94.     \28\ Jacobson, G. Swoope, C., Perry, M. Slosar, M. How are seniors choosing and changing health insurance plans? Kaiser Family Foundation. 2014. ---------------------------------------------------------------------------

    As discussed later in this section, CMS believes that it is challenging to apply the current standardized meaningful difference evaluation (which is applied consistently to all plans) in a manner that accommodates and evaluates important considerations objectively. CMS is concerned that the current evaluation may create unintended consequences related to innovative benefit designs. In addition, CMS's efforts in implementing more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices. For example, in MPF, plan details have been expanded to include MA and Part D benefits and a new consumer friendly tool for the CY 2018 Medicare open enrollment period which will assist beneficiaries in choosing a plan that meets their unique and financial needs based on a set of 10 quick questions.     Prior to implementing the meaningful difference evaluation for CY 2011 bid submissions, the beneficiary weighted average number of plans per county was about 30 in 2010 compared to 18 in 2017 (these numbers do not include SNPs or employer group plans which have additional criteria for enrollment). Private-fee-for-service (PFFS) plans represented 13 of the 30 plans in 2010 and less than 1 of the 18 plans in 2017. The Medicare Improvements for Patients and Providers Act of 2008 required PFFS plans to establish contracted provider networks by 2011 and many PFFS plans non-renewed. The weighted average number of plans has remained relatively stable since the decline of PFFS options. MA enrollment continued to grow from more than 11 million in July 2010 to 18.7 million in July 2017, fueled by the continued overall acceptance of managed care, the baby boom generation aging into Medicare beginning in 2011, and decreases in average plan premium during the time period.     As stated in the October 22, 2009, proposed rule (74 FR 54670 through 73) and April 15, 2010, final rule (75 FR 19736 through 40), CMS's goal for the meaningful difference evaluation was to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. The meaningful difference evaluation was initiated when cost sharing and benefits were relatively consistent within each plan and similar plans within the same contract could be readily compared by measuring estimated out-of-pocket costs and other factors currently integrated in the evaluation's methodology.     The current meaningful difference evaluation uses estimated enrollee out-of-pocket costs based on the CMS Out-of-Pocket Cost (OOPC) model. This model uses a nationally representative cohort of beneficiaries from the Medicare Beneficiary Surveys (MCBS)

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and is intended to be objective and applied in a standardized and consistent manner across plans. MCBS data collected by CMS from beneficiaries are used to create the cohort of beneficiaries whose medical and prescription data are used to estimate out-of-pocket costs. The OOPC model generates estimated out-of-pocket costs based on utilization from the cohort of beneficiaries and each plan's benefit design entered into the Plan Benefit Package submitted to CMS as part of the bidding process. Detailed information about the meaningful difference evaluation is available in the CY 2018 Final Call Letter issued April 3, 2017 (pages 115-118) and information about the CMS OOPC model is available at: [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html) Estimated enrollee cost sharing is determined by the cost sharing amounts for Part A, B, and D services and most mandatory supplemental benefits (for example, dental services). Benefit service categories within a plan may have a range of multiple and varying cost sharing amounts. For example, the outpatient procedures, tests, labs, and radiology services benefit category includes many services that may have a wide range of cost sharing amounts. The OOPC model uses the minimum or lowest cost sharing value placed in the Plan Benefit Package (PBP) for each service category to estimate out-of-pocket costs in these situations. As discussed in the CY 2018 Final Call Letter, the differences between similar plans must have at least a $20 per member per month estimated beneficiary out-of-pocket cost difference. Differences in plan type (for example, HMO, LPPO), SNP sub-type, and inclusion of Part D coverage are considered meaningful differences which aligns with beneficiary decision-making. Premiums, risk scores, actual plan utilization and enrollment are not included in the evaluation because these factors would introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity.     Based on CMS's efforts to revisit MA standards and the implementation of the governing law to find flexibility for MA beneficiaries and plans, MA organizations are able to: (1) Tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data which was communicated in CY 2011 guidance; (2) establish Provider Specific Plans (PSPs) designed to offer enrollees benefits through a subset of the overall contracted network in a given service area, which are sometimes referred to as narrower networks, and which was collected in the PBP beginning in CY 2011; and (3) beginning in CY 2019, provide different cost sharing and/or additional supplemental benefits for enrollees based on defined health conditions within the same plan (Flexibility in the Medicare Advantage Uniformity Requirements). These flexibilities allow MA organizations to provide beneficiaries with access to health care benefits that are tailored to individual needs, but make it difficult for CMS to objectively measure meaningful differences between plans. Items 1 and 3 provide greater cost sharing flexibility to address individual beneficiary needs, but result in a much broader range of cost sharing values being entered into PBP. As discussed in the previous paragraph, the CMS OOPC model uses the lowest cost sharing value for each service category to estimate out-of-pocket costs which may or may not be a relevant comparison between different plans for purposes of evaluating meaningful difference when variable cost sharing of this type is involved.     CMS remains committed to ensuring transparency in plan offerings so that beneficiaries can make informed decisions about their health care plan choices. It is also important to encourage competition, innovation, and provide access to affordable health care approaches that address individual needs. The current meaningful difference methodology evaluates the entire plan and does not capture differences in benefits that are tied to specific health conditions. As a result, the meaningful difference evaluation would not fully represent benefit and cost sharing differences experienced by enrollees and could lead to MA organizations to focus on CMS standards, rather than beneficiary needs, when designing benefit packages.     In order to capture differences in provider network, more tailored benefit and cost sharing designs, or other innovations, the evaluation process would have to use more varied and complex assumptions to identify plans that are not meaningfully different from one another. CMS believes that such an evaluation could result in more complicated and potentially confusing benefit designs to achieve differences between plans. This process may require greater administrative resources for MA organizations and CMS, while not producing results that are useful to beneficiaries.     The current meaningful difference methodology may force MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs. To satisfy current CMS meaningful difference standards, MA organizations may have to change benefit coverage or cost sharing in certain plans to establish the necessary benefit value difference, even if substantial difference exists based on factors CMS is currently unable to incorporate into the evaluation (such as tiered cost sharing, and unique benefit packages based on enrollee health conditions). Although these changes in benefits coverage may be positive or negative, CMS is concerned the meaningful difference requirement results in organizations potentially reducing the value of benefit offerings. On the basis of bid review activities performed over the past several years, CMS is concerned that benefits may be decreased or cost sharing increased to satisfy the meaningful difference evaluation. These are unintended consequences of the existing meaningful difference evaluation and may restrict innovative benefit designs that address individual beneficiary needs and affordability.     Beneficiaries may also consider plan and Part B premiums when choosing among health plan options. Making changes to the existing meaningful difference evaluation to consider premiums differences as sufficient to distinguish among otherwise similar plans may limit the value of CMS's evaluation by introducing factors that plans can easily leverage, such as risk selection, costs, and margin, to satisfy the evaluation test without resulting in additional benefit value or choice for enrollees.     Stakeholders have expressed concern that without the meaningful difference evaluation the number of bids and plan choices will likely increase and make beneficiary decisions more difficult. The number of plan bids may increase because of a variety of factors, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but CMS does not believe the number of similar plan options offered by the same MA organization in each county will necessarily increase significantly or create confusion in beneficiary decision-making. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision-making should help

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beneficiaries, caregivers, and family members make informed plan choices among more individualized plan offerings. Based on the previously stated information, CMS does not expect a significant increase in time spent in bid review as a direct result of eliminating meaningful difference nor increased health care provider burden.     In addition, new flexibilities in benefit design may allow MA organizations to address different beneficiary needs within existing plan options and reduce the need for new plan options to navigate existing CMS requirements. In addition, MA organizations may be able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums which would allow beneficiaries to make more effective decisions if the MA organizations are not required to change benefit and cost sharing designs in order to satisfy Sec. Sec.  422.254 and 422.256 Currently, MA organizations must satisfy CMS meaningful difference standards (and other requirements), rather than solely focusing on beneficiary purchasing needs when establishing a range of plan options.     CMS supports beneficiary decision-making by providing tools and materials that focus on key beneficiary purchasing criteria, such as eligibility to enroll in SNPs, need for Part D coverage, Part D formulary and benefit coverage, plan type preference (for example, HMO vs. PPO), network providers, medical benefit coverage, premiums, and the brand or organization offering the plan options. CMS is also taking steps to improve information available through MPF and 1-800-MEDICARE to help beneficiaries, caregivers, and family members make informed plan choices.     CMS continually evaluates consumer engagement tools and outreach materials (including marketing, educational, and member materials) to ensure information is formatted consistently so beneficiaries can easily compare multiple plans. CMS also provides annual guidance and model materials to MA organizations to assist them in providing resources, such as the plan's Annual Notice of Change and Evidence of Coverage, which contain valuable information for the enrollee to evaluate and select the best plan for their needs. To reinforce informed decision making, CMS invests substantial resources in engagement strategies such as 1-800-MEDICARE, MPF, standard and electronic mail, and social media to continuously communicate with beneficiaries, caregivers, family members, providers, community resources, and other stakeholders.     CMS will continue to furnish information to MA organizations and solicit comments on bid evaluation methodology through the annual Call Letter process or HPMS memoranda, as appropriate.     In addition, CMS is maintaining requirements around plans not misleading beneficiaries in communication materials, disapproving a bid if CMS finds that a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and non-renewing plans that fail to attract a sufficient number of enrollees over a sustained period of time (Sec. Sec.   422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects these measures will continue to protect beneficiaries from discriminatory plan benefit packages and health plans that demonstrate a lack of beneficiary interest if the meaningful difference requirement is eliminated. For all these reasons, CMS proposes to remove Sec. Sec.   422.254(a)(4) and 422.256(b)(4) to eliminate the meaningful difference requirement for MA bid submissions. CMS seeks comments and suggestions on the topics discussed in this section about making sure beneficiaries have access to innovative plans that meet their unique needs. 7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (Sec. Sec.  422.66 and 422.68)     Section 1851(c)(3)(A)(ii) of the Act provides the Secretary with the authority to implement default enrollment rules for the Medicare Advantage (MA) program in addition to the statutory direction that beneficiaries who do not elect an MA plan are defaulted to original (fee-for-service) Medicare. This provision states that the Secretary may establish procedures whereby an individual currently enrolled in a non-MA health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA plan offered by the organization if he or she does not elect to receive Medicare coverage in another way.     We initially addressed default enrollment upon conversion to Medicare in rulemaking (70 FR 4606 through 4607) in 2005, indicating that we would retain the flexibility to implement this provision through future instructions and guidance to MA organizations. Such subregulatory guidance was established later that same year and was applicable to the 2006 contract year. As outlined in Chapter 2 of the Medicare Managed Care Manual, we established an optional enrollment mechanism, whereby MA organizations may develop processes and, with CMS approval, provide seamless continuation of coverage by way of enrollment in an MA plan for newly MA eligible individuals who are currently enrolled in other health plans offered by the MA organization (such as commercial or Medicaid plans) at the time of the individuals' initial eligibility for Medicare. The guidance emphasized that MA organizations not limit seamless continuation of coverage to situations in which an enrollee becomes eligible for Medicare by virtue of age, but includes all newly eligible Medicare beneficiaries, including those whose Medicare eligibility is based on disability. We did not mandate that organizations implement a process for seamless continuation of coverage but, instead, gave organizations the option of implementing such a process for its enrollees who are approaching Medicare eligibility. From its inception, the guidance has required that individuals receive advance notice of the proposed MA enrollment and have the ability to ``opt out'' of such an enrollment prior to the effective date of coverage. This guidance has been in practice for the past decade for MA organizations that requested to use this voluntary enrollment mechanism, but we have encountered complaints and heard concerns about the practice. We are proposing new regulation text to establish limits and requirements for these types of default enrollments to address these concerns and our administrative experience with seamless continuation of coverage, commonly referred to as seamless conversion.     Based on our experience with the seamless conversion process thus far, we are proposing, to be codified at Sec.  422.66(c)(2), requirements for seamless default enrollments upon conversion to Medicare. As proposed in more detail later in this section, such default enrollments would be into dual eligible special needs plans (D- SNPs) and be subject to five substantive conditions: (1) The individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (2) the state has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization; (3) the individual does not opt out of the default enrollment; (4) the MA

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organization provides a notice that meets CMS requirements to the individual; and (5) CMS has approved the MA organization to use the default enrollment process before any enrollments are processed. We are also proposing that coverage under these types of default enrollments begin on the first of the month that the individual's Part A and Part B eligibility is effective. We are also proposing changes to Sec. Sec.   422.66(d)(1) and (d)(5) and 422.68 that coordinate with the proposal for Sec.  422.66     In the Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter, we explained how entities that sponsor Medicaid managed care organizations (MCOs) and affiliated D- SNPs can promote coverage of an integrated Medicare and Medicaid benefit through existing authority for seamless continuation of coverage of Medicaid MCO members as they become eligible for Medicare. We received positive comments from state Medicaid agencies that supported this enrollment mechanism and requested that we clarify the process for approval of seamless continuation of coverage as a mechanism to promote enrollment in integrated D-SNPs that deliver both Medicare and Medicaid benefits. We also received comments from beneficiary advocates asking that additional consumer protections, including requiring written beneficiary confirmation and a special enrollment period for those individuals who transition from non- Medicare products to Medicare Advantage. We believe that our proposal, described later in this section, adequately addresses the concerns on which these requests are based, given that the default enrollment process would be permissible only for individuals enrolled in a Medicaid managed care plan in states that support this process. This means that the Medicare plan into which individuals would be defaulted would be one that is offered by the same parent organization as their existing Medicaid plan, such that much of the information needed by the MA plan would already be in the possession of the MA organization to facilitate the default enrollment process. Also, default enrollment would not be permitted if the state does not actively support this process, ensuring an accurate source of data for use by MA organizations to appropriately identify and notify individuals eligible for default enrollment.     On October 21, 2016,\29\ in response to inquiries regarding this enrollment mechanism, its use by MA organizations, and the beneficiary protections currently in place, we announced a temporary suspension of acceptance of new proposals for seamless continuation of coverage. Based on our subsequent discussions with beneficiary advocates and MA organizations approved for this enrollment mechanism, it is clear that organizations attempting to conduct seamless continuation of coverage from commercial coverage (that is, private coverage and Marketplace coverage) find it difficult to comply with our current guidance and approval parameters. This is especially true of the requirement to identify commercial members who are approaching Medicare eligibility based on disability. Also challenging for these organizations is the requirement that they have the means to obtain the individual's Medicare number and are able to confirm the individual's entitlement to Part A and enrollment in Part B no fewer than 60 days before the MA plan enrollment effective date. ---------------------------------------------------------------------------

    \29\ [*https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/HPMS\_Memo\_Seamless\_Moratorium.pdf*](https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/HPMS_Memo_Seamless_Moratorium.pdf) ---------------------------------------------------------------------------

    In addition, the ability for organizations to conduct seamless enrollment of individuals converting to Medicare will be further limited due to the statutory requirement that CMS remove Social Security Numbers (SSNs) from all Medicare cards by April 2019. A new Medicare number will replace the SSN-based Health Insurance Claim Number (HICN) on the new Medicare cards for Medicare transactions. Beginning in April 2018, we'll start mailing the new Medicare cards with the new number to all people with Medicare. Given the random and unique nature of the new Medicare number, we believe MA organizations will be limited in their ability to automatically enroll newly eligible Medicare beneficiaries without having to contact them to obtain their Medicare numbers, as CMS does not share Medicare numbers with organizations for their commercial members who are approaching Medicare eligibility. We note that contacting the individual in order to obtain the information necessary to process the enrollment does not align with the intent of default enrollment, which is designed to process enrollments and have coverage automatically shift into the MA plan without an enrollment action required by the beneficiary.     Organizations operating Medicaid managed care plans are better able to meet these requirements when states provide data, including the individual's Medicare number, on those about to become Medicare eligible. As part of coordination between the Medicare and Medicaid programs, CMS shares with states, via the State MMA file, data of individuals with Medicaid who are newly becoming entitled to Medicare; such data includes the Medicare number of newly eligible Medicare beneficiaries. MA organizations with state contracts to offer D-SNPs would be able to obtain (under their agreements with state Medicare agencies) the data necessary to process the MA enrollment submission to CMS. Therefore, we are proposing to revise Sec.  422.66 to permit default enrollment only for Medicaid managed care enrollees who are newly eligible for Medicare and who are enrolled into a D-SNP administered by an MA organization under the same parent organization as the organization that operates the Medicaid managed care plan in which the individual remains enrolled. These requirements would be codified at Sec.  422.66(c)(2)(i) (as a limit on the type of plan into which enrollment is defaulted) and (c)(2)(i)(A) (requiring existing enrollment in the affiliated Medicaid managed care plan as a condition of default MA enrollment). At paragraph (c)(2)(i)(B), we are also proposing to limit these default enrollments to situations where the state has actively facilitated and approved the MA organization's use of this enrollment process and articulates this in the agreement with the MA organization offering the D-SNP, as well as providing necessary identifying information to the MA organization.     The option of default enrollment can be particularly beneficial for Medicaid managed care enrollees who are newly eligible for Medicare, because in the case that the parent organization of the Medicaid managed care plan also offers a D-SNP, default enrollment promotes enrollment in a plan that offers some level of integration of acute care, behavioral health and, for eligible beneficiaries, long-term care services and supports, including institutional care, and home and community-based services (HCBS). This is in line with CMS' support of state efforts to increase enrollment of dually eligible individuals in fully integrated systems of care and the evidence \30\ that such systems

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improve health outcomes. Further this proposal will provide states with additional flexibility and control. States can decide if they wish to allow their contracted Medicaid managed care plans to use default enrollment of Medicaid enrollees into D-SNPs and can control which D- SNPs receive default enrollments through two means: The contracts that states maintain with D-SNPs (Sec.  422.107(b)) and by providing the data necessary for MA organizations to successfully implement the process. Under our proposal, MA organizations can process default enrollments only for dual-eligible individuals in states where the contract with the state under Sec.  422.107 approves it and the state identifies eligibility and shares necessary data with the organization. ---------------------------------------------------------------------------

    \30\ There is a growing evidence that integrated care and financing models can improve beneficiary experience and quality of care, including:      Health Management Associates, Value Assessment of the Senior Care Options (SCO) Program, July 21, 2015, available at: [*http://www.mahp.com/unify-files/HMAFinalSCOWhitePaper\_2015\_07\_21.pdf;*](http://www.mahp.com/unify-files/HMAFinalSCOWhitePaper_2015_07_21.pdf;)      MedPAC chapter ``Care coordination programs for dual- eligible beneficiaries,'' June 2012, available at:   [*http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0;*](http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0;)      Anderson, Wayne L., Zhanlian Fen, and Sharon K. Long, RTI International and Urban Institute, Minnesota Managed Care Longitudinal Data Analysis, prepared for the U.S Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE), March 2016, available at:   [*https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis*](https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis). ---------------------------------------------------------------------------

    To ensure that Medicaid beneficiaries considered for default enrollment upon their conversion to Medicare are aware of the default MA enrollment and of the changes to their Medicare and Medicaid coverage, we also propose, at Sec.  422.66(c)(2)(i)(C) and (c)(2)(iv), that the MA organization must issue a notice no fewer than 60 days before the default enrollment effective date to the enrollee. The proposed revised notice \31\ must include clear information on the D- SNP, as well as instructions to the individual on how to opt out (or decline) the default enrollment and how to enroll in Original Medicare or a different MA plan. This notice requirement aims to help ensure a smooth transition of eligible individuals into the D-SNP for those who choose not to opt out. All MA organizations currently approved to conduct seamless conversion enrollment issue at least one notice 60 days prior to the MA enrollment effective date, so our proposal would not result in any additional burden to these MA organizations using this process. Recent discussions with MA organizations currently conducting seamless conversion enrollment have revealed that several of them already include in their process additional outreach, including reminder notices and outbound telephone calls to aid in the transition. We believe that these additional outreach efforts are helpful and we would encourage their use under our proposal. ---------------------------------------------------------------------------

    \31\ Enrollment requirements and burden are currently approved by OMB under control number 0938-0753 (CMS-R-267). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number. ---------------------------------------------------------------------------

    We also propose, in paragraph (c)(2)(i)(E) and (2)(ii), that MA organizations must obtain approval from CMS before implementing default enrollment. Under our proposal in paragraph (c)(2)(i)(B), CMS approval would be granted only if the applicable state approves the default enrollment through its agreement with the MA organization. MA organizations would be required to implement default enrollment in a non-discriminatory manner, consistent with their obligations under Sec.  422.110; that is, MA organizations could not select for default enrollment only certain of the members of the affiliated Medicaid plan who were identified as eligible for default enrollment. Lastly, we propose that CMS may suspend or rescind approval at any time if it is determined that the MA organization is not in compliance with the requirements. We request comment whether this authority to rescind approval should be broader; we have considered whether a time limit on the approval (such as 2 to 5 years) would be appropriate so that CMS would have to revisit the processes and procedures used by an MA organization under this proposed regulation in order to assure that the regulation requirements are still being followed. We are particularly interested in comment on this point in conjunction with our alternative (discussed later in this section) proposal to codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non-Medicare coverage.     Under our proposal, default enrollment of individuals at the time of their conversion to Medicare would be more limited than the default enrollments Congress authorized the Secretary to permit in section 1851(c)(3)(A)(ii) of the Act. However, we are also proposing some flexibility for MA organizations that wish to offer seamless continuation of coverage to their non-Medicare members, commercial, Medicaid or otherwise, who are gaining Medicare eligibility. As discussed in more detail below, affirmative elections would be necessary for individuals not enrolled in a Medicaid managed care plan, consistent with Sec.  422.50 However, because individuals enrolled in an organization's commercial plan, for example would already be known to the parent organization offering both the non-Medicare plan and the MA plan and the statute acknowledges that this existing relationship is somewhat relevant to Part C coverage, we propose to amend Sec.   422.66(d)(5) and to establish, through subregulatory guidance, a new and simplified positive (that is, ``opt in'') election process that would be available to all MA organizations for the MA enrollments of their commercial, Medicaid or other non-Medicare plan members. To reflect our change in policy with regard to a default enrollment process and this proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same entity as the individual's non-Medicare coverage, we are also proposing to add text in Sec.  422.66(d)(5) authorizing a simplified election for purposes of converting existing non-Medicare coverage, commercial, Medicaid or otherwise, to MA coverage offered by the same organization. This new mechanism would allow for a less burdensome process for MA organizations to offer enrollment in their MA plans to their non- Medicare health plan members who are newly eligible for Medicare. As the MA organization has a significant amount of the information from the member's non-Medicare enrollment, this new simplified election process aims to make enrollment easier for the newly-eligible beneficiary to complete and for the MA organization to process. It would align with the individual's Part A and Part B initial enrollment period (and initial coordinated election period for MA coverage), provided he or she enrolled in both Medicare Parts A and B when first eligible for Medicare. This new election process would provide a longer period of time for MA organizations to accept enrollment requests than the time period in which MA organizations would be required to effectuate default enrollments, as organizations would be able to accept enrollments throughout the individual's Initial Coverage Election Period (ICEP), which for an aged beneficiary is the 7-month period that begins 3 months before the month in which the individual turns 65 and ends 3 months after the month in which the individual turns 65. We would use existing authority to create this new enrollment

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mechanism which, if implemented, would be available to MA organizations in the 2019 contract year. We solicit comments on the proposed changes to the regulation text as well as the form and manner in which such enrollments may occur.     This optional simplified election process for the enrollment of non-Medicare plan members into MA upon their initial eligibility (or initial entitlement) for Medicare would provide individuals the option to remain with the organization that offers their non-Medicare coverage. A positive election in this circumstance provides an additional beneficiary protection for non-dually eligible individuals, so that they may actively choose a Medicare plan structure similar to that of their commercial, Medicaid or other non-Medicare health plans, as there may be significant differences between an organization's commercial plans, for example, and its MA plans in terms of provider networks, drug formularies, costs and benefit structures. While these differences may result in a more restrictive network, a mandated change in a primary care physician and increased out-of-pocket costs for converting enrollees, default enrollment of a dually eligible individual enrolled in a Medicaid plan into a D-SNP, triggers no premium liability or cost sharing for medical care or prescription drugs above levels that apply under Original Medicare. Further, the individual remains in the Medicaid managed care plan and is gaining additional Medicare coverage, which is not always the case in other contexts. We solicit comment on these coordinated proposals to implement section 1851(c)(3)(A)(ii) in general as discussed below and in two particular ways: (1) To permit default MA enrollments for dually-eligible beneficiaries who are newly eligible for Medicare under certain conditions and (2) to permit simplified elections for seamless continuations of coverage for other newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers the MA plan. We further invite comments regarding whether the CMS approval of an organization's request to conduct default enrollment should be limited to a specific time frame. In addition, we are proposing amendments to Sec. Sec.  422.66(d)(1) and 422.68 that are also related to MA enrollment. Currently, as described in the 2005 final rule (70 FR 4606 through 4607), Sec.  422.66(d)(1) requires MA organizations to accept, during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, enrollment requests from an individual who is enrolled in a non-Medicare health plan offered by the MA organization and who meets MA eligibility requirements. To better reflect section 1851(c)(3)(A)(ii), we are proposing to amend Sec.  422.66(d)(1) to add text clarifying that seamless continuations of coverage are available to an individual who requests enrollment during his or her Initial Coverage Election Period. In light of our proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same parent organization as the individual's non-Medicare coverage, we are also proposing a revision to Sec.  422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made. This proposed revision would codify the subregulatory guidance that MA organizations have been following since 2006. This proposal is also consistent with the proposal at Sec.  422.66(c)(2)(iii) regarding the effective date of coverage for default enrollments into D-SNPs. We also solicit comment on these related proposals.     In conclusion, we are proposing to add regulation text at Sec.   422.66(c)(2)(i) through (iv) to set limits and requirements for a default enrollment of the type authorized under section 1851(c)(3)(A)(ii). We are proposing a clarifying amendment to Sec.   422.66(d)(1) regarding when seamless continuation coverage can be elected and revisions to Sec.  422.66(d)(5) to reflect our proposal for a new and simplified positive election process that would be available to all MA organizations. Lastly, we are proposing revisions to Sec.   422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made.     We invite comments in general on our proposal, as well as on the alternatives presented. We recognize that our proposal narrows the scope of default enrollments compared to what CMS approved under section 1851(c)(3)(A) of the Act in the past. As we contemplated the future of the seamless conversion mechanism, we considered retaining processes similar to how the seamless conversion mechanism is outlined currently in section 40.1.4 of Chapter 2 of the Medicare Managed Care Manual and had been in practice through October 2016. We considered proposing regulations to codify that guidance as follows--      Articulating the requirements for an MA organization's proposal to use the seamless conversion mechanism, including identifying eligible individuals in advance of Medicare eligibility;      Establishing timeframes for processing and the effective date of the enrollment; and      Requiring notification to individuals at least 60 days prior to the conversion of their right to opt-out or decline the enrollment.     In considering this alternative, we contemplated adding additional beneficiary protections, including the issuance of an additional notice to ensure that individuals understood the implication of taking no action. While this alternative would have led to increased use of the seamless conversion enrollment mechanism than what had been used in the past, the operational challenges, particularly in relation to the new Medicare Beneficiary Identification number may be significant for MA organizations to overcome at this time.     We also considered proposing regulations to limit the use of default enrollment to only the aged population. While this alternative would simplify a MA organization's ability to identify eligible individuals, we have concerns about disparate treatment among newly eligible individuals based on their reason for obtaining Medicare entitlement.     We invite comments on our proposal and the alternate approaches, including the following:      Codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non- Medicare coverage.      Codify the existing parameters for this type of seamless conversion default enrollment, as described previously, but allow that use of default enrollment be limited to only the aged population.     If commenters recommend one or more alternate approaches, we ask for suggested solutions that address the concerns noted in this discussion, particularly related to the requirement that plans identify commercial members who are approaching Medicare eligibility based on disability, as well as how plans could confirm MA eligibility and process enrollments without access to the individual's Medicare number.

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8. Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (Sec.  422.60(g))     Beneficiaries who are dually eligible for both Medicare and Medicaid typically face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in unnecessary, duplicative, or missed services. One method for overcoming this challenge is through integrated care, which provides dually eligible beneficiaries with the full array of Medicaid and Medicare benefits for which they are eligible through a single delivery system, thereby improving quality of care, beneficiary satisfaction, care coordination, and reducing administrative burden.     Integrated care options are increasingly available for dually eligible beneficiaries, which include a variety of integrated D-SNPs. D-SNPs can provide greater integrated care than enrollees would otherwise receive in other MA plans or Medicare Fee-For-Service (FFS), particularly when an individual is enrolled in both a D-SNP and Medicaid managed care organization offered by the same organization. D- SNPs that meet higher standards of integration, quality, and performance benchmarks--known as highly integrated D-SNPs--are able to offer additional supplemental benefits to support integrated care pursuant to Sec.  422.102(e). D-SNPs that are fully integrated--known as Fully Integrated Dual-Eligible (FIDE) SNPs, as defined at Sec.   422.2 provide for a much greater level of integration and coordination than non-integrated D-SNPs, providing all primary, acute, and long-term care services and supports under a single entity.     While enrollment in integrated care options continues to grow, there are instances in which beneficiaries may face disruptions in coverage in integrated care plans. These disruptions can result from numerous factors, including market forces that impact the availability of integrated D-SNPs and state re-procurements of Medicaid managed care organizations. Such disruptions can result in beneficiaries being enrolled in two separate organizations for their Medicaid and Medicare benefits, thereby losing the benefits of integration achieved when the same entity offers both benefit packages. In an effort to protect the continuity of integrated care for dually eligible beneficiaries, we are proposing a limited expansion of our regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries in instances where integrated care coverage would otherwise be disrupted.     Section 1851(c)(1) of the Act authorizes us to develop mechanisms for beneficiaries to elect MA enrollment, and we have used this authority to create passive enrollment. The current regulation at Sec.   422.60(g) limits the use of passive enrollment to two scenarios: (1) In instances where there is an immediate termination of an MA contract; or (2) in situations in which we determine that remaining enrolled in a plan poses potential harm to beneficiaries. The passive enrollment defined in Sec.  422.60(g) requires beneficiaries to be provided prior notification and a period of time prior to the effective date to opt out of enrollment from a plan. Current Sec.  422.60(g)(3) provides every passively enrolled beneficiary with a special election period to allow for election of different Medicare coverage: Selecting a different managed care plan or opting out of MA completely and, instead, receiving services through Original Medicare (a FFS delivery system). A beneficiary who is offered a passive enrollment is deemed to have elected enrollment in the designated plan if he or she does not elect to receive Medicare coverage in another way.     Our proposal is a limited expansion of this regulatory authority to promote continued enrollment of dually eligible beneficiaries in integrated care plans to preserve and promote care integration under certain circumstances. The proposal includes use of these existing opt- out procedures and special election period. Therefore, we are proposing to redesignate these requirements from (g)(1) through (3) to (g)(3) through (g)(5) respectively, with minor revisions in proposed paragraph (g)(5) to describe the application of special election period and in proposed paragraph (g)(4) to make minor grammatical changes to the text to improve its readability and clarity.     Our proposal is to add authority to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP under certain circumstances. We anticipate that these proposed regulations would permit passive enrollments only when all the following conditions are met:      When necessary to promote integrated care and continuity of care;      Where such action is taken in consultation with the state Medicaid agency;      Where the D-SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and      Where certain other conditions are met to promote continuity and quality of care.     We expect that these factors would all occur in situations when affected beneficiaries would otherwise be experiencing an involuntary disruption in either their Medicare or Medicaid coverage. We anticipate using this new proposed authority exclusively in such situations.     All individuals would be provided with a special election period (which, as established in subregulatory guidance, lasts for 2 months), as described in Sec.  422.62(b)(4), provided they are not otherwise eligible for another SEP (for example, under proposed Sec.   423.38(c)(4)(ii)).     For illustrative purposes we have outlined two scenarios in which this proposed regulatory authority could be used to promote continued access to integrated care and maintain continuity of care for dually eligible individuals:      State Re-Procurement of Medicaid Managed Care Contracts: In several states, dually eligible beneficiaries receive Medicaid services through managed care plans that the state selects through a competitive procurement process. Some states also require that the sponsors of Medicaid health plans also offer a D-SNP in the same service area to promote opportunities for integrated care. Dually eligible beneficiaries can face disruptions in coverage due to routine state re-procurements of Medicaid managed care contracts. Individuals enrolled in Medicaid managed care plans that are not renewed are typically transitioned to a separate Medicaid managed care plan. In such a scenario, dually eligible beneficiaries enrolled in the non- renewing Medicaid managed care plan's corresponding D-SNP product would now be enrolled in two separate organizations for their Medicaid and Medicare services, resulting in non-integrated coverage. Under this proposed regulation, CMS would have the ability, in consultation with the state Medicaid agency that contracts with integrated D-SNPs, to passively enroll dually eligible beneficiaries facing such a disruption into an integrated D-SNP that corresponds with their new Medicaid managed care plan, thereby promoting continuous enrollment in integrated care.

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     Non-Renewal of D-SNP Contracts: Beneficiaries enrolled in an integrated D-SNP that non-renews its MA contract at the end of the contract year can face disruptions in integrated care coverage, requiring them to actively select a new MA plan or default into Original Medicare and a standalone prescription drug plan. While states are permitted to passively enroll beneficiaries for Medicaid coverage as defined in Sec.  438.54(c), CMS is not permitted to do so for Medicare coverage when an MA plan non-renews at the end of the contract year, as current authority for passive enrollment is limited to midyear terminations. Rather, beneficiaries in the D-SNP that is non-renewing its contract would need to actively select and enroll in an MA plan that integrates their Medicare and Medicaid coverage in order to continue the same level of integrated care. Permitting CMS the ability to passively enroll D-SNP enrollees into other integrated D-SNP plans in consultation with the state Medicaid agency would support beneficiaries remaining in integrated care.     With a limited expansion of our passive enrollment regulatory authority, we can better promote integrated care and continuity of care for dually eligible beneficiaries. Therefore, we are proposing to redesignate the introductory text in Sec.  422.60(g) as paragraph (g)(1), with a new heading, technical revisions to the existing text that specifies when passive enrollments may be implemented by CMS designated as (g)(1)(i) and (ii), and a new paragraph (iii). This new (g)(1)(iii) would authorize CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D-SNP into another integrated D-SNP, after consulting with the state Medicaid agency that contracts with the D-SNP or other integrated managed care plan, to promote continuity of care and integrated care.     We also propose to add a new paragraph (g)(2) to include a number of requirements that an MA plan would have to meet in order to qualify to receive passive enrollments under paragraph (g)(1)(iii). We also propose to include in paragraph (g)(1)(iii) a reference to new paragraph (g)(2) to make it clear that a contract with the state is also necessary for a D-SNP to be eligible to receive these passive enrollments. Specifically, we propose that in order to receive passive enrollments under the new authority, MA plans must be highly integrated, thereby restricting passive enrollment to those MA plans that operate as a FIDE SNP or meet the integration standard for a highly-integrated D-SNP, as defined in Sec.  422.2 and described in Sec.  422.102(e) respectively. In an effort to ensure continuity of care, acquiring MA plans would also be required to have substantially similar provider and facility networks and Medicare- and Medicaid- covered benefits as the integrated MA plan (or plans) from which beneficiaries are passively enrolled. MA plans receiving passive enrollment would also be required to not have any prohibition on new enrollment imposed by CMS and have appropriate limits on premium and cost-sharing for beneficiaries. If our proposed paragraphs (g)(1) and (g)(2) are finalized, we would describe in subregulatory guidance the procedure through which CMS would determine qualification for passive enrollment. We also propose that to receive these passive enrollments, that D-SNP must meet minimum quality standards based on MA Star Ratings; we direct the reader to the proposal at section III.A.12 of this rule regarding the MA Star Rating System. Our proposed regulation text refers to a requirement to have a minimum overall MA Star Rating of at least 3 stars, which represents average or above-average performance. The rating for the year prior to receipt of passive enrollment would be used in order to provide sufficient time for CMS, states, and MAOs to prepare for the passive enrollment process. Low- enrollment contracts or new plans without MA Star Ratings as defined in Sec.  422.252 would also be eligible for passive enrollment under our proposal, as long as the plan meets all other proposed requirements.     Our goal with this proposed requirement is to ensure that the D-SNP plans receiving these passive enrollments provide high-quality care, coverage and administration of benefits. As passive enrollments, in some sense, are a benefit to a plan, by providing an enrollee and associated payments without the plan having successfully marketed to the enrollee, we believe that it is important that these enrollments are limited to plans that have demonstrated commitment to quality. Further, it is important to ensure that when we are making an enrollment decision for a beneficiary who does not make an alternative coverage choice that we are guided by the beneficiary's best interests, which are likely served by a plan that is rated as having average or above-average performance on the MA Stars Rating System. However, we recognize that MA Star Ratings do not capture performance for those services that would be covered under Medicaid, including community behavioral health treatment and long-term services and supports. We welcome comments on the process for determining qualification for passive enrollment under this proposal and particularly on the minimum quality standards. We request that commenters identify specific measures and minimum ratings that would best serve our goals in this proposal and are specific or especially relevant to coverage for dually eligible beneficiaries.     In addition to the proposed minimum quality standards and other requirements for a D-SNP to receive passive enrollments, we are considering limiting our exercise of this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs. We seek comment on this potential further limitation on exercise of the proposed passive enrollment regulatory authority to better promote integrated care and continuity of care. In particular, we seek stakeholder feedback how to calculate the projected impact on Medicare and Medicaid costs from exercise of this authority.     The intent of the proposed passive enrollment regulatory authority is to better promote integrated care and continuity of care--including with respect to Medicaid coverage--for dually eligible beneficiaries. As such, we would implement this authority in consultation with the state Medicaid agencies that are contracting with these plan sponsors for provision of Medicaid benefits.     We considered proposing new beneficiary notification requirements for passive enrollments that occur under proposed paragraph (g)(1)(iii). We considered requiring MA organizations receiving the passive enrollment to provide two notifications to all potential enrollees prior to their enrollment effective date. We acknowledge that under the Financial Alignment Initiative demonstrations, states are required to provide two passive enrollment notices. Under the passive enrollment authority proposed here, we would continue to encourage, but not require, a second notice or additional outreach to impacted individuals. Given the existing beneficiary notifications that are currently required under Medicare regulations and concerns regarding the quantity of notifications sent to beneficiaries, we are not proposing to modify the existing notification requirements, so these existing standards would apply for existing passive enrollments and for the newly proposed passive enrollment authority.

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However, we solicit comment on alternatives regarding beneficiary notices, including comments about the content and timing of such notices. Our proposal redesignates the notice requirements to paragraph (g)(4) with minor grammatical revisions.     Finally, we propose a technical correction to a citation in Sec.   422.60(g), which discusses situations involving an immediate termination of an MA plan as provided in Sec.  422.510(a)(5). This citation is outdated, as the regulatory language at Sec.  422.510(a)(5) has been moved to Sec.  422.510(b)(2)(i)(B). We propose to replace the current citation with a reference to Sec.  422.510(b)(2)(i)(B). 9. Part D Tiering Exceptions (Sec. Sec.  423.560, 423.578(a) and (c)) a. Background     Section 1860D-4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering prescription drug benefits for Part D drugs through the use of a tiered formulary may request an exception to the plan sponsor's tiered cost-sharing structure. The statute requires such plan sponsors to have a process in place for making determinations on such requests, consistent with guidelines established by the Secretary. At the start of the Part D program, we finalized regulations at Sec.  423.578(a) that require plan sponsors to establish and maintain reasonable and complete exceptions procedures. These procedures permit enrollees, under certain circumstances, to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing applicable to alternative drugs on a lower cost-sharing tier of the plan sponsor's formulary. Such an exception is granted when the plan sponsor determines that the non-preferred drug is medically necessary based on the prescriber's supporting statement. The tiering exceptions regulations establish the general scope of issues that must be addressed under the plan sponsor's tiering exceptions process. Our goal with the exceptions rules codified in the Part D final rule (70 FR 4352) was to allow plan sponsors sufficient flexibility in benefit design to obtain pricing discounts necessary to offer optimal value to beneficiaries, while ensuring that beneficiaries with a medical need for a non-preferred drug are afforded the type of drug access and favorable cost-sharing called for under the law.     At the start of the program, most Part D formularies included no more than four cost-sharing tiers, generally with only one generic tier. For the 2006 and 2007 plan years respectively, about 83 percent and 89 percent of plan benefit packages (PBPs) that offered drug benefits through use of a tiered formulary had 4 or fewer tiers. Since that time, there have been substantial changes in the prescription drug landscape, including increasing costs of some generic drugs, as well as the considerable impact of high-cost drugs on the Part D program. Plan sponsors have responded by modifying their formularies and PBPs, resulting in the increased use of two generic-labeled drug tiers and mixed drug tiers that include brand and generic products on the same tiers. The flexibilities CMS permits in benefit design enable plan sponsors to continue to offer comprehensive prescription drug coverage with reasonable controls on out of pocket costs for enrollees, but increasingly complex PBPs with more variation in type and level of cost-sharing. For the 2017 plan year, about 91 percent of all Part D PBPs offer drug benefits through use of a tiered formulary. Over 98 percent of those tiered PBPs use a formulary containing 5 or 6 tiers; of those, about 98 percent contain two generic-labeled tiers.     These changes and increased complexities, and more than a decade of program experience, lead us to believe that our current regulations are no longer sufficient to ensure that tiering exceptions are understood by beneficiaries and adjudicated by plan sponsors in the manner the statute contemplates. For this reason, we propose to amend Sec. Sec.   423.560, 423.578(a) and 423.578(c) to revise and clarify requirements for how tiering exceptions are to be adjudicated and effectuated.     While section 1860D-4(g)(2) of the Act uses the terms ``preferred'' and ``non-preferred'' drug, rather than ``brand'' and ``generic'', it also gives the Secretary authority to establish guidelines for making a determination with respect to a tiering exception request. The statute further specifies that ``a non-preferred drug could be covered under the terms applicable for preferred drugs'' (emphasis added) if the prescribing physician determines that the preferred drug would not be as effective or would have adverse effects for the individual. The statute therefore contemplates that tiering exceptions must allow for an enrollee with a medical need to obtain favorable cost-sharing for a non-preferred product, but that such access be subject to reasonable limitations. Establishing regulations that allow plans to impose certain limitations on tiering exceptions helps ensure that all enrollees have access to needed drugs at the most favorable cost- sharing terms possible. b. General Rules     We are proposing to revise Sec.  423.578(a)(2) to read as follows: ``Part D plan sponsors must establish criteria that provide for a tiering exception consistent with paragraphs Sec.  423.578(a)(3) through (a)(6) of this section.'' We believe that inserting a cross- reference to paragraph (a)(6), which establishes allowable limitations on tiering exceptions, and which we are also proposing to revise, would streamline and clarify the requirements for such exceptions. The proposed revisions would establish rules that more definitively base eligibility for tiering exceptions on the lowest applicable cost sharing for the tier containing the preferred alternative drug(s) for treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug, and not based on tier labels. c. Limitations on Tiering Exceptions     We are also proposing to revise the regulations at Sec.   423.578(a)(6) to specify when a Part D plan sponsor may limit tiering exceptions. We believe the current text, which permits a plan sponsor to exempt any dedicated generic tier from its tiering exceptions procedures, is being applied in a manner that restricts tiering exceptions more stringently than is appropriate. Specifically, Part D sponsors have been considering any tier that is labeled ``generic'' to be exempt from tiering exceptions even if the tier also contains brand name drugs. This has become even more problematic with the increase in the number of PBPs with more than one tier labeled ``generic''. Based on an analysis of 2017 plan data entered into the Health Plan Management System (HPMS), for all Part D plans using a tiered formulary, 62 percent have indicated at least two tiers that contain only generic drugs, and 7 percent have three such tiers. Combined with the allowable exemption of a specialty tier (used by 99.8 percent of tiered Part D plans in 2017), almost two-thirds of all tiered PBPs could exempt 3 of their 5 or 6 tiers from tiering exceptions without any consideration of medical need or placement of preferred alternative drugs. To ensure appropriate enrollee access to tiering exceptions, we are proposing to revise Sec.  423.578(a)(6) to specify that a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives. Under this proposal, however, plans would be required to approve tiering exceptions for non-preferred generic drugs when

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the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives. In other words, plans would not be permitted to exclude a tier containing alternative drug(s) with more favorable cost-sharing from their tiering exceptions procedures altogether just because that lower-cost tier is dedicated to generic drugs. As described in the following paragraph, we are also proposing at Sec.  423.578(a)(6) to establish specific tiering exceptions policy for biological products.     Proposed Sec.  423.578(a)(6)(iii) would specify that, ``If a Part D plan sponsor maintains a specialty tier, as defined in Sec.  423.560, the sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception.'' We also propose to add the following definition to Subpart M at Sec.  423.560:     Specialty tier means a formulary cost-sharing tier dedicated to very high cost Part D drugs and biological products that exceed a cost threshold established by the Secretary. We note that, while the proposed definition of specialty tier does not refer to ``unique'' drugs as existing Sec.  423.578(a)(7) does, we do not intend to change the criteria for the specialty tier, which has always been based on the drug cost. This proposal would retain the current regulatory provision that permits Part D plan sponsors to disallow tiering exceptions for any drug that is on the plan's specialty tier. This policy is currently codified at Sec.  423.578(a)(7), which would be revised and redesignated as Sec.  423.578(a)(6)(iii). We believe that retaining the existing policy limiting the availability of tiering exceptions for drugs on the specialty tier is important because of the beneficiary protection that limits cost-sharing for the specialty tier to 25 percent coinsurance (up to 33 percent for plans that have a reduced or $0 Part D deductible), ensuring that these very high cost drugs remain accessible to enrollees at cost sharing equivalent to the defined standard benefit.     We also clarify that, if the specialty tier has cost sharing more preferable than another tier, then a drug placed on such other non- preferred tier is eligible for a tiering exception down to the cost sharing applicable to the specialty tier if an applicable alternative drug is on the specialty tier and the other requirements of Sec.   423.578(a) are met. In other words, while plans are not required to allow tiering exceptions for drugs on the specialty tier to a more preferable cost-sharing tier, the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exceptions.     We believe a shift in regulatory policy that establishes a distinction between non-preferred branded drugs, biological products, and non-preferred generic and authorized generic drugs, achieves needed balance between limitations in plans' exceptions criteria and beneficiary access, and aligns with how many plan sponsors already design their tiering exceptions criteria. Accordingly, we are proposing to revise Sec.  423.578(a)(6) to clarify and establish additional limitations plans would be permitted to place on tiering exception requests. First, we are proposing new paragraphs (i) and (ii), which would permit plans to limit the availability of tiering exceptions for the following drug types to a preferred tier that contains the same type of alternative drug(s) for treating the enrollee's condition:      Brand name drugs for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(b)(2)); and      Biological products, including follow-on biologics, licensed under section 351 the Public Health Service Act.     With the proposed revisions, that approved tiering exceptions for brand name drugs would generally be assigned to the lowest applicable cost-sharing associated with brand name alternatives, and approved tiering exceptions for biological products would generally be assigned to the lowest applicable cost-sharing associated with biological alternatives. Similarly, tiering exceptions for non-preferred generic drugs would be assigned to the lowest applicable cost-sharing associated with alternatives that are either brand or generic drugs (see further discussion later in this section related to assignment of cost-sharing for approved tiering exceptions to the lowest applicable tier). Given the widespread use of multiple generic tiers on Part D formularies, and the inclusion of generic drugs on mixed, higher-cost tiers, we believe these changes are needed to ensure that tiering exceptions for non-preferred generic drugs are available to enrollees with a demonstrated medical need. Procedures that allow for tiering exceptions for higher-cost generics when medically necessary promote the use of generic drugs among Part D enrollees and assist them in managing out of pocket costs.     We are also proposing at Sec.  423.578(a)(6)(i) to codify that plans are not required to offer tiering exceptions for brand name drugs or biological products at the cost-sharing level of alternative drug(s) for treating the enrollee's condition, where the alternatives include only the following drug types:      Generic drugs for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)), or      Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(t)(3)).     As discussed in the Call Letter, CMS collects Part D plan formulary data based on the National Library of Medicare RxNorm concept unique identifier (RxCUI), and not at the manufacturer-specific National Drug Code (NDC) level. This process does not allow us to clearly identify whether a plan sponsor includes coverage of authorized generic NDCs or not. We believe this position is consistent with how plans currently administer their formularies. Under this regulatory proposal, a plan sponsor could not completely exclude a lower tier containing only generic and authorized generic drugs from its tiering exception procedures, but would be permitted to limit the cost sharing for a particular brand drug or biological product to the lowest tier containing the same drug type. Plans would be required to grant a tiering exception for a higher cost generic or authorized generic drug to the cost sharing associated with the lowest tier containing generic and/or authorized generic alternatives when the medical necessity criteria is met. d. Alternative Drugs for Treatment of the Enrollee's Condition     In response to the 2018 Call Letter and RFI, we received comments from plan sponsors and PBMs requesting that CMS provide additional guidance on how to determine what constitutes an alternative drug for purposes of tiering exceptions, including establishment of additional limitations on when such exceptions are approvable. The statutory language for tiering and formulary exceptions at sections 1860D-4(g)(2) and 1860D-4(h)(2) of the Act, respectively, specifically refers to a preferred or formulary drug ``for treatment of the same condition.'' We interpret this language to be referring to the condition as it affects the enrollee--that is, taking into consideration the individual's overall clinical condition,

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including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen, which can factor into which drugs are appropriate alternative therapies for that enrollee. The Part D statute at Sec.  1860D-4(g)(2) requires that coverage decisions subject to the exceptions process be based on the medical necessity of the requested drug for the individual for whom the exception is sought. We believe that requirement reasonably includes consideration of alternative therapies for treatment of the enrollee's condition, based on the facts and circumstances of the case. e. Approval of Tiering Exception Requests     We are proposing to revise Sec.  423.578(c)(3) by renumbering the provision and adding a new paragraph (ii) to codify our current policy that cost sharing for an approved tiering exception request is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers. Under this proposal, assignment of cost sharing for an approved tiering exception must be at the most favorable cost- sharing tier containing alternative drugs, unless such alternative drugs are not applicable pursuant to limitations set forth under proposed Sec.  423.578(a)(6). We are also proposing to ***delete*** similar language from existing (c)(3) that proposed new paragraph (c)(3)(ii) would replace. f. Additional Technical Changes and Corrections     Finally, we are proposing various technical changes and corrections to improve the clarity of the tiering exceptions regulations and consistency with the regulations for formulary exceptions. Specifically, we are proposing the following:      Revise the introductory text of Sec.  423.578(a) to clarify that a ``requested'' non-preferred drug for treatment of an enrollee's health condition may be eligible for an exception.      Revise Sec.  423.578(a)(1) to include ``tiering'' when referring to the exceptions procedures described in this subparagraph.      Revise Sec.  423.578(a)(4) by making ``conditions'' singular and by adding ``(s)'' to ``drug'' to account for situations when there are multiple alternative drugs.      Revise Sec.  423.578(a)(5) by removing the text specifying that the prescriber's supporting statement ``demonstrate the medical necessity of the drug'' to align with the existing language for formulary exceptions at Sec.  423.578(b)(6). The requirement that the supporting statement address the enrollee's medical need for the requested drug is already explained in the introductory text of Sec.   423.578(a).      Redesignate paragraphs Sec.  423.578(c)(3)(i) through (iii) as paragraphs Sec.  423.578(c)(3)(i)(A) through (C), respectively. This proposed change would improve consistency between the regulation text for tiering and formulary exceptions.     We anticipate that the proposed changes to the tiering exceptions regulations will make this process more accessible and transparent for enrollees and less cumbersome for plan sponsors to administer. We also believe that, by helping plan sponsors ensure their tiering exceptions processes comply with CMS requirements, IRE overturn rates for tiering exception requests will remain low. 10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (Sec.  423.38)     As discussed in section III.A.2 of this proposed rule, the MMA added section 1860D-1(b)(3)(D) to the Act to establish a special election period (SEP) for full-benefit dual eligible (FBDE) beneficiaries under Part D. This SEP, codified at Sec.  423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by regulation (75 FR 19720). The SEP allows eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA-PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the annual enrollment period (AEP) each fall.     The MMA sought to strike a balance of promoting beneficiary plan choice, but also ensuring that FBDE beneficiaries who did not make an active election would still have Part D coverage. The statute directed the Secretary to enroll FBDE beneficiaries into a PDP if they did not enroll in a Part D plan on their own. (As noted previously, CMS extended the SEP through rulemaking to make it available to all other subsidy-eligible beneficiaries.) When the automatic enrollment of subsidy-eligible beneficiaries was originally proposed in rulemaking, we noted that beneficiaries would have the option to use the SEP if they determined there was a better plan option for them, and codified a continuous SEP (that is, that was available monthly).     At the time, we did not know on what factors FBDE beneficiaries would rely to make their plan choice. Now, with over 10 years of programmatic experience, we have observed certain enrollment trends in terms of FBDE and other LIS beneficiaries:      Most LIS beneficiaries do not make an active choice to join a PDP. For plan year 2015, over 71 percent of LIS individuals in PDPs were placed into that plan by CMS.      Once in a plan, whether it was a CMS-initiated enrollment or a choice they made on their own, most LIS beneficiaries do not make changes during the year. Of all LIS beneficiaries who were eligible for the SEP in 2016, less than 10 percent utilized it. Overall, we have seen slight growth of SEP usage over the past 5 years (for example, less than 8 percent in 2012, approximately 9 percent in 2014).      A small subset (0.8 percent) of LIS beneficiaries use the SEP to actively enroll in a plan of their choice and then disenroll within 2 months.     While we know that the majority of LIS-eligible beneficiaries do not take advantage of the SEP, we have seen the Medicare and Medicaid environment evolve in such a way that it may be disadvantageous to beneficiaries if they changed plans during the year, let alone if they made multiple changes. States and plans have noted that they are best able to provide or coordinate care if there is continuity of enrollment, particularly if the beneficiary is enrolled in an integrated product (as discussed later in this section). We now know that in addition to choice, there are other critical issues that must be considered in determining when and how often beneficiaries should be able to change their Medicare coverage during the year, such as coordination of Medicare-Medicaid benefits, beneficiary care management, and public health concerns such as the national opioid epidemic (and the drug management programs discussed in section II.A.1). In addition, there are different care models available now such as dual eligible special needs plans (D-SNPs), Fully Integrated Dual Eligible (FIDE) SNPs, and Medicare-Medicaid Plans (MMPs) that are discussed later in this section and specifically designed to meet the needs of high risk, high needs beneficiaries.     Current enrollment trends demonstrate that while a majority of subsidy-eligible beneficiaries still receive their Part D coverage through standalone PDPs, an increasing percentage of beneficiaries are enrolled in MA-PDs and other capitated managed care products, including over one in three dually eligible beneficiaries. A smaller but rapidly growing subset are enrolled in capitated

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Medicare managed care products that also integrate Medicaid services. For example:      The MMA established D-SNPs to provide coordinated care to dually eligible beneficiaries. Between 2007 and 2016, growth in D-SNPs has increased by almost 150 percent.      FIDE SNPs are a type of SNP created by the Affordable Care Act (ACA) in 2010 designed to promote full integration and coordination of Medicare and Medicare benefits for dually eligible beneficiaries by a single managed care organization. In 2017, there are 39 FIDE SNPs providing coverage to approximately 155,000 beneficiaries.      MMPs, which operate as part of a model test under Section 1115(A) of the Act, are fully-capitated health plans that serve dually eligible beneficiaries though demonstrations under the Financial Alignment Initiative. The demonstrations are designed to promote full access to seamless, high quality integrated health care across both Medicare and Medicaid. In 2017, there are 58 MMPs providing coverage to nearly 400,000 beneficiaries.     The current SEP, especially in the context of these products that integrate Medicare and Medicaid, highlights differences in Medicare and Medicaid managed care enrollment policies. Bringing Medicare and Medicaid enrollment policies into greater alignment, even partially, is a mechanism to reduce complexity in the health care system and better partner with states. Both are important priorities for CMS.     In addition, the application of the continuous SEP carries different service delivery implications for enrollees of MA-PD plans and related products than for standalone enrollees of PDPs. At the outset of the Part D program, when drug coverage for dually eligible beneficiaries was transitioned from Medicaid to Medicare, there were concerns about how CMS would effectively identify, educate, and enroll dually eligible beneficiaries. While processes (for example, auto- enrollment, reassignment) were established to facilitate coverage, the continuous SEP served as a fail-safe to ensure that the beneficiary was always in a position to make a choice that best served their healthcare needs. Unintended consequences have resulted from this flexibility, including, as noted by the Medicare Payment Advisory Commission (MedPAC \32\), opportunities for marketing abuses. ---------------------------------------------------------------------------

    \32\ Medicare Payment Advisory Commission, ``Report to Congress: Medicare Payment Policy,'' March 2008. ---------------------------------------------------------------------------

    Among the key obstacles the SEP (and resulting plan movement) can present are--      Interfering with the coordination of care among the providers, health plans, and states;      Hindering the ability for beneficiaries to benefit from case management and disease management;      Wasting the effort and resources needed to conduct enrollee needs assessments and developing plans of care for services covered by Medicare and Medicaid;      Limiting a plan's opportunity for continuous treatment of chronic conditions; and      Diminishing incentives for plans to innovate and invest in serving potentially high-cost members.     While we still support in the underlying principle that LIS beneficiaries should have the ability to make an active choice, we find that plan sponsors are better able to administer benefits to beneficiaries, including coordination of Medicare and Medicaid benefits, and maximize care management and positive health outcomes, if dual and other LIS-eligible beneficiaries are held to the similar election period requirements as all other Part D-eligible beneficiaries. Therefore, we are proposing to amend Sec.  423.38(c)(4) to make the SEP for FBDE and other subsidy-eligible individuals available only in certain circumstances. These circumstances would be considered separate and unique from one another, so there could be situations where a beneficiary could still use the SEP multiple times if he or she meets more than one of the conditions proposed as follows. Specifically, we are proposing to revise to Sec.  423.38(c) to specify that the SEP is available only as follows:      In new paragraph (c)(4)(i), eligible beneficiaries (that is, those who are dual or other LIS-eligible and meet the definition of at-risk beneficiary or potential at-risk beneficiary under proposed Sec.  423.100) would be able to use the SEP once per calendar year.      In new paragraph (c)(4)(iii), eligible beneficiaries who have been assigned to a plan by CMS or a State would be able to use the SEP before that election becomes effective (that is, opt out and enroll in a different plan) or within 2 months of their enrollment in that plan.      In new paragraph (c)(9), dual and other LIS-eligible beneficiaries who have a change in their Medicaid or LIS-eligible status would have an SEP to make an election within 2 months of the change, or of being notified of such change, whichever is later. This SEP would be available to beneficiaries who experience a change in Medicaid or LIS status regardless of whether they have been identified as potential at-risk beneficiaries or at-risk beneficiaries under proposed Sec.  423.100 In addition, we are also proposing to remove the phrase ``at any time'' in the introductory language of Sec.   423.38(c) for the sake of clarity.     The onetime annual SEP opportunity would be able to be used at any time of the year to enroll in a new plan or disenroll from the current plan, provided that their eligibility for the SEP has not been limited consistent with section 1860D-1(b)(3)(D) of the Act, as amended by CARA (as discussed in section III.A.2 of this proposed rule). We believe that the onetime annual SEP would still provide dually eligible beneficiaries adequate opportunity to change their coverage during the year if desired, but is also responsive to consistent feedback we have received from States and plans that have noted that the current SEP, which allows month-to-month movement, can disrupt continuity of care, especially in integrated care plans. They specifically noted that effective care management can best be achieved through continuous enrollment.     Beneficiaries who have been enrolled in a plan by CMS or a state (that is, through processes such as auto enrollment, facilitated enrollment, passive enrollment, default enrollment (seamless conversion), or reassignment), would be allowed a separate, additional use of the SEP, provided that their eligibility for the SEP has not been limited consistent with section 1860D-1(b)(3)(D) of the Act, as amended by CARA. These beneficiaries would still have a period of time before the election takes effect to opt out and choose their own plan or they would be able to use the SEP to make an election within 2 months of the assignment effective date. Once a beneficiary has made an election (either prior to or after the effective date) it would be considered ``used'' and no longer would be available. If a beneficiary wants to change plans after 2 months, he or she would have to use the onetime annual election opportunity discussed previously, provided that it has not been used yet. If that election has been used, the beneficiary would have to wait until they are eligible for another election period to make a change.

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    Under a new proposed SEP, individuals who have a change in their Medicaid or LIS-eligible status would have an election opportunity that is separate from, and in addition to, the two scenarios discussed previously. (As discussed in section III.A.2 of this rule, and unlike the other two conditions discussed previously, individuals identified as ``at risk'' would be able to use this SEP.) This would apply to individuals who gain, lose, or change Medicaid or LIS eligibility. We believe that in these instances, it would be appropriate to give these beneficiaries an opportunity to re-evaluate their Part D coverage in light of their changing circumstances. Beneficiaries eligible for this SEP would need to use it within 2 months of the change or of being notified of the change, whichever is later.     We considered multiple alternatives related to the SEP proposal. We describe two such alternatives in the following discussion:     Limit of two or three uses of the SEP per year. In 2016, 1.2 million beneficiaries used the SEP for FBDE or other subsidy-eligible individuals, including over 27,000 who used the SEP three or more times, and over 1,700 who used the SEP five or more times during the year. These SEP changes are in addition to changes made during the AEP and any other election periods for which a beneficiary may qualify. We believe that any overuse of the SEP creates significant inefficiencies and impedes meaningful continuity of care and care coordination. As such, we considered applying a simple numerical limit to the number of times the LIS SEP could be used by any beneficiary within each calendar year. We specifically considered limits of either two or three uses of the SEP per year.     Compared to our proposal to limit the use of the SEP to one time per calendar year, this alternative would permit more opportunities for midyear changes. However, it could still allow for a high level of membership churning. Relative to our proposal, it would also be less effective in limiting the opportunities for aggressive marketing to LIS beneficiaries outside of the AEP. We welcome comments on this alternative.     Limits on midyear MA-PD plan switching. We also considered a more complex option, drawing heavily on earlier MedPAC recommendations.\33\ Under this alternative we would: ---------------------------------------------------------------------------

    \33\ Medicare Payment Advisory Commission, ``Report to Congress: Medicare Payment Policy,'' March 2008. ---------------------------------------------------------------------------

     Modify the SEP to prohibit its use to elect a non- integrated MA-PD plan. As such, the SEP would not be used for switching between MA-PD plans, movement from integrated products to a non- integrated MA-PD plan, or movement from Medicare FFS to an MA-PD plan. Beneficiaries would still be able to select non-integrated MA-PD plans during other enrollment periods, such as the AEP, the open enrollment period (OEP) outlined in section III.C.2 of this proposed rule, and any other SEP for which they may be eligible; and      Allow continuous use of the dual SEP to allow eligible beneficiaries to enroll into FIDE SNPs or comparably integrated products for dually eligible beneficiaries through model tests under section 1115(A) of the Act.     This alternative would still permit continuous election of Medicare FFS with a standalone PDP throughout the year and a continuous option to change between standalone PDPs.     We believe this alternative would create greater stability among plans and limit the opportunities for misleading and aggressive marketing to dually-eligible individuals. It would also maintain the opportunity for continuous enrollment into integrated products to reflect our ongoing partnership with states to promote integrated care. However, this alternative would be more complex to administer and explain to beneficiaries, and it encourages enrollment into a limited set of MA plans compared to all the plans available to the beneficiary under the MA program. We welcome comments on this alternative.     We believe that our proposed approach to narrowing of the scope of the SEP preserves a dual or other LIS-eligible beneficiary's ability to make an active choice. As noted previously, less than 10 percent of the LIS population used the dual SEP in 2016. We acknowledge that even though this is a small percentage of the population, given the number of beneficiaries who receive Extra Help, this equates to over a million elections. We note, though, that of this group, the majority (74.5 percent) used the SEP one time. Under our proposal, this population would still be able to make an election, thus, we believe that the majority of beneficiaries would not be negatively impacted by these changes. We opted for our proposed approach, as opposed to the alternatives, because we believe it encourages continuity of enrollment and care, without overcomplicating both beneficiary understanding of how the SEP is available to them, as well as plan sponsor operational responsibilities.     If the proposal is finalized, we would revise our messaging and beneficiary education materials as necessary to ensure that dual and other LIS-eligible beneficiaries understand that the SEP is no longer an unlimited opportunity. We would also need to ensure that beneficiaries who are assigned to a plan by CMS or the State understand that they must use the SEP within 2 months after the new coverage begins if they wish to change from the plan to which they were assigned.     We note that other election periods, including the AEP, the new OEP, or other SEPs (for example, when moving to a new service area), would still be available to individuals. In addition, the proposed limitations would also apply to the Part C SEP established in sub- regulatory guidance for dual-eligible individuals or individuals who lose their dual-eligibility.     We welcome public comment on this proposal and the considered alternatives. Specifically, we seek input on the following areas:      Are there other limited circumstances where the dual SEP should be available?      Are there special considerations CMS should keep in mind if we finalize this policy?      Are there other alternative approaches we should consider in lieu of narrowing the scope of the SEP?      In addition to CMS outreach materials, what are the best ways to educate the affected population and other stakeholders of the new proposed SEP parameters? 11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System a. Introduction     We are committed to transforming the health care delivery system-- and the Medicare program--by putting a strong focus on person-centered care, in accordance with the CMS Quality Strategy, so each provider can direct their time and resources to each beneficiary and improve their outcomes. As part of this commitment, one of our most important ***strategic*** goals is to improve the quality of care for Medicare beneficiaries. The Part C and D Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by health and drug plans, physicians, hospitals, and other Medicare providers. We currently publicly report the quality and performance of health and drug plans on the Medicare Plan Finder tool on [*www.medicare.gov*](http://www.medicare.gov) in the form of summary and overall ratings for the contracts under which each MA plan (including MA-PD plans) and Part D plan is offered, with drill downs to

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ratings for domains, ratings for individual measures, and underlying performance data. We also post additional measures on the display page \34\ at [*www.cms.gov*](http://www.cms.gov) for informational purposes. The goals of the Star Ratings are to display quality information on Medicare Plan Finder for public accountability and to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance. In addition, CMS has started to incorporate efforts to recognize the challenges of serving high risk, high needs populations while continuing the focus on improving health care for these important groups. ---------------------------------------------------------------------------

    \34\ [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings) (under the downloads). ---------------------------------------------------------------------------

    In this rule as part of the Administration's efforts to improve transparency, we propose to codify the existing Star Ratings System for the MA and Part D programs with some changes. As noted later in this section in more detail, the proposed changes include more clearly delineating the rules for adding, updating, and removing measures and modifying how we calculate Star Ratings for contracts that consolidate. Although the rulemaking process will create a longer lead time for changes, codifying the Star Ratings methodology will provide plans with more stability to plan multi-year initiatives, because they will know the measures several years in advance. We have received comments for the past several years from MA organizations and other stakeholders asking that CMS use Federal Register rulemaking for the Star Ratings System; we discuss in section III.12.c (regarding plans for the transition period before the codified rules are used) how section 1832(b) authorizes CMS to establish and annually modify the Star Ratings System using the Advance Notice and Rate Announcement process because the system is an integral part of the policies governing Part C payment. We think this is an appropriate time to codify the methodology, because the rating system has been used for several years now and is relatively mature so there is less need for extensive changes every year; the smaller degree of flexibility in having codified regulations rather than using the process for adopting payment methodology changes may be appropriate. Further, by adopting and codifying the rules that govern the Star Ratings System, we are demonstrating a commitment to transparency and predictability for the rules in the system so as to foster investment. b. Background     We originally acted upon our authority to disseminate information to beneficiaries as the basis for developing and publicly posting the 5-star ratings system (sections 1851(d) and 1852(e) of the Act). The MA statute explicitly requires that information about plan quality and performance indicators be provided to beneficiaries in an easy to understand language to help them make informed plan choices. These data are to include disenrollment rates, enrollee satisfaction, health outcomes, and plan compliance with requirements.     The Part D statute (at section 1860D-1(c)) imposes a parallel information dissemination requirement with respect to Part D plans, and refers specifically to comparative information on consumer satisfaction survey results as well as quality and plan performance indicators. Part D plans are also required by regulation (Sec.  423.156) to make Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data available to CMS and are required to submit pricing and prescription drug event data under statutes and regulations specific to those data. Regulations require plans to report on quality improvement and quality assurance and to provide data which CMS can use to help beneficiaries compare plans (Sec. Sec.  422.152 and 423.153). In addition we may require plans to report statistics and other information in specific categories (Sec. Sec.  422.516 and 423.514).     Currently, for similar reasons of providing information to beneficiaries to assist them in plan enrollment decisions, we also review and rate section 1876 cost plans on many of the same measures and publish the results. We also propose to continue to include 1876 cost contracts in the MA and Part D Star Rating system to provide comparative information to Medicare beneficiaries making plan choices. We propose specific text, to be codified at Sec.  417.472(k), noting that 1876 cost contracts must agree to be rated under the quality rating system specified at subpart D of part 422. Cost contracts are also required by regulation (Sec.  17.472(j)) to make CAHPS survey data available to CMS. As is the case today, no quality bonus payments (QBP) would be associated with the ratings for 1876 cost contracts.     In line with Sec. Sec.  422.152 and 423.153, CMS uses the Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), CAHPS data, Part C and D Reporting requirements and administrative data, and data from CMS contractors and oversight activities to measure quality and performance of contracts. We have been displaying plan quality information based on that and other data since 1998.     Since 2007, we have published annual performance ratings for stand- alone Medicare PDPs. In 2008, we introduced and displayed the Star Ratings for Medicare Advantage Organizations (MAOs) for both Part C only contracts (MA-only contracts) and Part C and D contracts (MA-PDs). Each year since 2008, we have released the MA Star Ratings. An overall rating combining health and drug plan measures was added in 2011, and differential weighting of measures (for example, outcomes being weighted 3 times the value of process measures) began in 2012. The measurement of year to year improvement began in 2013, and an adjustment (Categorical Adjustment Index) was introduced in 2017 to address the within-contract disparity in performance revealed in our research among beneficiaries that are dual eligible, receive a low income subsidy, and/or are disabled.     The MA and Part D Star Ratings measure the quality of care and experiences of beneficiaries enrolled in MA and Part D contracts, with 5 stars as the highest rating and 1 star as the lowest rating. The Star Ratings provide ratings at various levels of a hierarchical structure based on contract type, and all ratings are determined using the measure-level Star Ratings. Contingent on the contract type, ratings may be provided and include overall, summary (Part C and D), and domain Star Ratings. Information about the measures, the hierarchical structure of the ratings, and the methodology to generate the Star Ratings is detailed in the annually updated Medicare Part C and D Star Ratings Technical Notes, referred to as Technical Notes, available at [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings).     The MA and Part D Star Ratings System is designed to provide information to the beneficiary that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care. The information included in the ratings is selected based on its relevance and importance such that it can meet the data needs of beneficiaries using it to inform plan choice. While encouraging improved health outcomes of beneficiaries in an efficient, person centered, equitable, and high quality manner is one of the

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primary goals of the ratings, they also provide feedback on specific aspects of care that directly impact outcomes, such as process measures and the beneficiary's perspective. The ratings focus on aspects of care that are within the control of the health plan and can spur quality improvement. The data used in the ratings must be complete, accurate, reliable, and valid. A delicate balance exists between measuring numerous aspects of quality and the need for a small data set that minimizes reporting burden for the industry. Also, the beneficiary or his or her representative must have enough information to make an informed decision without feeling overwhelmed by the volume of data.     The Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Healthcare and Education Reconciliation Act (Pub. L. 111-152), provides for quality ratings, based on a 5-star rating system and the information collected under section 1852(e) of the Act, to be used in calculating payment to MA organizations beginning in 2012. Specifically, sections 1853(o) and 1854(b)(1)(C) of the Act provide, respectively, for an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and benchmark available to the MA organization to use as a rebate. Under the Act, Part D plan sponsors are not eligible for quality based payments or rebates. We finalized a rule on April 15, 2011 to implement these provisions and to use the existing Star Ratings System that had been in place since 2007 and 2008. (76 FR 21485-21490).\35\ In addition, the Star Ratings measures are tied in many ways to responsibilities and obligations of MA organizations and Part D sponsors under their contracts with CMS. We believe that continued poor performance on the measures and overall and summary ratings indicates systemic and wide-spread problems in an MA plan or Part D plan. In April 2012, we finalized a regulation to use consistently low summary Star Ratings--meaning 3 years of summary Star Ratings below 3 stars--as the basis for a contract termination for Part C and Part D plans. (Sec. Sec.  422.510(a)(14) and 423.509(a)(13)). Those regulations further reflect the role the Star Ratings have had in CMS' oversight, evaluation, and monitoring of MA and Part D plans to ensure compliance with the respective program requirements and the provision of quality care and health coverage to Medicare beneficiaries. ---------------------------------------------------------------------------

    \35\ The ratings were first used as part of the Quality Bonus Payment Demonstration for 2012 through 2014 and then used for payment purposes as specified in sections 1853(o) and 1854(b)(1)(C) and the regulation at 42 CFR 422.258(d)(7). ---------------------------------------------------------------------------

    The true potential of the use of the MA and Part D Star Ratings System to reach our goals and to serve as a catalyst for change can only be realized by working in tandem with our many stakeholders including beneficiaries, industry, and advocates. The following guiding principles have been used historically in making enhancements to the MA and Part D Star Ratings:      Ratings align with the current CMS Quality Strategy.      Measures developed by consensus-based organizations are used as much as possible.      Ratings are a true reflection of plan quality and enrollee experience; the methodology minimizes risk of misclassification.      Ratings are stable over time.      Ratings treat contracts fairly and equally.      Measures are selected to reflect the prevalence of conditions and the importance of health outcomes in the Medicare population.      Data are complete, accurate, and reliable.      Improvement on measures is under the control of the health or drug plan.      Utility of ratings is considered for a wide range of purposes and goals.     ++ Accountability to the public.     ++ Enrollment choice for beneficiaries.     ++ Driving quality improvement for plans and providers.      Ratings minimize unintended consequences.      Process of developing methodology is transparent and allows for multi-stakeholder input.     We are using these goals to guide our proposal and how we interpret and apply the proposed regulations once finalized. For each provision we are proposing, we solicit comment on whether our specific proposed regulation text best serves these guiding principles. We also solicit comment on whether additional or other principles are better suited for these roles in measuring and communicating quality in the MA and Part D programs in a comparative manner.     As we continue to consider making changes to the MA and Part D programs in order to increase plan participation and improve benefit offerings to enrollees, we would also like to solicit feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. We welcome all comments on those topics, and will consider them for changes through this or future rulemaking or in connection with interpreting our regulations (once finalized) on the Star Rating system measures. However, we are particularly interested in receiving stakeholder feedback on the following topics:      Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.      Whether CMS' current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality.      How CMS should measure overall improvement across the Star Ratings measures. We are requesting input on additional improvement adjustments that could be implemented, and the effect that these adjustments could have on new entrants (that is, new MA organizations and/or new plans offered by existing MA organizations).      Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.      In order to further encourage plan participation and new market entrants, whether CMS should consider implementing a demonstration to test alternative approaches for putting new entrants (that is, new MA organizations) on a level playing field with renewing plans from a Star Ratings perspective for a pre-determined period of time.      Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.      Including survey measures of physicians' experiences. (Currently, we measure beneficiaries' experiences with their health and drug plans through the CAHPS survey.) Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services, and we would welcome comments.

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c. Basis, Purpose and Applicability of the Quality Star Ratings System     We propose to codify regulation text, at Sec. Sec.  422.160 and 423.180, that identifies the statutory authority, purpose, and applicability of the Star Ratings System regulations we are proposing to add to part 422 subpart D and part 423 subpart D. Under our proposal, the existing purposes of the quality rating system--to provide comparative information to Medicare beneficiaries pursuant to sections 1851(d) and 1860D-1(c) of the Act, to identify and apply the payment consequences for MA plans under sections 1853(o) and 1854(b)(1)(C) of the Act, and to evaluate and oversee overall and specific performance by plans--would continue. To reflect how the Part D ratings are used for MA-PD plan QBP status and rebate retention allowances, we also propose specific text, to be codified at Sec.   423.180(b)(2), noting that the Part D Star Rating will be used for those purposes.     We are proposing here, broadly stated, to codify the current quality Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019. We are proposing some changes, such as how we handle consolidations from the current Star Ratings program, but overall the proposal is to continue the Star Ratings System as it has been developed and has stabilized. Data will be collected and performance will be measured using these proposed rules and regulations for the 2019 measurement period; the associated quality Star Ratings will be used to assign QBP ratings for the 2022 payment year and released prior to the annual coordinated election period held in late 2020 for the 2021 contract year. Application of the final regulations resulting from this proposal will determine whether the measures proposed in section III.A.12.i of the proposed rule (Table 2) are updated, transitioned to or from the display page, and otherwise used in conjunction with the 2019 performance period.     Under our proposal, the current quality Star Ratings System and the procedures for revising it will remain in place for the 2019 and 2020 quality Star Ratings. Section 1853(b) of the Act authorizes an advance notice and rate announcement to announce and seek comment for proposed changes to the MA payment methodology, which includes the Part C and D Star Ratings program. The statute identifies specific notice and comment timeframes, but that process does not require publication in the Federal Register. We have used the draft and final Call Letter, which are attachments to the Advance Notice and final Rate Announcement respectively,\36\ to propose for comment and finalize changes to the quality Star Ratings System since the ratings became a component of the payment methodology for MA and MA-PD plans. (76 FR 214878 through 89). Because the Star Ratings System has been integrated into the payment methodology since the 2012 contract year (as a mechanism used to determine how much a plan is paid, and not the mechanism by which (or a rule about when) a plan is paid), the Star Ratings are part of the process for setting benchmarks and capitation rates under section 1853, and the process for announcing changes to the Star Ratings System falls within the scope of section 1853(b). Although not expressly required by section 1853(b), CMS has historically solicited comment on significant changes to the ratings system using a Request for Comment process before the Advance Notice and draft Call Letter are released; this Request for Comment \37\ provides MAOs, Part D sponsors, and other stakeholders an opportunity to request changes to and raise concerns about the Star Ratings methodology and measures before CMS finalizes its proposal for the Advance Notice. We intend to continue the current process at least until the 2019 measurement period that we are proposing as the first measurement period under these new regulations, but we may discontinue that process at a later date as the rulemaking process may provide sufficient opportunity for public input. In addition, CMS issues annually the Technical Notes \38\ that describe in detail how the methodology is applied from the changes in policy adopted through the Advance Notice and Rate Announcement process. We intend to continue the practice of publishing the Technical Notes during the preview periods. Under our proposal, we would also continue to use the draft and final Call Letters as a means to provide subregulatory application), interpretation, and guidance of the final version of these proposed regulations where necessary. Our proposed regulation text does not detail these plans for continued use of the current process and future for subregulatory guidance because we believe such regulation text would be unnecessary. We propose to codify the first performance period (2019) and first payment year (2022) to which our proposed regulations would apply at Sec.  422.160(c) and Sec.  423.180(c). ---------------------------------------------------------------------------

    \36\ Advance Notices and Rate Announcements are posted each year on the CMS Web site at: [*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html*](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html)     \37\ Requests for Comment are posted at   [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings) under the downloads.     \38\   [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings) (under the downloads) for the Technical Notes. ---------------------------------------------------------------------------

d. Definitions     There are a number of technical and other terms relevant to our proposed regulations. Therefore, we propose the following definitions for the respective subparts in part 422 and part 423 in paragraph (a) of Sec. Sec.  422.162 and 423.182 respectively. Some proposed definitions are discussed in more detail later in this preamble in connection with other proposed regulation text related to the definition.      CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.      Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.      Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy or have disability status in that contract (or plan as applicable).      Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure- specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify

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the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.      Consolidation means when an MA organization/Part D sponsor that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.      Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.      Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.      Domain rating means the rating that groups measures together by dimensions of care.      Dual Eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.      HEDIS is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.      Highest rating means the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.      Highly-rated contract means a contract that has 4 or more stars for their highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).      HOS means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.      Low Income Subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see Sec.  423.34 for definition of a low-income subsidy eligible individual).      Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.      Measure score means the numeric value of the measure or an assigned `missing data' message.      Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1-5 star scale.      Overall Rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.      Part C Summary Rating means a global rating that summarizes the health plan quality and performance on Part C measures.      Part D Summary Rating means a global rating of the prescription drug plan quality and performance on Part D measures.      Plan Benefit Package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by PDP sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.      Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (``signal'') rather than random variation (``noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).      Reward factor means a rating-specific factor added to the contract's summary or overall (or both) rating if a contract has both high and stable relative performance.      Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same. Although not part of the proposed regulatory definition, we clarify that CMS uses statistical tests (for example, t-test) to determine if a contract's measure value is statistically different (greater than or less than depending on the test) from the national mean for that measure, or whether conversely, the observed differences from the national mean could have arisen by chance.      Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.      Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by ***deleting*** the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place ***deleted***. e. Contract Ratings     Star Ratings and data reporting are at the contract level for most measures. Currently, data for measures are collected at the contract level including data from all PBPs under the contract, except for the following Special Needs Plan (SNP)-specific measures which are collected at the PBP level: Care for Older Adults--Medication Review, Care for Older Adults--Functional Status Assessment, and Care for Older Adults--Pain Assessment. The SNP-specific measures are rolled up to the contract level by using an enrollment-weighted mean of the SNP PBP scores. Subject to the discussion later in this section about the feasibility and burden of collecting data at the PBP (plan) level and the reliability of ratings at the plan level, we propose to continue the practice of calculating the Star Ratings at the contract level and all PBPs under the contract would have the same overall and/or summary ratings.     However, beneficiaries select a plan, rather than a contract, so we have considered whether data should be collected and measures scored at the plan level. We have explored the feasibility of separately reporting quality data for individual D-SNP PBPs, instead of the current reporting level. For example, in order for CAHPS measures to be reliably scored, the number of respondents must be at least 11 people and reliability must be at least 0.60 Our current analyses show that, at the PBP level, CAHPS measures could be reliably reported for only about one-third of D-SNP PBPs due to sample size

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issues, and HEDIS measures could be reliably reported for only about one-quarter of D-SNP PBPs. If reporting were done at the plan level, a significant number of D-SNP plans would not be rated and in lieu of a Star Rating, Medicare Plan Finder would display that the plan is ``too small to be rated.'' However, when enough data are available, plan level quality reporting would better reflect the quality of care provided to enrollees in that plan. Plan-level quality reporting would also give states that contract with D-SNPs plan-specific information on their performance and provide the public with data specific to the quality of care for dual eligible (DE) beneficiaries enrolled in these plans. For all plans as well as D-SNPs, reporting at the plan level would significantly increase plan burden for data reporting and would have to be balanced against the availability of additional clinical information available at the plan level. Plan-level ratings would also potentially increase the ratings of higher-performing plans when they are in contracts that have a mix of high and low performing plans. Similarly, plan-level ratings would also potentially decrease the ratings of lower-performing plans that are currently in contracts with a mix of high and low performing plans. Measurement reliability issues due to small sample sizes would also decrease our ability to measure true performance at the plan level and add complexities to the rating system. We are soliciting comments on balancing the improved precision associated with plan level reporting (relative to contract level reporting) with the negative consequences associated with an increase in the number of plans without adequate sample sizes for at least some measures; we ask for comments about this for D-SNPs and for all plans as we continue to consider whether rating at the plan level is feasible or appropriate. In particular, we are interested in feedback on the best balance and whether changing the level at which ratings are calculated and reported better serves beneficiaries and our goals for the Star Ratings System.     We are also exploring whether some measure data could be reported at a higher level (parent organization versus contract) to ease and simplify reporting and still remain useful (for example, call center measures as we anticipate that parent organizations use a consolidated call center to serve all contracts and plans) to incorporate into the Star Ratings. Further, we are exploring if contract market area reporting is feasible when a contract covers a large geographic area. For example, when HEDIS reporting began in 1997, there were contract- specific market areas that evolved into reporting by market area for five states with large Medicare populations.\39\ We are planning to continue work in this area to determine the best reporting level for each measure that most accurately reflects performance and minimizes to the extent possible plan reporting burden. As we consider alternative reporting units, we welcome comments and suggestions about requiring reporting at different levels (for example, parent organization, contract, plan, or geographic area) by measure. ---------------------------------------------------------------------------

    \39\ The following states were divided into multiple market areas: CA, FL, NY, OH, and TX. ---------------------------------------------------------------------------

    We propose to continue at this time calculating the same overall and/or summary Star Ratings for all PBPs offered under an MA-only, MA- PD, or PDP contract. We propose to codify this policy in regulation text at Sec. Sec.  422.162(b) and 423.182(b). We also propose a cost plan regulation at Sec.  417.472(k) to require cost contracts to be subject to the part 422 and part 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System as they are measured and rated like an MA plan. Specifically, we propose, at paragraph (b)(1) that CMS will calculate overall and summary ratings at the contract level and propose regulation text that cross-references other proposed regulations regarding the calculation of measure scoring and rating, and domain, summary and overall ratings. Further, we propose to codify, at (b)(2) of each section, that data from all PBPs offered under a contract will continue to be used to calculate the ratings for the contract. For SNP specific measures collected at the PBP level, we propose that the contract level score would be an enrollment-weighted mean of the PBP scores using enrollment in each PBP as reported as part of the measure specification, which is consistent with current practice. The proposed text is explicit that domain and measure ratings, other than the SNP-specific measures, are based on data from all PBPs under the contract. f. Contract Consolidations     We are proposing a change in how contract-level Star Ratings are assigned in the case of contract consolidations. We have historically permitted MAOs and Part D sponsors to consolidate contracts when a contract novation occurs or to better align business practices. As noted in MedPAC's March 2016 Report to Congress ([*https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*](https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs)), there has been a continued increase in the number of enrollees being moved from lower Star Rating contracts that do not receive a QBP to higher Star Rating contracts that do receive a QBP as part of contract consolidations, which increases the size of the QBPs that are made to MAOs due to the large enrollment increase in the higher rated, surviving contract. We are worried that this practice results in masking low quality plans under higher rated surviving contracts. This does not provide beneficiaries with accurate and reliable information for enrollment decisions, and it does not truly reward higher quality contracts. We propose here to modify from the current policy the calculation of Star Ratings for surviving contracts that have consolidated. Instead of assigning the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, we propose to assign and display on Medicare Plan Finder Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Under this proposal, the calculation of the measure, domain, summary, and overall ratings would be based on these enrollment-weighted mean scores. The number of contracts this would impact is small relative to all contracts that qualify for QBPs. During the period from 1/1/2015 through 1/1/2017 annual consolidations for MA contracts ranged from a low of 7 in 2015 to a high of 19 in 2016 out of approximately 500 MA contracts. As proposed in Sec. Sec.  422.162(b)(3)(i)-(iii) and 423.182(b)(3)(i)-(iii), CMS will use enrollment-weighted means of the measure scores of the consumed and surviving contracts to calculate ratings for the first and second plan years following the contract consolidations. We believe that use of enrollment-weighted means will provide a more accurate snapshot of the performance of the underlying plans in the new consolidated contract, such that both information to beneficiaries and QBPs are not somehow inaccurate or misleading. We also propose, however, that the process of weighting the enrollment of each contract and applying this general rule would vary depending on the specific types of measures involved in order to take into account the measurement period and

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data collection processes of certain measures. Our proposal would also treat ratings for determining quality bonus payment (QBP) status for MA contracts differently than displayed Star Ratings for the first year following the consolidation for consolidations that involve the same parent organization and plans of the same plan type.     We propose to codify our new policy at Sec. Sec.  422.162(b)(3) and 423.182(b)(3). First, we propose generally, at paragraph (b)(3)(i) of each regulation, that CMS will assign Star Ratings for consolidated contracts using the provisions of paragraph (b)(3). We are proposing in Sec.  422.162(b)(3) both a specific rule to address the QBP rating following the first year after the consolidation and a rule for subsequent years. As Part D plan sponsors are not eligible for QBPs, the Part D regulation text is proposed without the QBP aspect. We propose in Sec.  422.162(b)(3)(iv) and Sec.  423.182(b)(3)(ii) the process for assigning Star Ratings for posting on the Medicare Plan Finder for the first 2 years following the consolidation.     For the first contract year following a consolidation, as proposed at paragraphs Sec.  422.162(b)(3)(iv) and Sec.  423.182(b)(3)(ii), we propose to use the enrollment-weighted means as calculated below to set Star Ratings for publication (and, in Sec.  422.162(b)(3)(iii), use of certain enrollment-weighted means for establishing QBP status:      The Star Ratings measure scores for the consolidated entity's first plan year would be based on enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey- based and call center measures.      The survey-based measures (that is, CAHPS, HOS, and HEDIS measures collected through CAHPS or HOS) would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. For example, for a contract consolidation that is effective January 1, 2021 the CAHPS sample for the 2021 Star Ratings would be pulled in January 2020 so enrollment in January 2020 would be used. The call center measures would use mean enrollment during the study period. We believe that these proposals for survey-based measures are more nuanced and account for how the data underlying those measures are gathered. By using the enrollment-weighted means we are reflecting the true underlying performance of both the surviving and consumed contracts.     For the second year following the consolidation, for all MA and Part D Sponsors, the Star Ratings would be calculated as follows:      The enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts would be used for all measures except HEDIS, CAHPS, and HOS.      The current reporting requirements for HEDIS and HOS already combine data from the surviving and consumed contract(s) following the consolidation, so we are not proposing any modification or averaging of these measure scores. For example, for HEDIS if an organization consolidates one or more contracts during the change over from measurement to reporting year, then only the surviving contract is required to report audited summary contract-level data but it must include data on all members from all contracts involved. For this reason, we are proposing regulation text that HEDIS and HOS measure data will be used as reported in the second year after consolidation.      The CAHPS survey sample that would be selected following the consolidation would be modified to include enrollees in the sample universe from which the sample is drawn from both the surviving and consumed contracts. If there are two contracts (that is, Contract A is the surviving contract and Contract B is the consumed contract) that consolidate, and Contract A has 5,000 enrollees eligible for the survey and Contract B has 1,000 eligible for the survey, the universe from which the sample would be selected would be 6,000.     After applying these rules for calculating the measure scores in the first and second year after consolidation, CMS would use the other rules proposed in Sec. Sec.  422.166 and 423.186 to calculate the measure, domain, summary, and overall Star Ratings for the consolidated contract. In the third year after consolidation and subsequent years, the performance period for all the measures would be after the consolidation, so our proposal is limited to the Star Ratings issued the first 2 years after consolidation.     When consolidations involve two or more contracts for health and/or drug services of the same plan type under the same parent organization combining into a single contract at the start of a contract year, we propose to calculate the QBP rating for that first year following the consolidation using the enrollment-weighted mean, using traditional rounding rules, of what would have been the QBP ratings of the surviving and consumed contracts using the contract enrollment in November of the year the Star Ratings were released. In November of each year following the release of the ratings on Medicare Plan Finder, the preliminary QBP ratings are displayed in the Health Plan Management System (HPMS) for the year following the Star Ratings year. For example, the first year the consolidated entity is in operation is plan year 2020; the 2020 QBP rating displayed in HPMS in November 2018 would be based on the 2019 Star Ratings (which are released in October 2018) and calculated using the weighted mean of the November 2018 enrollment of the surviving and consumed contracts. Because the same parent organization is involved in these situations, we believe that many administrative processes and procedures are identical in the Medicare health plans offered by the sponsoring organization, and using a weighted mean of what would have been their QBP ratings accurately reflects their performance for payment purposes. In subsequent years after the first year following the consolidation, QBPs status would be determined based on the consolidated entity's Star Rating posted on Medicare Plan Finder. Under our proposal, the measure, domain, summary, and in the case of MA-PD plans the overall Star Ratings posted on Medicare Plan Finder for the second year following consolidation would be based on the enrollment-weighted measure scores so would include data from all contracts involved. Consequently, the ratings used for QBP status determinations would reflect the care provided by both the surviving and consumed contracts.     In conclusion, we are proposing a new set of rules regarding the calculation of Star Ratings for consolidated contracts to be codified at paragraphs (b)(3)(i) through (iv) of Sec. Sec.  422.162 and 423.182 In most cases, we propose that the Star Ratings for the first and second year following the consolidation to be an enrollment-weighted mean of the scores at the measure level for the consumed and surviving contracts. For the QBP rating for the first year following the consolidation, we propose to use the enrollment-weighted mean of the QBP rating of the surviving and consumed contracts (which would be the overall or summary rating depending on the plan type) rather than averaging measure scores. We solicit comment on this proposal and whether our separate treatment of different measure types during the first and second year adequately addresses the differences in how data are collected (and submitted) for those measures during the different

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periods. We would also like to know whether sponsoring organizations believe that the special rule for consolidations involving the same parent organization and same plan types adequately addresses how those situations are different from cases where an MA organization buys or sells a plan or contract from or to a different entity and whether these rules should be extended to situations where there are different parent organizations involved. For commenters that support the latter, we also request comment on how CMS should determine that the same administrative processes are used and whether attestations from sponsoring organizations or evidence from prior audits should be required to support such determinations. g. Data Sources     Under 1852(e) of the Act, MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. The Star Ratings System is based on information collected consistent with section 1852(e) of the Act. Section 1852(e)(3)(B) of the Act prohibits the collection of data on quality, outcomes, and beneficiary satisfaction other than the types of data that were collected by the Secretary as of November 1, 2003; there is a limited exception for SNPs to collect, analyze, and report data that permit the measurement of health outcomes and other indicia of quality. The statute does not require that only the same data be collected, but that we do not change or expand the type of data collected until after submission of a Report to Congress (prepared in consultation with MA organizations and accrediting bodies) that explains the reason for the change(s). We clarify here that the types of data included under the Star Ratings System are consistent with the types of data collected as of November 1, 2003. Since 1997, Medicare managed care organizations have been required to annually report quality of care performance measures through HEDIS. We have also been conducting the CAHPS survey since 1997 to measure beneficiaries' experiences with their health plans, and since 2007 we have been measuring experiences with drug plans with CAHPS. HOS began in 1998 to capture changes in the physical and mental health of MA enrollees. To some extent, these surveys have been revised and updated over time, but the same types of data--clinical measures, beneficiary experiences, and changes in physical and mental health, respectively--have remained the focus of these surveys. In addition, there are several measures in the Stars Ratings System that are based on performance that address telephone customer service, members' complaints, disenrollment rates, and appeals; however these additional measures are not collected directly from the sponsoring organizations for the primary purpose of quality measurement. These additional measures are calculated from information that CMS has gathered as part of the administration of the Medicare program, such as information on appeals forwarded to the Independent Review Entity under subparts M, enrollment, and compliance and enforcement actions.     The Part D program was implemented in 2006, and while there is no parallel provision regarding applicable Part D sources of data, we have used similar datasets, for example CAHPS survey data, for beneficiaries' experiences with prescription drug plans. Section 1860D- 4(d) of the Act specifically directs the administration and collection of data from consumer surveys in a manner similar to those conducted in the MA program. All of these measures reflect structure, process, and outcome indices of quality that form the measurement set under Star Ratings. Since 2007, we have publicly reported a number of measures related to the drug benefit as part of the Star Ratings. For MA organizations that offer prescription drug coverage, we have developed a series of measures focusing on administration of the drug benefit. Similar to MA measures of quality relative to health services, the Part D measures focus on customer service and beneficiary experiences, effectiveness, and access to care relative to the drug benefit. We believe that the Part D Star Ratings are consistent with the limitation expressed in section 1852(e) of the Act even though the limitation does not apply to our collection of Part D quality data from Part D sponsors.     We intend to continue to base the types of information collected in the Part C Star Ratings on section 1852(e) of the Act, and we propose at Sec.  422.162(c)(1) that the type of data used for Star Ratings will be data consistent with the section 1852(e) limits and data gathered from CMS administration of the MA program. In addition, we propose in Sec.  422.162(c)(1) and in Sec.  423.182(c)(1) to include measures that reflect structure, process, and outcome indices of quality, including Part C measures that reflect the clinical care provided, beneficiary experience, changes in physical and mental health, and benefit administration, and Part D measures that reflect beneficiary experiences and benefit administration. The measures encompass data submitted directly by MA organizations (MAOs) and Part D sponsors to CMS, surveys of MA and Part D enrollees, data collected by CMS contractors, and CMS administrative data. We also propose, primarily so that the regulation text is complete on this point, a regulatory provision at Sec. Sec.  422.162(c)(2) and 423.182(c)(2) that requires MA organizations and Part D plan sponsors to submit unbiased, accurate, and complete quality data as described in paragraph(c)(1) of each section. Our authority to collect quality data is clear under the statute and existing regulations, such as section 1852(e)(3)(A) and 1860D-4(d) and Sec. Sec.  422.12(b)(2) and 423.156 We propose the paragraph (c)(2) regulation text to ensure that the quality ratings system regulations include a regulation on this point for readers and to avoid confusion in the future about the authority to collect this data. In addition, it is important that the data underlying the ratings are unbiased, accurate, and complete so that the ratings themselves are reliable. This proposed regulation text would clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance. h. Adding, Updating, and Removing Measures     We are committed to continuing to improve the Part C and D Star Ratings System by focusing on improving clinical and other outcomes. We anticipate that new measures will be developed and that existing measures will be updated over time. NCQA and the Pharmacy Quality Alliance (PQA) continually work to update measures as clinical guidelines change and develop new measures focused on health and drug plans. To address these anticipated changes, we propose in Sec. Sec.   422.164 and 423.184 specific rules to govern the addition, update, and removal of measures. We also propose to apply these rules to the measure set proposed in this rulemaking, to the extent that there are changes between the final rule and the Star Ratings based on the performance periods beginning on or after January 2019.     As discussed in more detail in the following paragraphs, we propose the following general rules to govern adding, updating, and removing measures:      For data quality issues identified during the calculation of the Star Ratings for a given year, we propose to continue our current practice of

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removing the measure from the Star Ratings.      That new measures and substantive updates to existing measures would be added to the Star Ratings System based on future rulemaking but that prior to such a rulemaking, CMS would announce new measures and substantive updates to existing measures and solicit feedback using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act (that is the Call Letter attachment to the Advance Notice and Rate Announcement).      That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be updated with regular updates from the measure stewards through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act when the changes are not substantive.      That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be removed from use in the Star Ratings when there has been a change in clinical guidelines associated with the measure or reliability issues identified in advance of the measurement period; CMS would announce the removal using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Removal might be permanent or temporary, depending on the basis for the removal.     We are proposing specific rules for updating and removal that would be implemented through subregulatory action, so that rulemaking will not be necessary for certain updates or removals. Under this proposal, CMS would announce application of the regulation standards in the Call Letter attachment to the Advance Notice and Rate Announcement process under section 1853(b) of the Act.     First, we propose to codify, at Sec. Sec.  422.164(a) and 423.184(a), regulation text stating the general rule that CMS would add, update, and remove measures used to calculate Star Ratings as provided in Sec. Sec.  422.164 and 423.184 In each paragraph regarding addition, updating, and removal of measures and the use of improvement measures, we also propose rules to identify when these types of changes would not involve rulemaking based on application of the standards and authority in the regulation text. Under our proposal, CMS would solicit feedback of its application of the rules using the draft and final Call Letter each year.     Second, we propose, in paragraph (b) of these sections, that CMS would review the quality of the data on which performance, scoring, and rating of measures is done each year. We propose to continue our current practice of reviewing data quality across all measures, variation among organizations and sponsors, and measures' accuracy, reliability, and validity before making a final determination about inclusion of measures in the Star Ratings. The intent is to ensure that Star Ratings measures accurately measure true plan performance. If a systemic data quality issue is identified during the calculation of the Star Ratings, we would remove the measure from that year's rating under proposed paragraph (b).     Third, we propose to address the addition of new measures in paragraph (c).     In identifying whether to add a measure, we will be guided by the principles we listed in section III.A.12.b of the proposed rule. Measures should be aligned with best practices among payers and the needs of the end users, including beneficiaries. Our strategy is to continue to adopt measures when they are available, nationally endorsed, and in alignment with the private sector, as we do today through the use of measures developed by NCQA and the PQA, and the use of measures that are endorsed by the National Quality Forum (NQF). We propose to codify this standard for adopting new measures at Sec. Sec.   422.164(c)(1) and 423.184(c)(1). We do not intend this standard to require that a measure be adopted by an independent measure steward or endorsed by NQF in order for us to propose its use for the Star Ratings, but that these are considerations that will guide us as we develop such proposals. We also propose that CMS may develop its own measures as well when appropriate to measure and reflect performance in the Medicare program.     For the 2021 Star Ratings, we propose (at section III.A.12 ) of the proposed rule to have measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures. It is important to have a mix of different types of measures in the Star Ratings program to understand how all of the different facets of the provision of health and drug services interact. For example, process measures are evidence-based best practices that lead to clinical outcomes of interest. Process measures are generally easier to collect, while outcome measures are sometimes more challenging requiring in some cases medical record review and more sophisticated risk-adjustment methodologies.     Over time new measures will be added and measures will be removed from the Star Ratings program to meet our policy goals. As new measures are added, our general guidelines for deciding whether to propose new measures through future rulemaking will use the following criteria:      Importance: The extent to which the measure is important to making significant gains in health care processes and experiences, access to services and prescription medications, and improving health outcomes for MA and Part D enrollees.      Performance Gap: The extent to which the measure demonstrates opportunities for performance improvement based on variation in current health and drug plan performance.      Reliability and Validity: The extent to which the measure produces consistent (reliable) and credible (valid) results.      Feasibility: The extent to which the data related to the measure are readily available or could be captured without undue burden and could be implemented by the majority of MA and Part D contracts.      Alignment: The extent to which the measure or measure concept is included in one or more existing federal, State, and/or private sector quality reporting programs.     We would balance these criteria as part of our decision making process so that each new measure proposed for addition to the Star Ratings meets each criteria in some fashion or to some extent. We intend to apply these criteria to identify and adopt new measures for the Star Ratings, which will be done through future rulemaking that includes explanations for how and why we propose to add new measures. When we identify a measure that meets these criteria, we propose to follow the process in our proposed paragraphs (c)(2) through (4) of Sec. Sec.  422.164 and 423.184 We would initially solicit feedback on any potential new measures through the Call Letter.     As new performance measures are developed and adopted, we propose, at Sec. Sec.  422.164(c)(3) and (4) and 423.184(c)(3) and (4), that they would initially be incorporated into the display page for at least 2 years but that we would keep a new measure on the display page for a longer period if CMS finds there are reliability or validity issues with the measure. As noted in the

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Introduction, the rulemaking process will create a longer lead time for changes, in particular to add a new measure to the Star Ratings or to make substantive changes to measures as discussed later in this section. Here is an example timeline for adding a new measure to the Star Ratings. In this scenario, the new measure has already been developed by the NCQA and the PQA, and endorsed by the NQF. Otherwise, that process may add an extra 3 to 5 years to the timeline.      January 2019: Solicit feedback on whether to add the new measure in the draft 2020 Call Letter.      April 2019: Summarize feedback on adding the new measure in the 2020 Call Letter.      2020/2021: Propose adding the new measure to the 2024 Star Ratings (2022 measurement period) in a proposed rule; finalize through rulemaking (for 1/1/2022 effective date).      2020: Performance period and collection of data for the new measure and collection of data for posting on the 2022 display page.      2021: Performance period and collection of data for the new measure and collection of data for posting on the 2023 display page.      Fall 2021: Publish new measure on the 2022 display page (2020 measurement period).      January 1, 2022: Applicability date of new measure for Star Ratings.      2022: Performance period and collection of data for the new measure and collection of data for inclusion in the 2024 Star Ratings.      Fall 2022: Publish new measure on the 2023 display page (2021 measurement period).      Fall 2023: Publish new measure in the 2024 Star Ratings (2022 measurement period).      2025: QBP status and rebate retention allowances are determined for the 2025 payment year.     Fourth, at Sec. Sec.  422.164(d) and 423.184(d) we propose to address updates to measures based on whether an update is substantive or non-substantive. Since quality measures are routinely updated (for example, when clinical codes are updated), we propose to adopt rules for the incorporation of non-substantive updates to measures that are part of the Star Ratings System without going through new rulemaking. As proposed in paragraphs (d)(1) of Sec. Sec.  422.164 and 423.184, we would only incorporate updates without rulemaking for measure specification changes that do not substantively change the nature of the measure.     Substantive changes (for example, major changes to methodology) to existing measures would be proposed and finalized through rulemaking. In paragraphs (d)(2) of Sec. Sec.  422.164 and 423.184, we propose to initially solicit feedback on whether to make the substantive measure update through the Call Letter prior to the measurement period for which the update would be initially applicable. For example, if the change announced significantly expands the denominator or population covered by the measure (for example, the age group included in the measures is expanded), the measure would be moved to the display page for at least 2 years and proposed through rulemaking for inclusion in Star Ratings. We intend this process for substantive updates to be similar to the process we would use for adopting new measures under proposed paragraph (c). As appropriate, the legacy measure may remain in the Star Ratings while the updated measure is on the display page if, for example, the updated measure expands the population covered in the measure and the legacy measure would still be relevant and measuring a critical topic to continue including in the Star Ratings while the updated measure is on display. Adding the updated measure to the Star Ratings would be proposed through rulemaking.     We propose to adopt rules to incorporate specification updates that are non-substantive in paragraph (d)(1). Non-substantive updates that occur (or are announced by the measure steward) during or in advance of the measurement period will be incorporated into the measure and announced using the Call Letter. We propose to use such updated measures to calculate and assign Star Ratings without the updated measure being placed on the display page. This is consistent with current practice.     In paragraph (d)(1)(i-v) of Sec. Sec.  422.164 and paragraph (d)(1)(i-v) of 423.184, we propose to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period and how we would treat them under our proposal. The list includes updates in the following circumstances:      If the change narrows the denominator or population covered by the measure with no other changes, the updated measure would be used in the Star Ratings program without interruption. For example, if an additional exclusion--such as excluding nursing home residents from the denominator--is added, the change would be considered non- substantive and would be incorporated automatically. In our view, changes to narrow the denominator generally benefit Star Ratings of sponsoring organizations and should be treated as non-substantive for that reason.      If the change does not meaningfully impact the numerator or denominator of the measure, the measure would continue to be included in the Star Ratings. For example, if additional codes are added that increase the number of numerator hits for a measure during or before the measurement period, such a change would not be considered substantive because the sponsoring organization would generally benefit from that change. This type of administrative (billing) change has no impact on the current clinical practices of the plan or its providers, and thus would not necessitate exclusion from the Star Ratings System of any measures updated in this way.      The clinical codes for quality measures (such as HEDIS measures) are routinely revised as the code sets are updated. For updates to address revisions to the clinical codes without change in the intent of the measure and the target population, the measure would remain in the Star Ratings program and would not move to the display page. Examples of clinical codes that might be updated or revised without substantively changing the measure include:     ++ ICD-10-CM (``ICD-10'') code sets. Annually, there are new ICD 10 coding updates, which are effective from October 1 through September 30th of any given year.     ++ Current Procedural Terminology (CPT) codes. These codes are published and maintained by the American Medical Association (AMA) to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient.     ++ Healthcare Common Procedure Coding System (HCPCS) codes. These codes cover items, supplies, and non-physician services not covered by CPT codes.     ++ National Drug Code (NDC). The PQA updates NDC lists biannually, usually in January and July.      If the measure specification change is providing additional clarifications such as the following, the measure would also not move to the display page since this does not change the intent of the measure but provides more information about how to meet the measure specifications:     ++ Adding additional tests that would meet the numerator requirements.     ++ Clarifying documentation requirements (for example, medical record documentation).

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    ++ Adding additional instructions to identify services or procedures that meet (or do not meet) the specifications of the measure.      If the measure specification change is adding additional data sources, the measure would also not move to the display page because we believe such changes are merely to add alternative ways to collect the data to meet the measure specifications without changing the intent of the measure.     We solicit comment on our proposal to add non-substantive updates to measures and using the updated measure (replacing the legacy measure) to calculate Star Ratings. In particular, we are interested in stakeholders' views whether only non-substantive updates that have been adopted by a measure steward after a consensus-based or notice and comment process should be added to the Star Ratings under this proposed authority. Further, we solicit comment on whether there are other examples or situations involving non-substantive updates that should be explicitly addressed in the regulation text or if our proposal is sufficiently extensive.     In addition to updates and additions of measures, we are proposing rules to address the removal of measures from the Star Ratings to be codified in Sec. Sec.  422.164(e) and 423.184(e). In paragraph (e)(1) of each section, we propose the two circumstances under which a measure would be removed entirely from the calculation of the Star Ratings. The first circumstance would be changes in clinical guidelines that mean that the measure specifications are no longer believed to align with or promote positive health outcomes. As clinical guidelines change, we would need the flexibility to remove measures from the Star Ratings that are not consistent with current guidelines. We are proposing to announce such subregulatory removals through the Call Letter so that removals for this reason are accomplished quickly and as soon as the disconnect with positive clinical outcomes is definitively identified. We note that this proposal is consistent with our current practice. For example, previously we retired the Glaucoma Screening measure for HEDIS 2015 after the U.S Preventive Services Task Force concluded that the clinical evidence is insufficient to assess the balance of benefits and harms of screening for glaucoma in adults.     In addition to removal of measures because of changes in clinical guidelines, we currently review measures continually to ensure that the measure remains sufficiently reliable such that it is appropriate to continue use of the measure in the Star Ratings. We propose, at paragraph (e)(1)(ii), that we would also have authority to subregulatorily remove measures that show low statistical reliability so as to move swiftly to ensure the validity and reliability of the Star Ratings, even at the measure level. We will continue to analyze measures to determine if measure scores are ``topped out'' (that is, showing high performance across all contracts decreasing the variability across contracts and making the measure unreliable) so as to inform our approach to the measure, or if measures have low reliability. Although some measures may show uniform high performance across contracts and little variation between them, we seek evidence of the stability of such high performance, and we want to balance how critical the measures are to improving care, the importance of not creating incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures. If, for example, performance in a given measure has just improved across all contracts, or if no other measures capture a key focus in Star Ratings, a ``topped out'' measure which would have lower reliability may be retained in Star Ratings. Under our proposal to be codified at paragraph (e)(2), we would announce application of this rule through the Call Letter in advance of the measurement period.     We request comment on these proposals regarding the processes to add, update, and remove Star Ratings measures. i. Measure Set for Performance Periods Beginning on or After January 1, 2019     We are proposing the measures included in Table 2 to be collected for performance periods beginning on or after January 1, 2019 for the 2021 Part C and D Star Ratings. The CAHPS measure specification, including case-mix adjustment, is described in the Technical Notes and at ma-pdpcahps.org The HOS measure specification, including case-mix adjustment, is described at ([*http://hosonline.org/globalassets/hos-online/survey-results/hos\_casemix\_coefficient\_tables\_c17.pdf*](http://hosonline.org/globalassets/hos-online/survey-results/hos_casemix_coefficient_tables_c17.pdf)). These specifications are part of our proposal.     We are not proposing to codify this list of measures and specifications in regulation text in light of the regular updates and revisions contemplated by our proposals at Sec. Sec.  422.164 and 423.184 We intend, as proposed in paragraph (a) of these sections, that the Technical Notes for each year's Star Ratings would include the applicable full list of measures. BILLING CODE 4120-01-P

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[GRAPHIC] [TIFF OMITTED] TP28NO17.000

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[GRAPHIC] [TIFF OMITTED] TP28NO17.001

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[GRAPHIC] [TIFF OMITTED] TP28NO17.002

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[GRAPHIC] [TIFF OMITTED] TP28NO17.003

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[GRAPHIC] [TIFF OMITTED] TP28NO17.004

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[GRAPHIC] [TIFF OMITTED] TP28NO17.007

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j. Improvement Measures     In the 2013 Part C and D Star Ratings, we implemented the Part C and D improvement measures (CY2013 Rate Announcement, [*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf*](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf)). The improvement measures address the overall improvement or decline in individual measure scores from the prior to the current year. We propose to continue the current methodology detailed in the Technical Notes for calculating the improvement measures and to codify it at Sec. Sec.  422.164(f) and 423.184(f). For a measure to be included in the improvement calculation, the measure must have numeric value scores in both the current and prior year and not have had a substantive specification change during those years. In addition, the improvement measure will not include any data on measures that are already focused on improvement (for example, HOS measures focused on improving or maintaining physical or mental health). The Part C improvement measure includes only Part C measure scores, and the Part D improvement measure includes only Part D measure scores. All measures meeting these criteria would be included in the improvement measures under our proposal at paragraph (f)(1)(i) through (iv) of Sec. Sec.  422.164 and 423.184     Annually, the subset of measures to be included in the improvement measures following these criteria would be announced through the Call Letter, similar to our proposal for regular updates and removal of measures. Under our proposal, once the measures to be used for the improvement measures are identified, CMS would determine which contracts have sufficient data for purposes of applying and scoring the improvement measure(s). Following current practices, the improvement measure score would be calculated only for contracts that have numeric measure scores for both years for at least half of the measures identified for use in the improvement measure. We propose this standard for determining contracts eligible for an improvement measure at paragraph (f)(2).     We propose at part Sec. Sec.  422.164(f)(3) and (4) and 423.184(f)(3) and (4) the process for calculating the improvement measure score(s) and a special rule for any identified improvement measure for a contract that received a measure-level Star Rating of 5 in each of the 2 years examined, but whose associated measure score indicates a statistically significant decline in the time period. The improvement measure would be calculated in a series of distinct steps:      The improvement change score (the difference in the measure scores in the 2-year period) would be determined for each measure that has been identified as part of an improvement measure and for which a contract has a numeric score for each of the 2 years examined.      Each contract's improvement change score would be categorized as a significant change or not by employing a two tailed t- test with a level of significance of 0.05      The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.      The improvement measure score would then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.      The improvement measure score would be converted to a measure-level Star Rating using the hierarchical clustering algorithm.     The improvement measure score cut points would be determined using two separate clustering algorithms. Improvement measure scores of zero and above would use the clustering algorithm to determine the cut points for the Star Rating levels of 3 and above. Improvement measure scores below zero would be clustered to determine the cut points for 1 and 2 stars. The Part D improvement measure thresholds for MA-PDs and PDPs would be reported separately.     We propose a special rule in paragraph (f)(3) to hold harmless sponsoring organizations that have 5-star ratings for both years on a measure used for the improvement measure calculation. This hold harmless provision was added in 2014 to avoid the unintended consequence for contracts that score 5 stars on a subset of measures in each of the 2 years. For any identified improvement measure for which a contract received a rating of 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change. The measure will be included in the count of measures used to determine eligibility for the improvement measure and in the denominator of the improvement measure score. The intent of the hold harmless provision for a contract that receives a measure rating of 5 stars for each year is to prevent the measure from lowering a contract's improvement measure when the contract still demonstrates high performance. We propose in section III.A.12 of this proposed rule another hold harmless provision to be codified at Sec. Sec.  422.166(g)(1) and 423.186(g)(1).     We request comment on the methodology for the improvement measures, including rules for determining which measures are included, the conversion to a Star Rating, and the hold harmless provision for individual measures that are used for the determination of the improvement measure score. k. Data Integrity     The data underlying a measure score and rating must be complete, accurate, and unbiased for it to be useful for the purposes we have proposed at Sec. Sec.  422.160(b) and 423.180(b). As part of the current Star Ratings methodology, all measures and the associated data have multiple levels of quality assurance checks. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's measure data are incomplete, inaccurate, or biased. Data validation is a shared responsibility among CMS, CMS data providers, contractors, and Part C and D sponsors. When applicable (for example, data from the IRE, PDE, call center), CMS expects sponsoring organizations to routinely monitor their data and immediately alert CMS if errors or anomalies are identified so CMS can address these errors.     We propose to codify at Sec. Sec.  422.164(g) and 423.184(g) specific rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures. Data may be determined to be incomplete, inaccurate, or biased based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that impacted specific measure(s). One example of such situations that give rise to such determinations includes a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements. Our modifications to measure-specific ratings due to data integrity issues are separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies. This policy and

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these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when deficiencies have been identified that show we cannot objectively evaluate a sponsor's performance in an area.     As a standard practice, we check for flags that indicate bias or non-reporting, check for completeness, check for outliers, and compare measures to the previous year to identify significant changes which could be indicative of data issues. CMS has developed and implemented Part C and Part D Reporting Requirements Data Validation standards to assure that data reported by sponsoring organizations pursuant to Sec. Sec.  422.516 and 423.514 satisfy the regulatory obligation. Sponsor organizations should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications is posted on: [*http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx*](http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx) Information about Data Validation of Reporting Requirements data is posted on:   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html) and   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting\_ReportingOversight.html*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html)     We propose, in paragraphs (g)(1)(i) through (iii), rules for specific circumstances where we believe a specific response is appropriate. First, we propose a continuation of a current policy: To reduce HEDIS measures to 1 star when audited data are submitted to NCQA with an audit designation of ``biased rate'' or BR based on an auditor's review of the data if a plan chooses to report; this proposal would also apply when a plan chooses not to submit and has an audit designation of ``non-report'' or NR. Second, we propose to continue to reduce Part C and D Reporting Requirements data, that is, data required pursuant to Sec. Sec.  422.514 and 423.516, to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with data validation standards/ sub-standards for data directly used to calculate the associated measure. In our view, data that do not reach at least 95 percent on the data validation standards are not sufficiently accurate, impartial, and complete for use in the Star Ratings. As the sponsoring organization is responsible for these data and submits them to CMS, we believe that a negative inference is appropriate to conclude that performance is likely poor. Third, we propose a new specific rule to authorize scaled reductions in Star Ratings for appeal measures in both Part C and Part D.     The data downgrade policy was adopted to address instances when the data that would be used for specific measures are not reliable for measuring performance due to their incompleteness or biased/erroneous nature. For instances where the integrity of the data is compromised because of the action or inaction of the sponsoring organization (or its subcontractors or agents), this policy reflects the underlying fault of the sponsoring organization for the lack of data for the applicable measure. Without some policy for reduction in the rating for these measures, sponsoring organizations could ``game'' the Star Ratings and merely fail to submit data that illustrate poor performance. We believe that removal of the measure from the ratings calculation would unintentionally reward poor data compilation and submission activities such that our only recourse is to reduce the rating to 1 star for affected measures.     For verification and validation of the Part C and D appeals measures, we propose to use statistical criteria to determine if a contract's appeals measure-level Star Ratings would be reduced for missing IRE data. The criteria would allow us to use scaled reductions for the appeals measures to account for the degree to which the data are missing. The completeness of the IRE data is critical to allow fair and accurate measurement of the appeals measures. All plans are responsible and held accountable for ensuring high quality and complete data to maintain the validity and reliability of the appeals measures.     In response to stakeholder concerns about CMS' prior practice of reducing measure ratings to one star based on any finding of data inaccuracy, incompleteness, or bias, CMS initiated the Timeliness Monitoring Project (TMP) in CY 2017.\40\ The first submission for the TMP was for the measurement year 2016 related to Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. The timeframe for the submitted data was dependent on the enrollment of the contract with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period.\41\ ---------------------------------------------------------------------------

    \40\ This project was discussed in the November 28, 2016 HPMS memo, ``Industry-wide Appeals Timeliness Monitoring.'' [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf),   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf)     \41\ Contracts with a mean annual enrollment of less than 50,000 are required to submit data for a three-month time period. Contracts with a mean enrollment of at least 50,000 but at most 250,000 are required to submit data for a two-month time period. Contracts with a mean enrollment greater than 250,000 are required to submit data for a one-month period. ---------------------------------------------------------------------------

    We propose to use multiple data sources whenever possible, such as the TMP data or information from audits to determine whether the data at the Independent Review Entity (IRE) are complete. Given the financial and marketing incentives associated with higher performance in Star Ratings, safeguards are needed to protect the Star Ratings from actions that inflate performance or mask deficiencies.     CMS is proposing to reduce a contract's Part C or Part D appeal measures Star Ratings for IRE data that are not complete or otherwise lack integrity based on the TMP or audit information. The reduction would be applied to the measure-level Star Ratings for the applicable appeals measures. There are varying degrees of data issues and as such, we are proposing a methodology for reductions that reflects the degree of the data accuracy issue for a contract instead of a one-size fits all approach. The methodology would employ scaled reductions, ranging from a 1-star reduction to a 4-star reduction; the most severe reduction for the degree of missing IRE data would be a 4-star reduction which would result in a measure-level Star Rating of 1 star for the associated appeals measures (Part C or Part D). The data source for the scaled reduction is the TMP or audit data, however the specific data used for the determination of a Part C IRE data completeness reduction are independent of the data used for the Part D IRE data completeness reduction. If a contract receives a reduction due to missing Part C IRE data, the reduction would be applied to both of the contract's Part C appeals measures. Likewise, if a contract receives a reduction due to missing Part D IRE data, the reduction would be applied to both of the contract's Part D appeals measures. We solicit comment on this proposal and its scope; we are looking in particular for comments related to how to use the process we are proposing

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in this proposal to account for data integrity issues discovered through means other than the TMP and audits of sponsoring organizations.     CMS' proposed scaled reduction methodology is a three-stage process using the TMP or audit information to determine: First, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, the basis for the estimate of the error rate; and finally, whether the estimated error rate is significantly greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars.     Once the scaled reduction for a contract is determined using this methodology, the reduction would be applied to the contract's associated appeals measure-level Star Ratings. The minimum measure- level Star Rating is 1 star. If the difference between the associated appeals measure-level Star Rating (before the application of the reduction) and the identified scaled reduction is less than one, the contract would receive a measure-level Star Rating of 1 star for the appeals measure.     The error rate for the Part C and Part D appeals measures using the TMP or audit data and the projected number of cases not forwarded to the IRE for a 3-month period would be used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. A minimum error rate is proposed to establish a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold allows the focus of the possible reductions on contracts with error rates that have the greatest potential to distort the signal of the appeals measures. Since the timeframe for the TMP data is dependent on the enrollment of the contract, with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a 2-month period, and larger contracts submitting data from a one-month period, the use of a projected number of cases allows a consistent time period for the application of the criteria proposed.     The calculated error rate formula (Equation 1) for the Part C measures is proposed to be determined by the quotient of the number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during TMP or audit data collection period and the number of cases not forwarded to the IRE during the same period. [GRAPHIC] [TIFF OMITTED] TP28NO17.008

    The calculated error rate formula (Equation 2) for the Part D measures is proposed to be determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases. [GRAPHIC] [TIFF OMITTED] TP28NO17.009

    The projected number of cases not forwarded to the IRE in a 3-month period would be calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the TMP time period. Contracts with mean annual enrollments greater than 250,000 that submitted data from 1-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 3.0 Contracts with mean enrollments of 50,000 but at most 250,000 that submitted data from a 2-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.5 Small contracts with mean enrollments less than 50,000 that submitted data for a 3-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.0     Under this proposal, contract ratings would be subject to a possible reduction due to lack of IRE data completeness if both following conditions are met The calculated error rate is 20 percent or more.      The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.     The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions, the contract would not be subject to reductions for IRE data completeness issues.     If a contract is subject to a possible reduction based on the aforementioned conditions, a confidence interval estimate for the true error rate for the contract would be calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent.     The midpoint of the score interval would be determined using Equation 3. [GRAPHIC] [TIFF OMITTED] TP28NO17.010

    The z score that corresponds to a level of statistical significance of 0.05, commonly denoted as z[alpha]/2 but for ease of presentation represented here as z. (The z value that will be used for the purpose of the calculation of the interval is 1.959964 ).     For the Part C appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 1. The total number of cases in Equation 3 is the number of cases that should have been in the IRE for the Part C TMP data.     For the Part D appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 2. The total number of cases in

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Equation 3 is the total number of untimely cases for the Part D appeals measures.     Letting the calculated error rate be represented by and the total number of cases represented as n, Equation 3 can be streamlined as Equation 4: [GRAPHIC] [TIFF OMITTED] TP28NO17.011

    The lower bound of the confidence interval estimate for the error rate is calculated using Equation 5 below: [GRAPHIC] [TIFF OMITTED] TP28NO17.012

    For each contract subject to a possible reduction, the lower bound of the interval estimate of the error rate would be compared to each of the thresholds in Table 3. If the contract's calculated lower bound is higher than the threshold, the contract would receive the reduction that corresponds to the highest threshold that is less than the lower bound. In other words, the contract's lower bound is being employed to determine whether the contract's error rate is significantly greater than the thresholds of 20 percent, 40 percent, 60 percent, and 80 percent. The proposed scaled reductions are in Table 3, and would be codified in narrative form at paragraph (g)(1)(iii)(D) of both regulations.     The reductions due to IRE data completeness issues would be applied after the calculation of the measure-level Star Rating for the appeals measures. The reduction would be applied to the Part C appeals measures and/or the Part D appeals measures.     It is important to note that a contract's lower bound could be statistically significantly greater than more than one threshold. The reduction would be determined by the highest threshold that the contract's lower bound exceeds. For example, if the lower bound for a contract is 64.560000 percent, the contract's estimated value is significantly greater than the thresholds of 20 percent, 40 percent, and 60 percent because the lower bound value 64.560000 percent is greater than each of these thresholds. The lower bound for the contract's confidence interval is not greater than 80 percent. The contract would be subject to the reduction that corresponds to the 60 percent threshold, which is three stars.

 Table 3--Appeals Measure Star Ratings Reductions by the Incomplete Data                                Error Rate ------------------------------------------------------------------------                                                            Reduction for Proposed thresholds using the lower bound of  confidence    incomplete         interval  estimate of the error rate (%)             IRE data                                                               (stars) ------------------------------------------------------------------------ 20......................................................               1 40......................................................               2 60......................................................               3 80......................................................               4 ------------------------------------------------------------------------

    We propose regulation text at Sec.  422.164(g)(1)(iii)(A) through (N) and Sec.  423.184(g)(1)(iii)(A) through (K) to codify these parameters and formulas for the scaled reductions. We note that the proposed text for the Part C regulation includes specific paragraphs related to MA and MA-PD plans that are not included in the proposed text for the Part D regulation but that the two are otherwise identical.     In addition, we propose in Sec. Sec.  422.164(g)(2) and 423.184(g)(2) to authorize reductions in a Star Rating for a measure when there are other data accuracy concerns (that is, those not specified in paragraph (g)(1)). We propose an example in paragraph (g)(2) of another circumstance where CMS would be authorized to reduce ratings based on a determination that performance data are incomplete, inaccurate, or biased. We also propose this other situation would result in a reduction of the measure rating to 1 star.     We have taken several steps in past years to protect the integrity of the data we use to calculate Star Ratings. However, we welcome comments about alternative methods for identifying inaccurate or biased data and comments on the proposed policies for reducing stars for data accuracy and completeness issues. Further, we welcome comments on the proposed methodology for scaled reductions for the Part C and Part D appeals measures to address the degree of missing IRE data. l. Measure-Level Star Ratings     We propose in Sec. Sec.  422.166(a) and 423.186(a) the methods for calculating Star Ratings at the measure level. As part of the Part C and D Star Ratings System, Star Ratings are currently calculated at the measure level. To separate a distribution of scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is a set of cut points. We propose to continue to determine cut points by applying either clustering or a relative distribution and significance testing methodology; we propose to codify this policy in paragraphs (a)(1) of each section. We propose in paragraphs (a)(2) and (a)(3) of each section that for non-CAHPS measures, we would use a clustering methodology and that for CAHPS measures, we would use relative distribution and significance testing. Measure scores would be converted to a 5-star scale ranging from 1 to 5, with whole star increments for the cut points. A rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Consistent with current policy, we propose to use the two methodologies described as follows to convert measure scores to measure-level Star Ratings.     The clustering method would be applied to all Star Ratings measures, except for the CAHPS measures. For each individual measure, we would determine the measure cut points using all measure scores for all contracts required to report that do not have missing, flagged as biased, or erroneous data. For the Part D measures, we propose to determine MA-PD and PDP cut points separately. The scores would

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be grouped such that scores within the same rating (that is 1 star, 2 stars, etc.) are as similar as possible, and scores in different ratings are as different as possible. The hierarchical clustering algorithm and the associated tree and cluster assignments using SAS (a statistical software package) are currently used to determine the cut points for the assignment of the measure-level Star Ratings. We intend to continue use of this software under this proposal, but improvements in statistical analysis will not result in rulemaking or changes in these proposed rules. Rather, we believe that the software used to apply the clustering methodology is generally irrelevant.     Conceptually, the clustering algorithm identifies natural gaps within the distribution of the scores and creates groups (clusters) that are then used to identify the cut points that result in the creation of a pre-specified number of categories. The Euclidean distance between each pair of contracts' measure scores serves as the input for the clustering algorithm. The hierarchical clustering algorithm begins with each contract's measure score being assigned to its own cluster. Ward's minimum variance method is used to separate the variance of the measure scores into within-cluster and between-cluster sum of squares components in order to determine which pairs of clusters to merge. For the majority of measures, the final step in the algorithm is done a single time with five categories specified for the assignment of individual scores to cluster labels. The cluster labels are then ordered to create the 1 to 5-star scale. The range of the values for each cluster (identified by cluster labels) is examined and would be used to determine the set of cut points for the Star Ratings. The measure score that corresponds to the lower bound for the measure-level ratings of 2 through 5 would be included in the star-specific rating category for a measure for which a higher score corresponds to better performance. For a measure for which a lower score is better, the process would be the same except that the upper bound within each cluster label would determine the set of cut points. The measure score that corresponds to the cut point for the ratings of 2 through 5 would be included in the star-specific rating category. In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters. Under our proposal to use clustering to set cut points, we would not require the same number of observations (contracts) within each rating and instead would use a data-driven approach.     As proposed in paragraphs (a)(2)(ii) of each section the improvement measures for Part C and Part D would require the clustering algorithm to be done twice for the identification of the cut points that would allow the conversion of the improvement measure scores to the star scale. The Part D improvement measure score clustering for MA- PDs and PDPs would be reported separately. Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating, while improvement scores less than zero would be assigned either 1 or 2 stars. The clustering would be conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero. For contracts with improvement scores greater than or equal to zero, the clustering process would result in three clusters with measure-level Star Ratings of 3, 4, or 5 with the lower bound of each cluster serving as the cut point for the associated Star Rating. For those contracts with improvement scores less than zero, the clustering algorithm would result in two clusters with measure-level Star Ratings of 1 or 2.     We propose in paragraphs (a)(3) of each section to use percentile standing relative to the distribution of scores for other contracts, measurement reliability standards, and statistical significance testing to determine star assignments for the CAHPS measures. This method would combine evaluating the relative percentile distribution of scores with significance testing and measurement reliability standards in order to maximize the accuracy of star assignments based on scores produced from the CAHPS survey. For CAHPS measures, contracts are first classified into base groups by comparisons to percentile cut points defined by the current-year distribution of case-mix adjusted contract means. Percentile cut points would then be rounded to the nearest integer on the 0-100 reporting scale, and each base group would include those contracts whose rounded mean score is at or above the lower limit and below the upper limit. Then, the number of stars assigned would be determined by the base group assignment, the statistical significance and direction of the difference of the contract mean from the national mean, an indicator of the statistical reliability of the contract score on a given measure (based on the ratio of sampling variation for each contract mean to between-contract variation), and the standard error of the mean score. Table 4, which we propose to codify at Sec. Sec.   422.166(a)(3) and 423.186(a)(3), details the CAHPS star assignment rules for each rating. All statistical tests, including comparisons involving standard error, would be computed using unrounded scores.     We propose that if the reliability of a CAHPS measure score is very low for a given contract, less than 0.60, the contract would not receive a Star Rating for that measure. For purposes of applying the criterion for 1 star on Table 3, at item (c), low reliability scores would be defined as those with at least 11 respondents and reliability greater than or equal to 0.60 but less than 0.75 and also in the lowest 12 percent of contracts ordered by reliability. The standard error would be considered when the measure score is below the 15th percentile (in base group 1), significantly below average, and has low reliability: In this case, 1 star would be assigned if and only if the measure score is at least 1 standard error below the unrounded cut point between base groups 1 and 2. Similarly, when the measure score is at or above the 80th percentile (in base group 5), significantly above average, and has low reliability, 5 stars would be assigned if and only if the measure score is at least 1 standard error above the unrounded cut point between base groups 4 and 5.

                  Table 4--CAHPS Star Assignment Rules ------------------------------------------------------------------------           Star                  Criteria for assigning star ratings ------------------------------------------------------------------------ 1.......................  A contract is assigned one star if both                            criteria (a) and (b) are met plus at least                            one of criteria (c) and (d):                           (a) Its average CAHPS measure score is lower                            than the 15th percentile; AND                           (b) its average CAHPS measure score is                            statistically significantly lower than the                            national average CAHPS measure score;                           (c) the reliability is not low; OR                           (d) its average CAHPS measure score is more                            than one standard error (SE) below the 15th                            percentile.

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  2.......................  A contract is assigned two stars if it does                            not meet the one[dash]star criteria and meets                            at least one of these three criteria:                           (a) Its average CAHPS measure score is lower                            than the 30th percentile and the measure does                            not have low reliability; OR                           (b) its average CAHPS measure score is lower                            than the 15th percentile and the measure has                            low reliability; OR                           (c) its average CAHPS measure score is                            statistically significantly lower than the                            national average CAHPS measure score and                            below the 60th percentile. 3.......................  A contract is assigned three stars if it meets                            at least one of these three criteria:                           (a) Its average CAHPS measure score is at or                            above the 30th percentile and lower than the                            60th percentile, AND it is not statistically                            significantly different from the national                            average CAHPS measure score; OR                           (b) its average CAHPS measure score is at or                            above the 15th percentile and lower than the                            30th percentile, AND the reliability is low,                            AND the score is not statistically                            significantly lower than the national average                            CAHPS measure score; OR                           (c) its average CAHPS measure score is at or                            above the 60th percentile and lower than the                            80th percentile, AND the reliability is low,                            AND the score is not statistically                            significantly higher than the national                            average CAHPS measure score. 4.......................  A contract is assigned four stars if it does                            not meet the 5-star criteria and meets at                            least one of these three criteria:                           (a) Its average CAHPS measure score is at or                            above the 60th percentile and the measure                            does not have low reliability; OR                           (b) its average CAHPS measure score is at or                            above the 80th percentile and the measure has                            low reliability; OR                           (c) its average CAHPS measure score is                            statistically significantly higher than the                            national average CAHPS measure score and                            above the 30th percentile. 5.......................  A contract is assigned five stars if both                            criteria (a) and (b) are met plus at least                            one of criteria (c) and (d):                           (a) Its average CAHPS measure score is at or                            above the 80th percentile; AND                           (b) its average CAHPS measure score is                            statistically significantly higher than the                            national average CAHPS measure score;                           (c) the reliability is not low; OR                           (d) its average CAHPS measure score is more                            than one SE above the 80th percentile. ------------------------------------------------------------------------

    We request comments on our proposed methods to determine cut points. For certain measures, we previously published pre-determined 4- star thresholds. If commenters recommend pre-determined 4-star thresholds, we request suggestions on how to minimize generating Star Ratings that do not reflect a contract's ``true'' performance, otherwise referred to as the risk of ``misclassifying'' a contract's performance (for example, scoring a ``true'' 4-star contract as a 3- star contract, or vice versa, or creating ``cliffs'' in Star Ratings and therefore, potential benefits between plans with nearly identical Star Ratings on different sides of a fixed threshold), and how to continue to create incentives for quality improvement. We also welcome comments on alternative recommendations for revising the cut point methodology. For example, we are considering methodologies that would minimize year-to-year changes in the cut points by setting the cut points so they are a moving average of the cut points from the two or three most recent years or setting caps on the degree to which a measure cut point could change from one year to the next. We welcome comments on these particular methodologies and recommendations for other ways to provide stability for cut points from year to year. m. Hierarchical Structure of the Ratings     We propose to continue our existing policy to use a hierarchical structure for the Star Ratings. The basic building block of the MA Star Ratings System is, and under our proposal would continue to be, the measure. Because the MA Star Ratings System consists of a large collection of measures across numerous quality dimensions, the measures would be organized in a hierarchical structure that provides ratings at the measure, domain, Part C summary, Part D summary, and overall levels. The regulation text at Sec. Sec.  422.166 and 423.186 is built on this structure and provides for calculating ratings at each ``level'' of the system. The organization of the measures into larger groups increases both the utility and efficiency of the rating system. At each aggregated level, ratings are based on the measure-level stars. Ratings at the higher level are based on the measure-level Star Ratings, with whole star increments for domains and half-star increments for summary and overall ratings; a rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Half-star increments are used in the summary and overall ratings to allow for more variation at the higher hierarchical levels of the ratings system. We believe this greater variation and the broader range of ratings provide more useful information to beneficiaries in making enrollment decisions while remaining consistent with the statutory direction in sections 1853(o) and 1854(b) of the Act to use a 5-star system. These policies for the assignment of stars would be codified with other rules for the ratings at the domain, summary, and overall level. Domain ratings employ an unweighted mean of the measure-level stars, while the Part C and D summary and overall ratings employ a weighted mean of the measure-level stars and up to two adjustments. We propose to codify these policies at paragraphs (b)(2), (c)(1) and (d)(1) of Sec. Sec.  422.166 and 423.186 n. Domain Star Ratings     Groups of measures that together represent a unique and important aspect of quality and performance are organized to form a domain. Domain ratings summarize a plan's performance on a specific dimension of care. Currently the domains are used purely for purposes of displaying data on Medicare Plan Finder to organize the measures and help consumers interpret the data. We propose to continue this policy at Sec. Sec.  422.166(b)(1)(i) and 423.186(b)(1)(i).     At present, there are nine domains--five for Part C measures for MA-only and MA-PDs plans and four for Part D measures for MA-PDs. We propose to continue to group measures for purposes of display on Medicare Plan Finder and to continue use of the same domains as in current practice in Sec. Sec.  422.166(b)(1)(i) and 423.196(b)(1)(i). The current domains are listed in Tables 5 and 6.

                         Table 5--Part C Domains ------------------------------------------------------------------------                                  Domain ------------------------------------------------------------------------- Staying Healthy: Screenings, Tests and Vaccines. Managing Chronic (Long Term) Conditions. Member Experience with Health Plan.

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  Member Complaints and Changes in the Health Plan's Performance. Health Plan Customer Service. ------------------------------------------------------------------------

                         Table 6--Part D Domains ------------------------------------------------------------------------                                  Domain ------------------------------------------------------------------------- Drug Plan Customer Service. Member Complaints and Changes in the Drug Plan's Performance. Member Experience with the Drug Plan. Drug Safety and Accuracy of Drug Pricing. ------------------------------------------------------------------------

    Currently, Star Ratings for domains are calculated using the unweighted mean of the Star Ratings of the included measures. They are displayed to the nearest whole star, using a 1-5 star scale. We propose to continue this policy at paragraph (b)(2)(ii). We also propose that a contract must have stars for at least 50 percent of the measures required to be reported for that domain for that contract type to have that domain rating calculated in order to have enough data to reflect the contract's performance on the specific dimension. For example, if a contract is rated only on one measure in Staying Healthy: Screenings, Tests and Vaccines, that one measure would not necessarily be representative of how the contract performs across the whole domain so we do not believe it is appropriate to calculate and display a domain rating. We propose to continue this policy by providing, at paragraph (b)(2)(i), that a minimum number of measures must be reported for a domain rating to be calculated. o. Part C and D Summary Ratings     In the current rating system the Part C summary rating provides a rating of the health plan quality and the Part D summary rating provides a rating of the prescription drug plan quality. We are proposing, at Sec. Sec.  422.166(c) and 423.186(c), to codify regulation text governing the adoption of Part C summary ratings and Part D summary ratings. An MA-only plan and a Part D standalone plan would receive a summary rating only for, respectively, Part C measures and Part D measures.     First, in paragraphs (c)(1) of each section, we propose the overall formula for calculating the summary ratings for Part C and Part D. Under current policy, the summary rating for an MA-only contract is calculated using a weighted mean of the Part C measure-level Star Ratings with up to two adjustments: The reward factor (if applicable) and the categorical adjustment index (CAI); similarly, the current summary rating for a PDP contract is calculated using a weighted mean of the Part D measure-level Star Ratings with up to two adjustments: The reward factor (if applicable) and the CAI. We propose in Sec. Sec.   422.166(c)(1) and 423.186(c)(1) that the Part C and Part D summary ratings would be calculated as the weighted mean of the measure-level Star Ratings with an adjustment to reward consistently high performance (reward factor) and the application of the CAI, pursuant to paragraph (f) (where we propose the specifics for these adjustments) for Parts C and D, respectively.     Second, and also consistent with current policy, we propose an MA- only contract and PDP would have a summary rating calculated only if the contract meets the minimum number of rated measures required for its respective summary rating: A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated. The proposed regulation text would be codified as paragraph (c)(2)(i) of Sec. Sec.  422.166 and 423.186 The same rules would be applied to both the Part C and Part D summary ratings for the minimum number of rated measures and flags for display. We would apply this regulation to require a MA-PD to have a Part C and a Part D summary rating if the minimum requirement of rated measures for each summary rating type is met. The improvement measures are based on identified measures that are each counted towards meeting the proposed requirement for the calculation of a summary rating. We propose (at paragraph (c)(2)(ii)) that the improvement measures themselves are not included in the count of minimum number of measures for the Part C or Part D summary ratings.     Third, we propose a paragraph (c)(3) in both Sec. Sec.  422.166 and 423.186 to provide that the summary ratings are on a 1 to 5 star scale in half-star increments. Traditional rounding rules would be employed to round the summary rating to the nearest half-star. The summary rating would be displayed in HPMS and Medicare Plan Finder to the nearest half-star. As proposed in Sec. Sec.  422.166(h) and 423.186(h), if a contract has not met the measure requirement for calculating a summary rating, the display in HPMS (and on Medicare Plan Finder) for the applicable summary rating would be the flag ``Not enough data available'' or if the measurement period is less than 1 year past the contract's effective date the flag would be ``Plan too new to be measured''.     We welcome comments on the calculations for the Part C and D summary ratings. p. Overall Rating     The overall Star Rating is a global rating that summarizes the plan's quality and performance for the types of services offered by the plans under the rated contract. We propose at Sec. Sec.  422.166(d) and 423.186(d) to codify the standards for calculating and assigning overall Star Ratings for MA-PD contracts. The overall rating for an MA- PD contract is proposed to be calculated using a weighted mean of the Part C and Part D measure level Star Ratings, respectively, with an adjustment to reward consistently high performance described in paragraph (f)(1) and the application of the CAI, pursuant to described in paragraph (f)(2).     Consistent with current policy, we propose at paragraph (d)(2) that an MA-PD would have an overall rating calculated only if the contract receives both a Part C and Part D summary rating, and scores for at least 50% of the measures are required to be reported for the contract type to have the overall rating calculated. As with the Part C and D summary ratings, the Part C and D improvement measures would not be included in the count for the minimum number of measures for the overall rating. Any measure that shares the same data and is included in both the Part C and Part D summary ratings would be included only once in the calculation for the overall rating; for example, Members Choosing to Leave the Plan and Complaints about the Plan. As with summary ratings, we propose that overall MA-PD ratings would use a 1 to 5 star scale in half-star increments; traditional rounding rules would be employed to round the overall rating to the nearest half-star. These policies are proposed as paragraphs (d)(2)(i) through (iv).     In accordance with our general proposed policy at Sec. Sec.   422.166(h) and 423.186(h), the overall rating would be posted on HPMS and Medicare Plan Finder, with specific messages for lack of ratings for certain reasons. Applying that rule, if an MA-PD contract has only one of the two required summary ratings, the overall rating would not be calculated and the display in HPMS would be the flag ``Not enough data available.''     For QBP purposes, low enrollment contracts and new MA plans are defined in Sec.  422.252 Low enrollment contract

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means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcomes Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan; new MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. Low enrollment contracts and new plans do not receive an overall or summary rating because of the lack of necessary data. However, they are treated as qualifying plans for the purposes of QBPs. Section 1853(o)(3)(A)(ii)(II) of the Act, as implemented at Sec.  422.258(d)(7), provides that for 2013 and subsequent years, CMS shall develop a method for determining whether an MA plan with low enrollment is a qualifying plan for purposes of receiving an increase in payment under section 1853(o). This determination is applied at the contract level and thus determines whether a contract (meaning all plans under that contract) is a qualifying contract. The statute, at section 1853(o)(3)(A)(iii) of the Act, provides for treatment of new MA plans as qualifying plans eligible for a specific QBP. We therefore propose, at Sec. Sec.   422.166(d)(3) and 423.186(d)(3), that low enrollment contracts (as defined in Sec.  422.252 of this chapter) and new MA plans (as defined in Sec.  422.252 of this chapter) do not receive an overall and/or summary rating; they would be treated as qualifying plans for the purposes of QBPs as described in Sec.  422.258(d)(7) of this chapter and announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. This proposal would merely codify existing policy and practice. q. Measure Weights     Prior to the 2012 Part C and D Plan Ratings (now known as Star Ratings), all individual measures included in the program were weighted equally, suggesting equal importance. Based on feedback from stakeholders, including health and drug plans and beneficiary advocacy groups, we moved to provide greater weight to clinical outcomes and lesser weight to process measures. Patient experience and access measures were also given greater weight than process measures, but not as high as outcome measures. The differential weighting was implemented to help create further incentives to drive improvement in clinical outcomes, patient experience, and access. These differential weights for measures were implemented for the 2012 Ratings following a May 2011 Request for Comments and adopted in the CY2013 Rate Announcement and Final Call Letter.     In the Contract Year 2012 Final Rule for Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs rule (79 FR 21486), we stated that scoring methodologies should also consider improvement as an independent goal. To this end, we implemented in the CY 2013 Rate Announcement the Part C and D improvement measures that measure the overall improvement or decline in individual measure scores from the prior to the current year. Given the importance of recognizing quality improvement as an independent goal, for the 2015 Star Ratings, we proposed and subsequently finalized through the 2015 Rate Announcement and final Call Letter an increase in the weight of the improvement measure from 3 times to 5 times that of a process measure. This weight aligns the Part C and D Star Ratings program with value- based purchasing programs in Medicare fee-for-service which heavily weight improvement.     We are proposing in Sec. Sec.  422.166(e) and 423.186(e) to continue the current weighting of measures in the Part C and D Star Ratings program by assigning the highest weight (5) to improvement measures, followed by outcome and intermediate outcome measures (weight of 3), then by patient experience/complaints and access measures (weight of 1.5), and finally process measures (weight of 1). We are considering increasing the weight of the patient experience/complaints and access measures and are interested in stakeholder feedback on this potential change in order to reflect better the importance of these issues in plan performance. If we were to increase the weight, we are considering increasing it from a weight of 1.0 to between 1.5 and 3 similar to outcome measures. This increased weight would reflect CMS' commitment to serve Medicare beneficiaries by putting the patients first, including their assessments of the care received by plans. We solicit comment on this point, particularly the potential change in the weight of the patient experience/complaints and access measures.     Table 7 includes the proposed measure categories, the definitions of the measure categories, and the weights. In calculating the summary and overall ratings, a measure given a weight of 3 counts three times as much as a measure given a weight of 1. In section III.A.12 of this proposed rule, we propose (as Table 2) the measure set and include the category and weight for each measure; those weight assignments are consistent with this proposal. We propose that as new measures are added to the Part C and D Star Ratings, we would assign the measure category based on these categories and the regulation text proposed at Sec. Sec.  422.166(e) and 423.186(e), subject to two exceptions. We propose in paragraphs (e)(2) of each section as the first exception, to assign new measures to the Star Ratings program a weight of 1 for their first year in the Star Ratings. In subsequent years the weight associated with the measure weighting category would be used. This is consistent with current policy.

                              Table 7--Measure Categories, Definitions and Weights ----------------------------------------------------------------------------------------------------------------               Measure category                                    Definition                          Weight ---------------------------------------------------------------------------------------------------------------- Improvement.................................  Part C and Part D improvement measures are derived               5                                                through comparisons of a contract's current and                                                prior year measure scores. Outcome and Intermediate Outcome............  Outcome measures reflect improvements in a                       3                                                beneficiary's health and are central to assessing                                                quality of care. Intermediate outcome measures                                                reflect actions taken which can assist in                                                improving a beneficiary's health status.                                                Controlling Blood Pressure is an example of an                                                intermediate outcome measure where the related                                                outcome of interest would be better health status                                                for beneficiaries with hypertension. Patient Experience/Complaints...............  Patient experience measures reflect beneficiaries'             1.5                                                perspectives of the care and services they                                                received. Access......................................  Access measures reflect processes and issues that              1.5                                                could create barriers to receiving needed care.                                                Plan Makes Timely Decisions about Appeals is an                                                example of an access measure.

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  Process.....................................  Process measures capture the health care services                1                                                provided to beneficiaries which can assist in                                                maintaining, monitoring, or improving their                                                health status. ----------------------------------------------------------------------------------------------------------------

    In addition, we propose (at Sec. Sec.  422.166(e)(3) and 423.186(e)(3)) a second exception to the general weighting rule for MA and Part D contracts that have service areas that are wholly located in Puerto Rico. We recognize the additional challenge unique to Puerto Rico related to the medication adherence measures used in the Star Ratings Program due to the lack of Low Income Subsidy (LIS). For the 2017 Star Ratings, we implemented a different weighting scheme for the Part D medication adherence measures in the calculation of the overall and summary Star Ratings for contracts that solely serve the population of beneficiaries in Puerto Rico. We propose, at Sec. Sec.   422.166(e)(3) and 423.186(e)(3), to continue to reduce the weights for the adherence measures to 0 for the summary and overall rating calculations and maintain the weight of 3 for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico. We request comment on our proposed weighting strategy for Measure Weights generally and for Puerto Rico, including the weighting values themselves. r. Application of the Improvement Measure Scores     Consistent with current policy, we propose at Sec. Sec.  422.166(g) and 423.186(g) a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings. We are proposing, in paragraphs (g)(1)(i) through (iii), a series of rules that specify when the improvement measure is included in calculating overall and summary ratings.     MA-PDs would have the hold harmless provisions for highly-rated contracts applied for the overall rating. For an MA-PD that receives an overall rating of 4 stars or more without the use of the improvement measures and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded overall rating with and without the improvement measures is done. The overall rating with the improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The overall rating without the improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The higher overall rating would be used for the overall rating. For an MA-PD that has an overall rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the overall rating would exclude the improvement measure. For all others, the overall rating would include the improvement measure.     MA-only and PDPs would have the hold harmless provisions for highly-rated contracts applied for the Part C and D summary ratings, respectively. For an MA-only or PDP that receives a summary rating of 4 stars or more without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded summary rating with and without the improvement measure and up to two adjustments, the reward factor (if applicable) and CAI, is done. The higher summary rating would be used for the summary rating for the contract's highest rating. For MA-only and PDPs with a summary rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the summary rating would exclude the improvement measure. For all others, the summary rating would include the improvement measure. MA-PDs would have their summary ratings calculated with the use of the improvement measure regardless of the value of the summary rating.     In addition, at paragraph (g)(2), we also propose text to clarify that summary ratings use only the improvement measure associated with the applicable Part C or D performance.     We welcome comments on the hold harmless improvement provision we propose to continue to use, particularly any clarifications in how and when it should be applied. s. Reward Factor (Formerly Referred to as Integration Factor)     In 2011, the integration factor was added to the Star Ratings methodology to reward contracts that have consistently high performance. The integration factor was later renamed the reward factor. (The reference to either reward or integration factor refers to the same aspect of the Star Ratings.) This factor is calculated separately for the Part C summary rating, Part D summary rating for MA- PDs, Part D summary rating for PDPs, and the overall rating for MA-PDs. It is currently added to the summary (Part C or D) and overall rating of contracts that have both high and stable relative performance for the associated summary or overall rating. The contract's performance will be assessed using its weighted mean relative to all rated contracts without adjustments.     The contract's stability of performance will be assessed using its weighted variance relative to all rated contracts at the same rating level (overall, summary Part C, and summary Part D). The Part D summary thresholds for MA-PDs are determined independently of the thresholds for PDPs. We propose to codify the calculation and use of the reward factor in Sec. Sec.  422.166(f)(1) and 423.186(f)(1).     Annually, we propose to update the performance and variance thresholds for the reward factor based upon the data for the Star Ratings year, consistent with current policy. A multistep process would be used to determine the values that correspond to the thresholds for the reward factors for the summary and/or overall Star Ratings for a contract. The determination of the reward factors would rely on the contract's ranking of its weighted variance and weighted mean of the measure-level stars to the summary or overall rating relative to the distribution of all contracts' weighted variance and weighted mean to the summary and/or overall rating. A contract's weighted variance would be calculated using the quotient of the following two values: (1) The product of the number of applicable measures based on rating-type and the sum of the products of the weight of each applicable measure and its squared deviation \42\ and (2) the product of one less than the number of applicable measures and the sum of the weights of the applicable measures. A contract's weighted mean performance would be

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found by calculating the quotient of the following two values: (1) The sum of the products of the weight of a measure and its associated measure-level Star Ratings of the applicable measures for the rating- type and (2) the sum of the weights of the applicable measures for the rating type. The thresholds for the categorization of the weighted variance and weighted mean for contracts would be based upon the distribution of the calculated values of all rated contracts of the same type. Because highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean is calculated both with and without the improvement measures. ---------------------------------------------------------------------------

    \42\ A deviation is the difference between the performance measure's Star Rating and the weighted mean of all applicable measures for the contract. ---------------------------------------------------------------------------

    A contract's weighted variance is categorized into one of three mutually exclusive categories, identified in Table 8A, based upon the weighted variance of its measure-level Star Ratings and its ranking relative to all other contracts' weighted variance for the rating type (Part C summary for MA-PDs and MA-only, overall for MA-PDs, Part D summary for MA-PDs, and Part D summary for PDPs), and the manner in which the highest rating for the contract was determined--with or without the improvement measure(s). For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance for the rating type (Part C summary, Part D summary) with the improvement measure. Similarly, a contract's weighted mean is categorized into one of three mutually exclusive categories, identified in Table 8B, based on its weighted mean of all measure-level Star Ratings and its ranking relative to all other contracts' weighted means for the rating type (Part C summary for MA-PDs and MA-only, overall, Part D summary for MA-PDs, and Part D summary for PDPs) and the manner in which the highest rating for the contract was determined--with or without the improvement measure(s). For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted means for the rating type (Part C summary, Part D summary) with the improvement measure. Further, the same threshold criterion is employed per category regardless of whether the improvement measure was included or excluded in the calculation of the rating. The values that correspond to the thresholds are based on the distribution of all rated contracts and are determined with and without the improvement measure(s) and exclusive of any adjustments. Table 8A details the criteria for the categorization of a contract's weighted variance for the summary and overall ratings. Table 8B details the criteria for the categorization of a contract's weighted mean (performance) for the overall and summary ratings. The values that correspond to the cutoffs are provided each year during the plan preview and are published in the Technical Notes.

                                      Table 8A--Categorization of a Contract Based on Its Weighted Variance Ranking --------------------------------------------------------------------------------------------------------------------------------------------------------                 Variance category                                                                 Ranking -------------------------------------------------------------------------------------------------------------------------------------------------------- Low.............................................  Below the 30th percentile. Medium..........................................  At or above the 30th percentile to less than the 70th percentile. High............................................  At or above the 70th percentile. --------------------------------------------------------------------------------------------------------------------------------------------------------

                                   Table 8B--Categorization of a Contract Based on Weighted Mean (Performance) Ranking --------------------------------------------------------------------------------------------------------------------------------------------------------       Weighted mean  (performance) category                                                       Ranking -------------------------------------------------------------------------------------------------------------------------------------------------------- High............................................  At or above the 85th percentile. Relatively High.................................  At or above the 65th percentile to less than the 85th percentile. Other...........................................  Below the 65th percentile. --------------------------------------------------------------------------------------------------------------------------------------------------------

    These definitions of high, medium, and low weighted variance ranking and high, relatively high, and other weighted mean ranking would be codified in narrative form in paragraph (f)(1)(ii).     A contract's categorization for both weighted mean and weighted variance determines the value of the reward factor. Table 9 shows the values of the reward factor based on the weighted variance and weighted mean categorization; these values would be codified, as a chart, in paragraph (f)(i)(iii). The weighted variance and weighted mean thresholds for the reward factor are available in the Technical Notes and updated annually.

       Table 9--Categorization of a Contract for the Reward Factor ------------------------------------------------------------------------                                         Weighted mean          Weighted variance              (performance)     Reward  factor ------------------------------------------------------------------------ Low...............................  High................             0.4 Medium............................  High................             0.3 Low...............................  Relatively High.....             0.2 Medium............................  Relatively high.....             0.1 High..............................  Other...............             0.0 ------------------------------------------------------------------------

    We propose to continue the use of a reward factor to reward contracts with consistently high and stable performance over time. Further, we propose to continue to employ the methodology described in this subsection to categorize and determine the reward factor for contracts. As proposed in paragraphs (c)(1) and (d)(1), these reward factor adjustments would be applied at the summary and overall rating level.

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t. Categorical Adjustment Index     A growing body of evidence links the prevalence of beneficiary- level social risk factors with performance on measures included in Medicare value-based purchasing programs, including MA and Part D Star Ratings. With support from our contractors, we undertook research to provide scientific evidence as to whether MA organizations or Part D sponsors that enroll a disproportionate number of vulnerable beneficiaries are systematically disadvantaged by the current Star Ratings. In 2014, we issued a Request for Information to gather information directly from organizations to supplement the data that CMS collects, as we believe that plans and sponsors are uniquely positioned to provide both qualitative and quantitative information that is not available from other sources. In February and September 2015, we released details on the findings of our research.\43\ We have also reviewed reports about the impact of socio-economic status (SES) on quality ratings, such as the report published by the NQF posted at [*www.qualityforum.org/risk\_adjustment\_ses.aspx*](http://www.qualityforum.org/risk_adjustment_ses.aspx) and the Medicare Payment Advisory Commission's (MedPAC) Report to the Congress: Medicare Payment Policy posted at   [*http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0*](http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0). We have more recently been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE \44\) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and we have been considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use in nine Medicare value-based purchasing programs. The report also included considerations for strategies to account for social risk factors in these programs. A January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.\45\ ---------------------------------------------------------------------------

    \43\ The February release can be found at [*https://www.cms.gov/medicareprescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html*](https://www.cms.gov/medicareprescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html)     The September release can be found at   [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf)     \44\   [*https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*](https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs).     \45\ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press--   [*https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social*](https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social). ---------------------------------------------------------------------------

    We have also engaged NCQA and the PQA to examine their measure specifications used in the Star Ratings program to determine if re- specification is warranted. The majority of measures used for the Star Ratings program are consensus-based. Measure specifications can be changed only by the measure steward (the owner and developer of the measure). Thus, measure scores cannot be adjusted for differences in enrollee case mix unless required by the measure steward. Measure re- specification is a multiyear process. For example, NCQA has a standard process for reviewing any measure and determining whether a measure requires re-specification. NCQA's re-evaluation process is designed to ensure any resulting measure updates have desirable attributes of relevance, scientific soundness, and feasibility:      Relevance describes the extent to which the measure captures information important to different groups, for example, consumers, purchasers, policymakers. To determine relevance, NCQA assesses issues such as health importance, financial importance, and potential for improvement among entities being measured.      Scientific soundness captures the extent to which the measure adheres to clinical evidence and whether the measure is valid, reliable, and precise.      Feasibility captures the extent to which a measure can be collected at reasonable cost and without undue burden. To determine feasibility, NCQA also assesses whether a measure is precisely specified and can be audited. The overall process for assessing the value of re-specification emphasizes multi-stakeholder input, use of evidence-based guidelines and data, and wide public input.     Beginning with 2017 Star Ratings, we implemented the CAI that adjusts for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy and/or are dual eligible (LIS/DE) and/or have disability status. We developed the CAI as an interim analytical adjustment while we developed a long-term solution. The adjustment factor varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and beneficiaries with disabilities. By design, the CAI values are monotonic in at least one dimension (LIS/DE or disability status) and thus, contracts with larger LIS/DE and/or disability percentages realize larger positive adjustments. MA-PD contracts can have up to three rating-specific CAI adjustments--one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). MA-only contracts can have one adjustment for the Part C summary rating. PDPs can have one adjustment for the Part D summary rating. We propose to codify the calculation and use of the reward factor and the CAI in Sec. Sec.  422.166(f)(2) and 423.186(f)(2), while we consider other alternatives for the future.     As is currently done today, the adjusted measure scores of a subset of the Star Ratings measures would serve as the foundation for the determination of the index values. Measures would be excluded as candidates for adjustment if the measures are already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures), if the focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures), if the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied, or if the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). We propose to codify these paragraphs for determining the measures for CAI values at paragraph (f)(2)(ii).The categorization of a beneficiary as LIS/DE for the CAI would rely on the monthly indicators in the enrollment file. For the determination of the CAI values, the measurement period would correspond to the previous Star Ratings year's measurement period. For the identification of a contract's final adjustment category for its application of the CAI in the current year's Star Ratings Program, the measurement period would align with the Star Ratings year. If a beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period, the

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beneficiary would be categorized as LIS/DE. For the categorization of a beneficiary as disabled, we would employ the information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems. Disability status would be determined using the variable original reason for entitlement (OREC) for Medicare. The percentages of LIS/DE and disability per contract would rely on the Medicare enrollment data from the applicable measurement year. The counts of beneficiaries for enrollment and categorization of LIS/DE and disability would be restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. Further, a beneficiary would be assigned to the contract based on the December file of the applicable measurement period. We propose to codify these paragraphs for determining the enrollment counts at paragraph (f)(2)(i)(B).     Using the subset of the measures that meet the basic inclusion requirements, we propose to select the measure set for adjustment based on the analysis of the dispersion of the LIS/DE within-contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. For the selection of the Part D measures, MA-PDs and PDPs would be independently analyzed. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately, and the difference between the LIS/DE and non-LIS/DE performance rates per contract would be calculated. CMS would use a logistic mixed effects model for estimation purposes that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract and LIS/DE.     Using the analysis of the dispersion of the within-contract disparity of all contracts included in the modelling, the measures for adjustment would be identified employing the following decision criteria: (1) A median absolute difference between LIS/DE and non-LIS/ DE beneficiaries for all contracts analyzed is 5 percentage points or more or \46\ (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts. We propose to codify these paragraphs for the selection criteria for the adjusted measures for the CAI at paragraph (f)(2)(iii). ---------------------------------------------------------------------------

    \46\ The use of the word `or' in the decision criteria implies that if one condition or both conditions are met, the measure would be selected for adjustment. ---------------------------------------------------------------------------

    The Part D measures for PDPs would be analyzed separately. In order to apply consistent adjustments across MA-PDs and PDPs, the Part D measures would be selected by applying the selection criteria to MA-PDs and PDPs independently and, then, selecting measures that met the criteria for either delivery system. The measure set for adjustment of Part D measures for MA-PDs and PDPs would be the same after applying the selection criteria and pooling the Part D measures for MA-PDs and PDPs. We propose to codify these paragraphs for the selection of the adjusted measure set for the CAI for MA-PDs and PDPs at (f)(2)(iii)(C). We also seek comment on the proposed methodology and criteria for the selection of the measures for adjustment. Further, we seek comment on alternative methods or rules to select the measures for adjustment for future rulemaking.     Annually, while the CAI is being developed using the rules we are proposing here, we would release on CMS.gov an updated analysis of the subset of the Star Ratings measures identified for adjustment using this rule as ultimately finalized. Basic descriptive statistics would include the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences. The set of measures for adjustment for the determination of the CAI would be announced in the draft Call Letter.     We propose, at paragraph (f)(2)(iv) of each regulation, to determine the adjusted measure scores for LIS/DE and disability status from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts. The approach employed to determine the adjusted measure scores approximates case-mix adjustment using a beneficiary-level, logistic regression model with contract fixed effects and beneficiary- level indicators of LIS/DE and disability status, similar to the approach currently used to adjust CAHPS patient experience measures. However, unlike CAHPS case-mix adjustment, the only adjusters would be LIS/DE and disability status.     The sole purpose of the adjusted measure scores is for the determination of the CAI values. The adjusted measure scores would be converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.     All contracts would have their adjusted summary rating(s) and for MA-PDs, an adjusted overall rating, calculated employing the standard methodology proposed at Sec. Sec.  422.166 and 423.186 (which would also be outlined in the Technical Notes each year), using the subset of adjusted measure-level Star Ratings and all other unadjusted measure- level Star Ratings. In addition, all contracts would have their summary rating(s) and for MA-PDs, an overall rating, calculated using the traditional methodology and all unadjusted measure-level Star Ratings.     For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled). The initial categories would be created using all groups formed by the initial LIS/DE and disabled groups. The total number of initial categories would be the product of the number of initial groups for LIS/DE and the number of initial groups for the disabled dimension.     The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled). The mean difference within each final adjustment category by rating-type (Part C, Part D for MA-PD, Part D for PDPs, or overall) would be the CAI values for the next Star Ratings year.     The percentage of LIS/DE is a critical element in the categorization of contracts into the final adjustment category to identify a contract's CAI. Starting with the 2017 Star Ratings, we applied an additional adjustment for contracts that solely serve the population of beneficiaries in Puerto Rico to address the lack of LIS in Puerto Rico. The adjustment results in a modified percentage of LIS/ DE beneficiaries that is subsequently used to categorize contracts into the final adjustment category for the CAI.     We propose to continue this adjustment and to calculate the contract-level modified LIS/DE percentage for Puerto Rico using the following sources of information: The most recent data available at the time of the development of the model of both the 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL, and

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the Medicare enrollment data from the same measurement period used for the Star Ratings year.     The data to develop the model would be limited to the 10 states, drawn from the 50 states plus the District of Columbia, with the highest proportion of people living below the FPL as identified by the 1-year ACS estimates. Further, the Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states. A linear regression model would be developed using the known LIS/DE percentage and the corresponding DE percentage from the subset of MA contracts.     The estimated slope from the linear regression approximates the expected relationship between LIS/DE for each contract in Puerto Rico and its DE percentage. The intercept term is adjusted for use with Puerto Rico contracts by assuming that the Puerto Rico model will pass through the point (x, y) where x is the observed average DE percentage in the Puerto Rico contracts based on the enrollment data, and y is the expected average percentage of LIS/DE in Puerto Rico. The expected average percentage of LIS/DE in Puerto Rico (the y value) is not observable, but is estimated by multiplying the observed average percentage of LIS/DE in the 10 highest poverty states by the ratio based on the most recent 5-year ACS estimates of the percentage living below 150 percent of the FPL in Puerto Rico compared to the corresponding percentage in the set of 10 states with the highest poverty level. (Further details of the methodology can be found in the CAI Methodology Supplement available at [*http://go.cms.gov/partcanddstarratings*](http://go.cms.gov/partcanddstarratings).)     Using the model developed from this process, the estimated modified LIS/DE percentage for contracts operating solely in Puerto Rico would be calculated. The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent. All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.     We propose to continue to employ the LIS/DE indicator for contracts operating solely in Puerto Rico while the CAI is being used as an interim analytical adjustment. Further, we propose that the modeling results would continue to be detailed in the appendix of the Technical Notes and the modified LIS/DE percentages would be available for contracts to review during the plan previews.     We propose to continue the use of the CAI while the measure stewards continue their examination of the measure specifications and ASPE completes their studies mandated by the IMPACT Act and formalizes final recommendations. Contracts would be categorized based on their percentages of LIS/DE and disability using the data as outlined previously. The CAI value would be the same for all contracts within each final adjustment category. The CAI values would be determined using data from all contracts that meet reporting requirements from the prior year's Star Rating data. The CAI calculation for the PDPs would be performed separately and use the PDP specific cut points. Under our proposal, CMS would include the CAI values in the draft and final Call Letter attachment of the Advance Notice and Rate Announcement each year while the interim solution is applied. The values for the CAI value would be displayed to 6 decimal places. Rounding would take place after the application of the CAI value and if applicable, the reward factor; standard rounding rules would be employed. (All summary and overall Star Ratings are displayed to the nearest half-star.)     While we consider the recommendations from the ASPE report, findings from measure developers, and work by NQF on risk adjustment for quality measures, we are continuing to collaborate with stakeholders. We are seeking to balance accurate measurement of genuine plan performance, effective identification of disparities, and maintenance of incentives to improve the outcomes for disadvantaged populations. Keeping this in mind, we continue to seek public comment on whether and how we should account for low SES and other social risk factors in the Part C and D Star Ratings.     We look forward to continuing to work with stakeholders as we consider the issue of accounting for LIS/DE, disability and other social risk factors and reducing health disparities in CMS programs. As we have stated previously, we are continuing to consider options to how to measure and account for social risk factors in our Star Ratings program. What we discovered though our research to date is, although a sponsoring organization's administrative costs may increase as a result of enrolling significant numbers of beneficiaries with LIS/DE status or disabilities, the impacts of SES on the quality ratings are quite modest, affect only a small subset of measures, and do not always negatively impact the measures. However, CMS would like to better understand whether, how, and to what extent a sponsoring organization's administrative costs differ for caring for low-income beneficiaries and we welcome comment on that topic. Administrative costs may include non- medical costs such as transportation costs, coordination costs, marketing, customer service, quality assurance and costs associated with administering the benefit. We continue our commitment toward ensuring that all beneficiaries have access to and receive excellent care, and that the quality of care furnished by plans is assessed fairly in CMS programs. u. High and Low Performing Icons     Consistent with our current practice, we are proposing regulation text to govern assignment of high and low performing icons at Sec. Sec.  422.166(i) and 423.186(i). We propose to continue current policy that a contract would receive a high performing icon as a result of its performance on the Part C and D measures. The high performing icon would be assigned to an MA-only contract for achieving a 5-star Part C summary rating, a PDP contract for a 5-star Part D summary rating, and an MA-PD contract for a 5-star overall rating.     We propose that a contract would receive a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon would be calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years (for example, the 2016, 2017, and 2018 Star Ratings). If the contract had any combination of Part C and Part D summary ratings of 2.5 or lower in all 3 years of data, it would be marked with a low performing icon. A contract must have a summary rating in either Part C or Part D for all 3 years to be considered for this icon. These rules would be codified at Sec. Sec.  422.166(i)(2)(i) and 423.186(i)(2)(i).     We also propose, at paragraph (i)(2)(ii), to continue our policy of disabling the Medicare Plan Finder online enrollment function for Medicare health and prescription drug plans with the low-performing icon to ensure that beneficiaries are fully aware that they are enrolling in a plan with low quality and performance ratings; we believe this is an important beneficiary protection to ensure that the decision to enroll in a low rated and low performing plan has been thoughtfully considered. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in ***geographical*** areas with limited plans) will be warned, via explanatory

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messaging of the plan's poorly rated performance and directed to contact the plan directly to enroll. v. Plan Preview of Star Ratings     We propose in Sec. Sec.  422.166(i)(3) and 423.186(i)(3) that CMS have plan preview periods before each Star Ratings release, consistent with current practice. Part C and D sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the first plan preview, we expect Part C and D sponsors to closely review the methodology and their posted numeric data for each measure. The second plan preview would include any revisions made as a result of the first plan preview. In addition, our preliminary Star Ratings for each measure, domain, summary score, and overall score would be displayed. During the second plan preview, we expect Part C and D sponsors to again closely review the methodology and their posted data for each measure, as well as their preliminary Star Rating assignments. As part of this regulation, we are proposing that CMS continue to offer plan preview periods, but are not codifying the details of each period because over time the process has evolved to provide more data to sponsors to help validate their data. We envision it to continue to evolve in the future and do not believe that codifying specific display content is necessary.     It is important that Part C and D sponsors regularly review their underlying measure data that are the basis for the Part C and D Star Ratings. For measures that are based on data reported directly from sponsors, any issues or problems should be raised well in advance of CMS' plan preview periods. A draft version of the Technical Notes would be available during the first plan preview. The draft is then updated for the second plan preview and finalized when the ratings data have been posted to Medicare Plan Finder.     We welcome comments on the proposed plan preview process. w. Technical Changes     We also propose a number of technical changes to other existing regulations that refer to the quality ratings of MA and Part D plans; we propose to make technical changes to refer to the proposed new regulation text that provides for the calculation and assignment of Star Ratings. Specifically, we propose:      In Sec.  422.258(d)(7), to revise paragraph (d)(7) to read: Increases to the applicable percentage for quality. Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to the 5-star rating system (based on the data collected under section 1852(e) of the Act) specified in subpart D of this part 422. Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.      In Sec.  422.260(a), to revise the paragraph to read: Scope. The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA-PDs and Part C summary rating for MA-only contracts for the contract assigned pursuant to subpart 166 of this part 422.      In Sec.  422.260(b), to revise the definition of ``quality bonus payment (QBP) determination methodology'' to read: Quality bonus payment (QBP) determination methodology means the quality ratings system specified in subpart 166 of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP.      In Sec.  422.504(a)(18), to revise paragraph (a)(18) to read: To maintain a Part C summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 166 of this part 422. A Part C summary plan rating is calculated as provided in Sec.  422.166      In Sec.  423.505(b)(26), to revise paragraph (b)(26) to read: Maintain a Part D summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in Sec.  423.186     We welcome comment on these technical changes and whether there are additional changes that should be made to account for our proposal to codify the Star Ratings methodology and measures in regulation text. 12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (Sec. Sec.  423.100, 423.505)     Section 1860D-4(b)(1)(A) of the Act and Sec.  423.120(a)(8)(i) require a Part D plan sponsor to contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. Section 423.505(b)(18) requires Part D plan sponsors to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.     In the preamble to final rule published on January 28, 2005 (January 2005 final rule) (70 FR 4194) which implemented Sec.   423.120(a)(8)(i) and Sec.  423.505(b)(18), we indicated that standard terms and conditions, particularly for payment terms, could vary to accommodate geographic areas or types of pharmacies, so long as all similarly situated pharmacies were offered the same terms and conditions. We also stated that we viewed these standard terms and conditions as a ``floor'' of minimum requirements that all similarly situated pharmacies must abide by, but that Part D plans could modify some standard terms and conditions to encourage participation by particular pharmacies. We believe this approach strikes an appropriate balance between the any willing pharmacy requirement at section 1860D- 4(b)(1)(A) of the Act and the provisions of section 1860D-4(b)(1)(B) of the Act, which permits Part D plan sponsors to offer reduced cost sharing at preferred pharmacies.     The balancing of these goals has led to the development of preferred pharmacy networks in which certain pharmacies agree to additional or different terms from the standard terms and conditions. This has resulted in the development of ``standard'' terms and conditions that in some cases has had the effect, in our view, of circumventing the any willing pharmacy requirements and inappropriately excluding pharmacies from network participation. This section is intended to clarify or modify our interpretation of the existing regulations to ensure that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement.     First, we intend to clarify that the any willing pharmacy requirement applies to all pharmacies, regardless of how they have organized one or more lines of pharmacy business. Second, we propose to revise the definition of retail pharmacy and define mail-order pharmacy. Third, we propose to clarify our regulatory requirements for what constitutes ``reasonable and relevant'' standard contract terms and conditions. Finally, we propose to codify our existing guidance with respect to when a pharmacy must be provided with a

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Part D plan sponsor's standard terms and conditions. a. Any Willing Pharmacy Required for All Pharmacy Business Models     With the pharmaceutical distribution and pharmacy practice landscape evolving rapidly, and because pharmacies now frequently have multiple lines of business, many pharmacies no longer fit squarely into traditional pharmacy type classifications. For example, compounding pharmacies and specialty pharmacies, including but not limited to manufacturer-limited-access pharmacies, and those that may specialize in certain drugs, disease states, or both, are increasingly common, and Part D enrollees increasingly need access to their services. As noted previously, in implementing the any willing pharmacy provision, we indicated that standard terms and conditions could vary to accommodate different types of pharmacies so long as all similarly situated pharmacies were offered the same terms and conditions. In the original rule to implement Part D (70 FR 4194, January 28, 2005), we defined certain types of pharmacies (that is, retail, mail order, Long Term Care (LTC)/institutional, and I/T/U [Indian Health Service, Indian tribe or tribal organization, or urban Indian organization]) at Sec.   423.100 to operationalize various statutory provisions that specifically mention these types of pharmacies (for example, section 1860D-4(b)(1)(C)(iv) of the Act). However, these definitions were never intended to limit the scope of the any willing pharmacy requirement. Nevertheless, we have anecdotal evidence that some Part D plan sponsors have declined to permit willing pharmacies to participate in their networks on the grounds that they do not meet the Part D plan sponsor's definition of a pharmacy type for which it has developed standard terms and conditions.     Section 1860D-4(b)(1)(A) of the Act requires Part D plan sponsors to permit the participation of ``any pharmacy'' that meets the standard terms and conditions. Accordingly, it is not appropriate for Part D plan sponsors to offer standard terms and conditions for network participation that are specific to only one particular type of pharmacy, and then decline to permit a willing pharmacy to participate on the grounds that it does not squarely fit into that pharmacy type. Therefore, we are clarifying in this preamble that although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. In particular, we consider ``similarly situated'' pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.     Thus, Part D plan sponsors must not exclude pharmacies from their retail pharmacy networks solely on the basis that they, for example, maintain a traditional retail business while also specializing in certain drugs or diseases or providing home delivery service by mail to surrounding areas. Or as another example, a Part D plan sponsor must not preclude a pharmacy from network participation as a retail pharmacy because that pharmacy also operates a home infusion book of business, or vice versa. Later in this section we are proposing to codify our requirements for when a Part D sponsor must provide a pharmacy with a copy of its standard terms and conditions. These requirements, if finalized, would apply to all pharmacies, regardless of whether they fit into traditional pharmacy classifications or have unique or innovative business or care delivery models. b. Revise the Definition of Retail Pharmacy and Add a Definition of Mail-Order Pharmacy     Since the inception of the Part D program, Part D statute, regulations, and sub-regulatory guidance have referred to ``mail- order'' pharmacy and services without defining the term ``mail order''. Unclear references to the term ``mail order'' have generated confusion in the marketplace over what constitutes ``mail-order'' pharmacy or services. This confusion has contributed to complaints from pharmacies and beneficiaries regarding how Part D plan sponsors classify pharmacies for network participation, the Plan Finder, and Part D enrollee cost-sharing expectations. Additionally, pharmacies that are not mail-order pharmacies, but that may offer home delivery services by mail (relative to that pharmacy's overall operation), have complained because Part D plan sponsors classified them as mail-order pharmacies for network participation and required them to be licensed in all United States, territories, and the District of Columbia, as would be required for traditional mail-order pharmacies providing a mail-order benefit.     In creating the Part D program, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added the convenient access provision of section 1860D-4(b)(1)(C) of the Act and the level playing field provision of section 1860D- 4(b)(1)(D) of the Act. The convenient access provisions, as codified at Sec.  423.120(a)(1)-(7), require Part D plan sponsors to secure the participation in their networks a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary) and includes special provisions for standards with respect to Long Term Care (LTC) and I/T/U pharmacies (as defined at Sec.   423.100). The level playing field provision, as codified at Sec.   423.120(a)(10), requires Part D plan sponsors to permit enrollees to receive the same benefits, including extended days' supplies, through a pharmacy (other than a mail-order pharmacy) (that is, a retail pharmacy), although the Part D plan sponsor may require the enrollee to pay a higher level of cost-sharing to do so.     We currently define ``retail pharmacy'' at Sec.  423.100 to mean ``any licensed pharmacy that is not a mail-order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.'' Although we did not define ``non- retail pharmacy,'' Sec.  423.120(a)(3) provides that ``a Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, ``including pharmacies offering home delivery via mail- order and institutional pharmacies,'' provided the convenient access requirements are met (emphasis added). In the preamble to our January 2005 final rule, we also stated, ``examples of non-retail pharmacies include I/T/U, FQHC, Rural Health Center (RHC) and hospital and other provider-based pharmacies, as well as Part D [plan]-owned and operated pharmacies that serve only plan members'' (see 70 FR 4249). We also stated ``home infusion pharmacies will not count toward Part D plans' pharmacy access requirements (at Sec.  423.120(a)(1)) because they are not retail pharmacies'' (see 70 FR 4250).     Since 2005, our regulation at Sec.  423.120(a) has included access requirements for retail, home infusion, LTC, and I/T/U pharmacies. While mail-order pharmacies could be considered

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one of several subsets of non-retail pharmacies, we never defined the term mail-order pharmacy in regulation, nor have we specified access or service-level requirements at Sec.  423.120(a) for mail-order pharmacies.     As discussed previously, our classifications of certain types of pharmacies were never intended to limit or exclude participation of pharmacies, such as pharmacies with multiple lines of business, that do not fit into one of these classifications. Additionally, we have recognized since our January 2005 final rule that pharmacies may have multiple lines of business, including retail pharmacies that may offer home delivery services (see 70 FR 4235 and 4255).     Nonetheless, despite this guidance and specific access requirements for LTC and HI pharmacies at Sec.  423.120(a), some Part D plan sponsors interpreted ``including pharmacies offering home delivery via mail-order and institutional pharmacies'' at Sec.  423.120(a)(3) to mean that any pharmacies, even retail pharmacies, that may offer home delivery services by mail are mail-order pharmacies. Although Sec.   423.120(a)(3) specifically allows for access to non-retail pharmacies, and we intended ``including pharmacies offering home delivery via mail- order and institutional pharmacies'' to mean home infusion pharmacies, mail-order pharmacies, long-term care pharmacies, or other non-retail pharmacies that offer home delivery services by mail, some Part D plan sponsors began to require any interested pharmacies, even retail pharmacies, that may offer home delivery services by mail to contract as mail-order pharmacies in order to participate in the plan's contracted pharmacy network. Because Part D plan sponsors frequently require contracted mail-order pharmacies to be licensed in all United States, territories, and the District of Columbia, the classification of any pharmacies that may offer home delivery services by mail as mail-order pharmacies for purposes of contracting with Part D plan sponsors as a network pharmacy, including licensure requirements, led to complaints from beneficiaries and pharmacies, including retail, specialty, and other pharmacies.     Although the language at Sec.  423.120(a)(3) is specific to non- retail pharmacies, there is a great deal of confusion regarding mail- order pharmacy in the Part D marketplace. We believe it is inappropriate to classify pharmacies as ``mail-order pharmacies'' solely on the basis that they offer home delivery by mail. Because the statute at section 1860D-4(b)(1)(D) of the Act discusses cost sharing in terms of mail order versus other non-retail pharmacies, mail-order cost sharing is unique to mail-order pharmacies, as we have proposed to define the term. For example, while a non-retail home infusion pharmacy may provide services by mail, cost-sharing is commensurate with retail cost-sharing. Therefore, to clarify what a mail-order pharmacy is, we propose to define mail-order pharmacy at Sec.  423.100 as a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.     Although we propose to add the definition of mail-order pharmacy, we also believe that our existing definition of retail pharmacy has contributed, in part, to the confusion in the Part D marketplace. As discussed previously, the existing definition of ``retail pharmacy'' at Sec.  423.100 means ``any licensed pharmacy that is not a mail-order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.'' This definition, given the rapidly evolving pharmacy practice landscape, may be a source of some confusion given that it expressly excludes mail-order pharmacies, but not other non-retail pharmacies such as home infusion or specialty pharmacies.     We note that Medicaid recently adopted a definition of ``retail community pharmacy.'' Pursuant to section 1927(k)(10) of the Act, as amended by section 2503 of the Affordable Care Act (ACA), for purposes of Medicaid prescription drug coverage, CMS defines ``retail community pharmacy'' at Sec.  447.504(a) as ``an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the walk-in general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not- for-profit pharmacies, government pharmacies, or pharmacy benefit managers.'' Although this definition adds greater clarity about the locations or practice settings where retail pharmacies may be found, we were concerned that, for the purposes of the Part D program, the mention of additional types of pharmacies in our regulation could contribute to more confusion instead of less.     However, two aspects of this definition are similar to Part D statutory language in section 1860D-4(b)(1)(C) and (D) of the Act. The first is the concept that a retail pharmacy is open to dispense prescription medications to the walk-in general public, which echoes the requirement at section 1860D-4(b)(1)(C) of the Act that Part D plan sponsors secure the participation in their networks a sufficient number of pharmacies that dispense (other than mail order) drugs directly to patients. The second is the concept that prescriptions are dispensed at retail prices, or for the Part D program, retail cost-sharing, which echoes the requirement at section 1860D-4(b)(1)(D) of the Act that Part D plan sponsors permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail-order pharmacy), with any differential in charge paid by such enrollees. Because these concepts are consistent with the Part D statute, we believe their inclusion in our definition of retail pharmacy at Sec.  423.100 would be appropriate.     Therefore, to clarify what a retail pharmacy is, we propose to revise the definition of retail pharmacy at Sec.  423.100 First, we note that the existing definition of ``retail pharmacy'' is not in alphabetical order, and we propose a technical change to move it such that it would appear in alphabetical order. Second, we propose to incorporate the concepts of being open to the walk-in general public and retail cost-sharing such that the definition of retail pharmacy would mean ``any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.''     Although we were originally unsure whether Part D enrollees would need routine access to specialty drugs and specialty pharmacies beyond our out-of-network requirements (see 70 FR 4250), as the Part D program has evolved, the use of specialty drugs in the Part D program has grown exponentially and will likely continue to do so. The June 2016 MedPAC report (available at [*http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf*](http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf)) notes growth in the use of specialty drugs in the Part D program is currently outpacing other drugs and health spending, generally. Such drugs are often high-cost and complex, for

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diseases including, but not limited to, cancer, Hepatitis C, HIV/AIDS, multiple sclerosis, and rheumatoid arthritis. The report also highlights that each year since 2009, more than half of the United States Food and Drug Administration (FDA) approvals have been for specialty drugs. Because many specialty drugs can be self-administered on an outpatient basis, even in the patient's home, and for chronic or long-term use, increasing numbers of Part D enrollees need routine access to specialty drugs and specialty pharmacies. Nonetheless, because the pharmacy landscape is changing so rapidly, we believe any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace, and we decline to propose a definition of specialty pharmacy at this time.     Similar to specialty pharmacy, we also decline to further define non-retail pharmacy. The pharmacy types that we define and propose to modify and define in regulation describe functional lines of business that an individual pharmacy may have, solely, or in combination. However, unlike mail order, home infusion, I/T/U, FQHC, LTC, hospital, other institutional, other provider-based, and ``members-only'' Part D plan-owned and operated pharmacy types or lines of business that comprise ``non-retail'', the term ``non-retail'' does not, itself, define a unique pharmacy functional line of business, and does not lend itself to a clear definition. Consistent with statutory any willing pharmacy and preferred pharmacy provisions, mail-order pharmacies may be preferred or non-preferred. Part D plan sponsors may establish unique non-preferred mail-order cost-sharing, or may establish such non-preferred mail-order cost sharing commensurate with those for retail pharmacies.     We solicit comment on our proposed definition of mail-order pharmacy and our proposed modification to the definition of retail pharmacy. Specifically, we solicit comment regarding whether stakeholders believe these definitions strike the right balance to resolve confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models. c. Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions     As noted previously, since the beginning of the Part D program, we have considered standard terms and conditions for network participation to set a ``floor'' of minimum requirements by which all similarly situated pharmacies must abide. We further believe it is reasonable for a Part D plan sponsor to require additional terms and conditions beyond those required in the standard contract for network participation for pharmacies to have preferred status. Therefore, we implemented the requirements of section 1860D-4(b)(1)(A) of the Act by requiring that standard terms and conditions be ``reasonable and relevant,'' but declined to further define ``reasonable and relevant'' in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.     We note that a pharmacy's ability to participate in a preferred or specially labeled subset of the Part D plan sponsor's larger contracted pharmacy network or to offer preferred cost sharing assumes that, at a minimum, the pharmacy is able to participate in the network. Where there are barriers to a pharmacy's ability to participate in the network at all, it raises the question of whether the standard (that is, entry-level) terms and conditions are reasonable and relevant.     It has been our longstanding policy that Part D plans cannot restrict access to certain Part D drugs to specialty pharmacies within their Part D network in such a manner that contravenes the convenient access protections of section 1860D-4(b)(1)(C) of the Act and Sec.   423.120(a) of our regulations. (See Q&A at [*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess\_051706.pdf*](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf)). In 2006, we informed sponsors they cannot restrict access to drugs on the ``specialty/high cost'' tier to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (that is, a contracted network pharmacy that does not belong to the restricted subset). Since 2006, it has been our general policy that these types of special requirements for Part D plan sponsors to limit dispensing of specialty drugs be directly linked to patient safety or regulatory reasons.     As the specialty drug distribution market has grown, so has the number of organizations competing to distribute or dispense specialty drugs, such as pharmacy benefit managers (PBMs), health plans, wholesalers, health systems, physician practices, retail pharmacy chains, and small, independent pharmacies (see the URAC White Paper, ``Competing in the Specialty Pharmacy Market: Achieving Success in Value-Based Healthcare,'' available at   [*http://info.urac.org/specialtypharmacyreport*](http://info.urac.org/specialtypharmacyreport)). CMS is concerned that Part D plan sponsors might use their standard pharmacy network contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies. In fact, we have received complaints from pharmacies that Part D plan sponsors have begun to require accreditation of pharmacies, including accreditation by multiple accrediting organizations, or additional Part D plan-/PBM-specific credentialing criteria, for network participation. We agree that there is a role in the Part D program for pharmacy accreditation, to the extent pharmacy accreditation requirements in network agreements promote quality assurance. In particular, we support Part D plan sponsors that want to negotiate an accreditation requirement in exchange for, for example, designating a pharmacy as a specialty or preferred pharmacy in the Part D plan sponsor's contracted pharmacy network. However, we do not support the use of Part D plan sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (as discussed previously). Moreover, we are especially concerned about anecdotal reports that allege such standard terms and conditions for network participation are waived, for example, when a Part D plan sponsor needs a particular pharmacy in its network in order to meet convenient access requirements, or even for certain pharmacies that received preferred pharmacy status.     If the premise of accreditation or Part D plan sponsor- or PBM- specific credentialing requirements is to ensure more stringent quality standards, then there is no reasonable explanation for why a quality- related standard term or condition could be waived for situations when the Part D plan sponsor needs a particular pharmacy in its contracted

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pharmacy network in order to meet the convenient access standards or to designate a particular pharmacy with preferred pharmacy status. A term or condition which can be dropped in such situations is by definition not ``standard'' according to the plain meaning of the word. Waivers or inconsistent application of such standard terms and conditions is an explicit acknowledgement that such terms and conditions are not necessary for the ability of a pharmacy to perform its core functions, and are thus neither reasonable nor relevant for any willing pharmacy standard terms and conditions.     It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now. We continue to believe pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards, and Sec.  423.153(c)(1) requires representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states.     Additionally, because a pharmacy's ability to dispense certain medications is not dependent on it having the ability to dispense other medications, it is not relevant for sponsors to require pharmacies to dispense a particular roster of certain drugs or drugs for certain disease states in order to receive standard terms and conditions for network participation as a contracted network pharmacy for that Part D plan sponsor. Consequently, consistent with our longstanding policy, discussed previously, we would not expect Part D plan sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA- mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so. We solicit comment on this topic. d. Timing of Contracting Requirements     CMS has received complaints over the years from pharmacies that have sought to participate in a Part D plan sponsor's contracted network but have been told by the Part D plan sponsor that its standard terms are not available until the sponsor has completed all other network contracting. In other instances, pharmacies have told us that Part D plan sponsors delay sending them the requested terms and conditions for weeks or months or require pharmacies to complete extensive paperwork demonstrating their eligibility to participate in the sponsor's network before the sponsor will provide a document containing the standard terms and conditions. CMS believes such actions have the effect of frustrating the intent of the any willing pharmacy requirement, and as a result, we believe it is necessary to codify specific procedural requirements for the delivery of pharmacy network standard terms and conditions.     To this end, we propose to establish deadlines by which Part D plan sponsors must furnish their standard terms and conditions to requesting pharmacies. The first deadline we propose to establish is the date by which Part D plan sponsors must have standard terms and conditions available for pharmacies that request them. By mid-September of each year, Part D plan sponsors have signed a contract with CMS committing them to delivering the Part D benefit through an accessible pharmacy network during the upcoming year and have provided information about that network to CMS for posting on the Medicare Plan Finder Web site. At that point, Part D plan sponsors should have had ample opportunity to develop standard contract terms and conditions for the upcoming plan year. Therefore, we propose to require at Sec.  423.505(b)(18)(i) that Part D plan sponsors have standard terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year.     The second deadline we propose concerns the promptness of Part D plan sponsors' responses to pharmacy requests for standard terms and conditions. As discussed previously, we propose to require all Part D plan sponsors to have standard terms and conditions developed and ready for distribution by September 15. Therefore, we propose to require at Sec.  423.505(b)(18)(ii) that, after that date and throughout the following plan year, Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request. Part D plan sponsors would be required to clearly identify for interested pharmacies the avenue (for example, phone number, email address, Web site) through which they can make this request. In instances where the Part D plan sponsor requires a pharmacy to execute a confidentiality agreement with respect to the terms and conditions, the Part D plan sponsor would be required to provide the confidentiality agreement within two business days after receipt of the pharmacy's request and then provide the standard terms and conditions within 2 business days after receipt of the signed confidentiality agreement. While Part D plan sponsors may ask pharmacies to demonstrate that they are qualified to meet the Part D plan sponsors' standard terms and conditions before executing the contract, Part D plan sponsors would be required to provide the pharmacy with a copy of the contract terms for its review within the two-day timeframe. If finalized, this proposed requirement would permit pharmacies to do their due diligence with respect to whether a Part D plan sponsor's standard terms and conditions are acceptable at the same time Part D plan sponsors are conducting their own review of the qualifications of the requesting pharmacy. We specifically seek comment on whether these timeframes are the right length to address our goal but are operationally realistic. We also request examples of situations where a longer timeframe might be needed. 13. Changes to the Days' Supply Required by the Part D Transition Process     We promulgated regulations under the authority of section 1860D- 11(d)(2)(B) of the Act to require Part D sponsors to provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on the prescription drug plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). These regulations are codified at Sec.  423.120(b)(3). Specifically, these regulations require that a Part D sponsor ensure certain enrollees access to a temporary supply of drugs within the first 90 days under a new plan (including drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by ensuring a temporary fill when an enrollee requests a fill of a non-formulary drug during this time period. In the outpatient setting, the supply must be for at least 30 days of medication, unless the prescription is written for less. In the LTC setting, this supply must be for up to at least 91 days and may be up to 98 days, consistent with the dispensing increment, unless a less amount is prescribed.     We propose to make two changes to these regulations. First, we propose to shorten the required transition days'

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supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. Second, we propose a technical change to the current required days' transition supply in the outpatient setting to be a month's supply.     We provided our rationale for the transition fill days' supply requirement in the LTC setting in CMS final rule CMS-4085-F published on April 15, 2010 (75 FR 19678). In that final rule, we stated that for a new enrollee in a LTC facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. We further stated that, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens, we will require sponsors to honor multiple fills of non-formulary Part D drugs, as necessary during the entire length of the 90-day transition period. Thus, we required a Part D sponsor to provide a LTC resident enrolled in its Part D plan with at least a 31 day supply of a prescription with refills provided, if needed, up to a 93 days' supply (unless the prescription is written for less) (75 FR 19721). In a subsequent final rule published on April 15, 2011, we changed the 93 days' supply to 91 to 98 days' supply, as noted previously, to acknowledge variations in days' supplies that could result from the short-cycle dispensing of brand drugs in the LTC setting (76 FR 21460 and 21526).     We received and responded to a comment in the April 2010 final rule about transition and a longer timeframe in the LTC setting. We stated that a number of commenters supported our proposal of requiring an extended transition supply for enrollees residing in LTC facilities but that commenters requested that we provide the same protections to individuals requiring LTC in community-based settings. In our response to the comment, we indicated that residents of LTC institutions were more limited in access to prescribing physicians hired by LTC facilities due to a limited visitation schedule and more likely to require extended transition timeframes in order for the physician to work with the facility and LTC pharmacies on transitioning residents to formulary drugs. We further stated that we believed that community- based enrollees, in contrast, were less limited in their access to prescribing physicians and did not require an extended transition period to work with their physicians to successfully transition to a formulary drug. (75 FR 19721). Thus, the requirement to provide longer transition fill days' supply in the LTC setting was a result of our concerns that a longer timeframe would be needed in the LTC setting.     After more than 10 years of experience with Part D in LTC facilities, we have not seen the concerns that we expressed in the 2010 final rule materialize. We are not aware of any evidence that transition for a Part D beneficiary in the LTC setting necessarily takes any longer than it does for a beneficiary in the outpatient setting. We understand that it is common for Part D beneficiaries in the LTC setting to be cared for by on-staff or consultant physicians and other health professionals with prescriptive authority who are under contract with the LTC facility. Additionally, we also understand that Part D beneficiaries in the LTC setting are typically served by an on-site pharmacy or one under contract to service the LTC facility. Given this structure of the LTC setting, we understand that the LTC prescribers and pharmacies are readily available to address transition for Part D beneficiaries in the LTC setting. In addition, LTC facilities now have many years' experience with the Medicare Part D program generally and transition specifically.     While our concerns about the needed timeframe for transition in the LTC setting do not seem to have materialized, we have continuing concerns about drug waste and the costs associated with such waste in the LTC setting. Some of these concerns have been addressed by our rule requiring the short-cycle dispensing of brand drugs to Part D beneficiaries in LTC facilities in the April 2011 final rule. That rule, codified at 42 CFR 423.154, requires that all Part D sponsors require all network pharmacies servicing LTC facilities to dispense certain solid oral doses of covered Part D brand-name drugs to enrollees in such facilities in no greater than 14-day increments at a time to reduce drug waste. However, we now believe that CMS could eliminate additional drug waste and cost by no longer requiring a longer transition days' supply in the LTC setting. Therefore, we are proposing that the transition days' supply in the LTC setting be the same as it is in the outpatient setting.     Our second proposed change involves the current required 30 days' transition supply in the outpatient setting, which is codified at Sec.   423.120(b)(3)(iii)(A). We have received a number of inquiries from Part D sponsors regarding scenarios involving medications that do not easily add up to a 30 days' supply when dispensed (for example, drugs that typically are dispensed in 28-day packages). Historically, our response to those inquiries has been that the regulation requires plans to provide at least 30 days of medication, which requires plans to dispense more than one package to comply with the text of the regulation. However, the intent of the regulation was for the transition fill in the outpatient setting to be for at least a month's supply. For this reason, we are proposing a change to the regulation from ``30 days'' to ``a month's supply.'' If finalized, this change would mean that the regulation would require that a transition fill in the outpatient setting be for a supply of at least a month of medication, unless the prescription is written by the prescriber for less. Therefore, the supply would have to be for at least the days' supply that the applicable Part D prescription drug plans has approved as its retail month's supply in its Plan Benefit Package submitted to CMS for the relevant plan year, again, unless the prescription is written by the prescriber for less.     Together, our two proposals--if finalized--would mean that Sec.   423.120 (b)(3)(iii)(A) would be consolidated into Sec.  423.120 (b)(3)(iii) to read that the transition process must ``[e]nsure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least a month's supply of medication, unless the prescription is written by a prescriber for less than a month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of a month's supply of medication.'' Section 423.120(b)(3)(iii)(B) would be eliminated.     Please note that we also are proposing in II.A.15 Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes to revise Sec.  423.120(b)(3)(i)(B) to state that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as specified under paragraph Sec.  423.120(b)(3)(iv) or Sec.  423.120(b)(6) of this section.

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14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (Sec. Sec.  423.100, 423.120, and 423.128)     Section 1860D-4(b)(3)(E) of the Act requires Part D sponsors to provide ``appropriate notice'' to the Secretary, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its formulary, or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) implements that requirement by defining appropriate notice as that given at least 60 days prior to such change taking effect during a given contract year. We have recognized that both current and prospective enrollees of a prescription drug plan need to have the most current formulary information by the time of the annual election period described in Sec.  423.38(b) in order to enroll in the Part D plan that best suits their particular needs. To this end, Sec.  423.120(b)(6) prohibits Part D sponsors and MA organizations from removing a covered Part D drug from a formulary or changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual election period described in Sec.   423.38(b)(2) and 60 days subsequent to the beginning of the contract year associated with that annual election period. Our concern has been to prevent situations in which Part D sponsors change their formularies early in the contract year without providing appropriate notice as described in Sec.  423.120(b)(5) to new enrollees. Thus, Sec.   423.120(b)(6) has required that all materials distributed during the annual election period reflect the formulary the Part D sponsor will offer at the beginning of the contract year for which it is enrolling Part D eligible individuals. Lastly, under Sec.  423.128(d)(2)(iii), Part D sponsors must also provide current and prospective Part D enrollees with at least 60 days' notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. The general notice requirements and burden are currently approved by OMB under control number 0938-0964 (CMS-10141).     MedPAC observed that the continuity of a plan's formulary is very important to all beneficiaries in order to maintain access to the medications that were offered by the plan at the time the beneficiaries enrolled. While we agree with MedPAC's assertion, we acknowledge the need to balance formulary continuity with requests from Part D sponsors to provide greater flexibility to make midyear changes to formularies. Indeed, MedPAC made its observation in a report that suggested that CMS's rules regarding formulary changes warranted examination. There MedPAC pointed out, among other things, that CMS could provide Part D sponsors with greater flexibility to make changes such as adding a generic drug and removing its brand name version without first receiving agency approval. (MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, June 2016, page 192.)     This proposed rule would implement MedPAC's recommendation by permitting generic substitutions without advance approval as specified later in this section. We have also taken this opportunity to examine our regulations to determine how to otherwise facilitate the use of certain generics. Currently, Part D sponsors can add drugs to their formularies at any time; however, there is no guarantee that enrollees will switch from their brand name drugs to newly added generics. Therefore, Part D sponsors seeking to better manage the Part D benefit may choose to remove a brand name drug, or change its preferred or tiered cost-sharing, and substitute or add its therapeutic equivalent. But even this takes some time: Under current regulations, Part D sponsors must submit formulary change requests to CMS and provide specified notice before removing drugs or changing their cost-sharing (except for unsafe drugs or those withdrawn from the market). As noted earlier, the general notice requirements and burden are currently approved by OMB under control number 0938-0964 (CMS-10141). Also, as detailed previously, Sec.  423.120(b)(5)(i) requires 60 days' notice to specified entities prior to the effective date of changes and 60 days' direct notice to affected enrollees or a 60 day refill. The ability of Part D sponsors to make generic substitutions as approved by CMS is further limited by the fact that as detailed previously, under Sec.   423.120(b)(6), Part D sponsors generally cannot remove drugs or make cost-sharing changes from the start of the annual election period (AEP) until 2 months after the plan year begins.     We propose to provide Part D sponsors with more flexibility to implement generic substitutions as follows: The proposed provisions would permit Part D sponsors meeting all requirements to immediately remove brand name drugs (or to make changes in their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) therapeutically equivalent newly approved generics--rather than having to wait until the direct notice and formulary change request requirements have been met. The proposed provisions would also allow sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect 2 months after the start of the plan year. Related proposals would require advance general and retrospective direct notice to enrollees and notice to entities; clarify online notice requirements; except specified generic substitutions from our transition policy; and conform our definition of ``affected enrollees.'' Lastly, to address stakeholder requests for greater flexibility to make midyear formulary changes in general, we are also proposing to decrease the days of enrollee notice and refill required when (aside from generic substitution and drugs deemed unsafe or withdrawn from the market) drug removal or changes in cost-sharing will affect enrollees.     Specifically, we propose to add a new paragraph (b)(5)(iv) to Sec.   423.120 to permit Part D sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met. The generic drug would need to be offered at the same or a lower cost-sharing and with the same or less restrictive utilization management criteria originally applied to the brand name drug. The Part D sponsor could not have as a matter of timing been able to previously request CMS approval of the change because the generic drug had not yet been released to the market. Also, the Part D sponsor must have previously provided prospective and current enrollees general notice that certain generic substitutions could occur without additional advance notice. As proposed, we would permit Part D sponsors to substitute a generic drug for a brand name drug immediately rather than make that change effective, for instance, at the start of the next month. However, we solicit comment as to whether there would be a reason to require such a delay, especially given the fact that we are proposing not to require advance direct notice (rather, only advance general notice) or CMS approval. The proposed regulation would also require that, when generic drug substitutions occur, Part D sponsors must provide direct notice to affected enrollees and other specified notice to CMS and other entities. We also propose to specify in a revision to

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Sec.  423.120(b)(3)(i)(B) that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug under paragraph (b)(6) of this section.     A proposed exception to Sec.  423.120(b)(6) would permit Part D sponsors to make the above specified changes (removing covered Part D drugs from their formularies, or changing their cost-sharing, when substituting or adding their generic equivalents) during any time of the year. That section generally provides--with a current exception only for unsafe drugs and drugs removed from the market--that Part D sponsors generally cannot remove drugs or make cost-sharing changes between the beginning of the AEP and 60 days after the plan year begins. We believe that revising this provision would assist Part D sponsors by permitting substitutions to take place effect during a longer time period than is currently permitted. Given that the previous exception would permit generic substitutions prior to the start of the calendar year, we also propose to conform the definition of ``affected enrollees'' to clarify that applicable changes must affect their access to drugs during the current plan year.     We are aware that some may be concerned about not requiring advance CMS approval or advance direct notice to enrollees prior to making the permitted generic substitutions, or requiring a transition fill. But we would only permit immediate substitution when the generics are deemed therapeutically equivalent to the brand name drug being removed by the Federal Drug and Food Administration (FDA) and meet other requirements specified later in this section. This would not apply to follow-on biological products under current FDA guidance. The FDA has, in fact noted that, ``A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.'' (``Generic Drug Facts,'' see FDA Web site, [*https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm*](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm), accessed September 19, 2017, hereafter FDA, ``Abbreviated New Drug Application (ANDA): Generics''.) Additionally, immediate generic substitution has long been an established bedrock of commercial insurance, and we are not aware of any harm to the insured resulting from such policies.     Also, we do not believe a transition policy would be appropriate for these situations: The purpose of the transition process is to make sure that the medical needs of enrollees are safely accommodated in that they do not go without their medications or face an abrupt change in treatment. If the proposal to permit Part D sponsors to immediately substitute generics for brand name drugs upon market release were finalized, most enrollees in this situation would not have had an opportunity to try the drug prior to the drug substitution to see how it worked for them. In other words, an enrollee could not be certain that a generic substitution would not work, would constitute an abrupt change in treatment, or that the enrollee would be better served by taking no medication rather than the generic unless he or she had previously tried the generic drug.     Moreover, we have built beneficiary protections into the proposed provisions. First, proposed Sec.  423.120(b)(5)(iv)(A) addresses safety concerns by permitting Part D sponsors to add only therapeutically equivalent generic drugs. This means the FDA must have approved the generic drug in an abbreviated new drug application pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)), and it must be listed with the innovator drug in the publication ``Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) in which the FDA identifies drug products approved on the basis of safety and effectiveness by the FDA, and be considered by the FDA to be therapeutically equivalent to the brand name drug.     Second, we share the concern that prospective enrollees could be misled by Part D sponsors that deliberately offer brand name drugs during open enrollment periods only to remove them or change their cost-sharing as quickly as possible during the plan year. We believe that our proposed provision would address such problems: Under proposed Sec.  423.120(b)(5)(iv)(B), a Part D sponsor cannot substitute a generic for a brand name drug unless it could not have previously requested formulary approval for use of that drug. As a matter of operations, CMS permits Part D sponsors to submit formularies, and their respective change requests, only during certain windows. Under proposed Sec.  423.120(b)(5)(iv)(B), a Part D sponsor could not remove a brand name drug or change its preferred or tiered cost-sharing if that Part D sponsor could have included its generic equivalent with its initial formulary submission or during a later update window.     However, to be certain, that we have not missed practical or other complications that would hinder the ability of Part D sponsors to timely seek approval within the CMS timeframes, we solicit comment as to whether we should consider immediate substitution, potentially in limited circumstances, of specified generics for which Part D sponsors could have previously requested formulary approval. At the same time, we remain mindful of beneficiary protections and are hesitant to simply permit substitution of any generics regardless of how long they have been on the market. Accordingly, we welcome suggestions of any other practical cut-offs, as well as information on possible effects on beneficiaries that could result if we were to permit Part D sponsors to substitute specified generics that have been on the market for longer time periods.     Third, we believe the two-pronged approach of the proposed provision would provide appropriate notice for this type of formulary change. The general notice requirement of proposed Sec.   423.120(b)(iv)(C) would require that, before making any generic substitutions, a Part D sponsor provide all prospective and current enrollees with notice in the formulary and other applicable beneficiary communication materials stating that the Part D sponsor can remove, or change the preferred or tiered cost-sharing of, any brand name drug immediately without additional advance notice (beyond the general advance notice) when a new equivalent generic is added. This would, for instance, include the Evidence of Coverage (EOC). Proposed Sec.   423.120(b)(iv)(C) would also require that this general notice advise prospective and current enrollees that they will get direct notice about any specific drug substitutions made that would affect them and that the direct notice would advise them of the steps they could take to request coverage determinations and exceptions. Therefore, the general notice would advise enrollees about what might take place before any changes occur.     When the Part D sponsor substitutes a generic for a brand name drug, the proposed direct notice provision, Sec.  423.120(b)(5)(iv)(E), would require the Part D sponsor to provide affected enrollees with direct notice consistent with Sec.  423.120(b)(5)(ii). We currently require Part D sponsors to provide this information 60 days before such changes are made. Under the proposed changes, enrollees would receive the same information they receive under the current regulation--the only difference being that the notice could be provided

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after the effective date of the generic substitution. As discussed earlier, under the proposed provision Part D sponsors seeking to make immediate substitutions would be newly required to have previously provided general notice in beneficiary communication materials such as formularies and EOCs that certain generic substitutions could take place without additional advance notice.     We understand there may be concerns that the direct notice identifying the specific drug substitution would arrive after the formulary change has already taken place. As explained previously, we believe generic substitutions pose no threat to enrollee safety. Also, as noted earlier, we are proposing to revise Sec.  423.120(b)(6) to permit generic substitutions to take place throughout the entire year. This means that, under the proposed provision, a Part D sponsor meeting all the requirements would be able to substitute a generic drug for a brand name drug well before the actual start of the plan year (for instance, if a generic drug became available on the market days after the summer update). There is nothing in our regulation that would prohibit advance notice and, in fact, we would encourage Part D sponsors to provide direct notice as early as possible to any beneficiaries who have reenrolled in the same plan and are currently taking a brand name drug that will be replaced with a generic drug with the start of the next plan year. We would also anticipate that Part D sponsors will be promptly updating the formularies posted online and provided to potential beneficiaries to reflect any permitted generic substitutions--and at a minimum meeting any current timing requirements provided in applicable guidance. At this time we are not proposing to set a regulatory deadline by which Part D sponsors must update their formularies before the start of the new plan year. However, if we were to finalize this provision and thereafter find that Part D sponsors were not timely updating their formularies, we would reexamine this policy. And we would note, as regards timing, that Sec.   423.128(d)(2)(iii) requires that the current formulary posted online be updated at least monthly.     In cases in which the Part D sponsor would necessarily have to send notice after the fact, for example instances in which a drug is not released to the market until after the beginning of the plan year and the Part D sponsor then immediately makes a generic substitution, the proposed general notice would have already advised enrollees that they would receive information about any specific drug generic substitutions that affected them and that they would still be able to request coverage determinations and exceptions. While the timing would most likely mean most enrollees would only be able to make such requests after receiving a generic drug fill, in the vast majority of cases, an enrollee could not be certain that a generic substitution would not work unless he or she actually tried the generic drug. Additionally, we are strongly encouraging Part D sponsors to provide the retrospective direct notices of these generic substitutions (including direct notice to affected enrollees and notice to entities including CMS) no later than by the end of the month after which the change becomes effective. While sponsors are required to report this information to both enrollees and entities including CMS, we currently are not proposing to codify the end of month timing requirement; however, if we were to finalize this provision and thereafter find that Part D sponsors were not timely providing retrospective notice, we would reexamine this policy.     Fourth, enrollees would be protected from higher cost-sharing under proposed paragraph (b)(5)(iv)(A), which would require Part D sponsors to offer the generic with the same or lower cost-sharing and the same or less restrictive utilization management criteria as the brand name drug.     We also believe requirements and guidance regarding beneficiary communications will continue to provide beneficiary protections. Section 423.128(e)(5) currently requires Part D sponsors to furnish directly to enrollees an explanation of benefits (EOB) that includes any applicable formulary changes for which Part D plans are required to provide notice as described in Sec.  423.120(b)(5). As noted previously, Sec.  423.128(d)(2)(iii) currently requires Part D sponsors to post at least 60 days' notice of removals and cost-sharing changes online for current and prospective Part D enrollees. In light of our proposal for generic substitutions described previously, we propose to modify Sec.  423.128(d)(2)(iii) to require Part D sponsors to provide ``timely'' notice under 423.120(b)(5). This would mean that, under the proposed provision, a Part D sponsor would need to provide at least 30 days' online notice to affected enrollees before removing drugs or making cost-sharing changes except when adding a therapeutically equivalent generic as specified, and as has currently been the requirement, removing unsafe or withdrawn drugs. Part D sponsors could provide online notice after the effective date of changes only in those limited instances.     As regards content, Sec.  423.128(d)(2)(iii) requires--and would continue to do so under the proposed revisions--that Part D sponsors post online notice regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. Posting information online related to removing a specific drug or changing its cost-sharing solely to meet the content requirements of Sec.  423.128(d)(2)(iii) cannot replace general notice under proposed Sec.  423.120(b)(5)(iv)(C); direct notice to affected enrollees under Sec.  423.120(b)(5)(ii); or notice to CMS when required under Sec.  423.120(b)(5). For instance, as noted in the January, 28, 2005 final rule (70 FR 4265), we view online notification under Sec.   423.128(d)(2)(iii) on its own as an inadequate means of providing specific information to the enrollees who most need it, and we consider it an additional way that Part D sponsors provide notice of formulary changes to affected enrollees.     However, we do not mean to restrict or otherwise affect other rules governing the provisions of materials online. For instance, if Part D sponsors were able to fulfill CMS marketing and beneficiary communications requirements by posting a specific document online rather than providing it in paper, the fact the document was posted online would not preclude it from providing general notice required under our proposed provisions. In other words, if otherwise valid, provision of general notice in a document posted online could suffice as notice as regards that specified document under proposed Sec.   423.120(b)(5)(iv)(C). In contrast, we do not wish to suggest that posting one type of notice online would necessarily suffice to meet distinct notice requirements. For instance, providing the general advance notice that would be required under Sec.  423.120(b)(5)(iv)(C) in a document posted online could not meet the online content requirements of Sec.  423.128(d)(2)(iii) related to providing information about removing drugs or changing their cost-sharing. Nor, as noted previously, could the ***opposite*** apply: Posting the content required under Sec.  423.128(d)(2)(iii) online could not fulfill the advance general notice requirements that would be required under proposed Sec.  423.120(b)(5)(iv)(C) (or suffice to provide direct notice to affected enrollees under Sec.  423.120(b)(5)(ii) or notice to CMS under Sec.  423.120(b)(5)).     In addition to requiring the direct notice to affected enrollees discussed previously, proposed Sec.  423.120(b)(iv)(D) would also require Part D sponsors to provide the following entities with

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notice of the generic substitutions consistent with Sec.   423.120(b)(5)(ii): CMS, State Pharmaceutical Assistance Programs (as defined in Sec.  423.454), entities providing other prescription drug coverage (as described in Sec.  423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists. (To avoid repetition, we propose to revise the provision to refer to all of these entities as ``CMS and other specified entities'' for the purposes of Sec.  423.120(b).) Even though, as proposed, a Part D sponsor that met all of the requirements would be able to make the generic substitution immediately without submitting any formulary change requests to CMS, the Part D sponsor must include the generic substitution in the next available formulary submission to CMS. We note that Part D plans can determine the most effective means to communicate formulary change information to State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists and that, under our proposed provision, we would consider online posting sufficient for those purposes.     Lastly as part of our reexamination of the need to generally provide Part D sponsors greater flexibility in formulary changes, we plan to decrease the amount of direct notice required in cases where the removal of a drug or change in cost-sharing status will affect enrollees currently taking the drug. (This would contrast proposed notice requirements that would apply to immediate substitution of specified generics. There we would also require advance general notice that such changes can occur, and direct notice of the specific changes could be provided after their effective date.) Section 423.120(b)(5)(i) currently requires at least 60 days' notice to all entities prior to the effective date of changes and at least 60 days' direct notice to affected enrollees or a 60 day refill upon the request of an affected enrollee. We propose to reduce the notice requirement in both instances to at least 30 days and the refill requirement to a month. Beneficiaries would be affected, and therefore receive the 30 days' notice or a month refill, in cases in which, for instance, Part D sponsors planned to add prior authorization requirements as a result of new safety-related information or clinical guidelines. This proposal would permit Part D sponsors to institute formulary changes in half the time.     We are, again, aware that some may be concerned that we are reducing the number of days advance notice afforded to enrollees in these instances. But again, we believe current CMS requirements provide the necessary beneficiary protections, and that 30 (rather than 60) days' notice still will afford enrollees sufficient time to either change to a covered alternative drug or to obtain needed prior authorization or an exception for the drug affected by the formulary change. Existing CMS regulations establish robust beneficiary protections in the coverage and appeals process, including expedited adjudication timeframes for exigent circumstances (maximum timeframe of 24 hours for coverage determinations and 72 hours for level 1 and 2 appeals), and a requirement that Part D plan sponsors automatically forward all untimely coverage determinations and redeterminations to the IRE for independent review. Further, while 60 days' notice is currently required, we have no evidence to suggest that beneficiaries are currently utilizing the full 60 days. The reduction to 30 days would align these requirements with the timeframes for transition fills. And, with over 11 years of program experience, we have no evidence to suggest that 30 days has been an insufficient temporary days supply for transition fills.     (Note we are also proposing to amend the refill amount to months (namely a month) rather than days (it was 60 days previously) to conform to a proposed revision to the transition policy regulations at Sec.  423.120(b)(3).) For further discussion, see section III.A.15 of this proposed rule, Changes to the Transition.)     Summary: The following provides a high level summary of notice changes proposed in Sec.  423.120(b). Details on these requirements appear in the preamble and proposed provisions. This summary does not address other proposed changes (for instance, changes to transition requirements); notice provisions we do not propose to change (for instance, notice for safety edits); or other rules that may also apply (for instance, marketing and beneficiary communications rules regarding formulary updates).      Notice required for expedited substitutions of certain generics: Part D sponsors that would otherwise be permitted to make certain generic substitutions as specified under proposed Sec.   423.120(b)(5)(iv) would be required to provide the following types of notice:     ++ Advance general notice in the formulary and EOC and other applicable beneficiary communications stating that such changes may occur without notice.     ++ Notice that identifies the specific drug substitution made-- which may be provided after the effective date of the change--as follows:

--Direct notice to affected enrollees. --Notice posted online for current and prospective enrollees. --Notice to CMS. --Notice to other entities.

     Notice and refill required for certain other midyear formulary changes: Part D sponsors that would be otherwise permitted to remove or change the preferred or tiered cost-sharing status of drugs would be required to provide the below types of notice and refills under proposed Sec.  423.120(b)(5)(i) and (ii). However, these notice requirements do not apply when removing drugs deemed unsafe by the FDA or removed from the market by manufacturers (for applicable requirements see Sec.  423.120(b)(5)(iii).)      For affected enrollees--     ++ Advance direct written notice at least 30 days prior to the effective date; or     ++ Written notice of the change and a month supply of the brand name drug under the same terms as provided before the change; and      For entities and other enrollees:     ++ Advance notice identifying the specific drug changes to be made at least 30 days prior to the effective date of the change as follows:

--Notice posted online for current and prospective enrollees; --Notice to CMS; and --Notice to other entities. 15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing     Similar to the introduction of an abbreviated approval pathway for generic drugs provided by the Hatch-Waxman Act in 1984 to spur more competition through quicker approvals and introduction of lower cost therapeutic alternatives in the marketplace, Congress enacted the ``Biologics Price Competition and Innovation Act of 2009'' to balance innovation and consumer interests. Specifically, section 7002 of the ACA amended section 351 of the Public Health Service Act (PHS Act) (42 U.S.C 262), adding a subsection (k) to create an abbreviated licensure pathway for follow-on biological products that are demonstrated to be either ``biosimilar'' to or ``interchangeable'' with a United States Food and Drug Administration (FDA) licensed reference biological product. According to the FDA, ``a biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has

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no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.'' However, ``an interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.'' (See [*http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/*](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/)) Biosimilar biological products are, by definition, not interchangeable, and are not substitutable without a new prescription. Follow-on biological products are listed in the FDA's Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at   [*http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm*](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm) Part D plan sponsors are also encouraged to monitor the FDA's Web site for new biologic (BLA) approvals at   [*http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu*](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu)     Sections 1860D-2(b)(4) and 1860D-14(a)(1)(D)(ii-iii) of the Act specify lower Part D maximum copayments for low-income subsidy (LIS) eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act) than are available for all other Part D drugs. Currently the statutory cost sharing levels are set at the maximums. CMS does not interpret the statutory language to mean that each plan can establish lower LIS cost sharing on drugs, but rather, that CMS, through rulemaking, could establish lower cost sharing than the maximum amount, and it would therefore be the same for all Part D plans.     For the Part D program, CMS defines a ``generic drug'' at Sec.   423.4 as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)) is approved. Biosimilar and interchangeable biological products do not meet the section 1927(k)(7) definition of a multiple source drug or the CMS definition of a generic drug at Sec.  423.4 Consequently, follow-on biological products are subject to the higher Part D maximum copayments for LIS eligible individuals and non-LIS Part D enrollees in the catastrophic portion of the benefit applicable to all other Part D drugs. While the statutory maximum LIS copayment amounts apply to all phases of the Part D benefit, the statute only specifies non-LIS maximum copayments for the catastrophic phase. CMS clarified the applicable LIS and non-LIS catastrophic cost sharing in a March 30, 2015 Health Plan Management System (HPMS) memorandum. We advised that additional guidance may be issued for interchangeable biological products at a later date.

**Load-Date:** November 29, 2017

**End of Document**



[***European Union (Withdrawal) Bill.***](https://advance.lexis.com/api/document?collection=news&id=urn:contentItem:5RS0-CGM1-JDG9-Y429-00000-00&context=1516831)

Impact News Service

February 27, 2018 Tuesday

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**Length:** 48434 words

**Body**

London: UK Government has issued the following news release:

**12:**Clause 1, page 1, line 3, at end insert—

“( ) Regulations bringing into force subsection (1) may not be made until the Secretary of State has laid before both Houses of Parliament procedures agreed with the EU for continued coordination of foreign and security policy, including association with the EU’s military staff and the European Defence Agency, and these procedures have been approved by a resolution of each House of Parliament.”

* Lord Wallace of Saltaire (LD)    Share this contribution My Lords, the Minister argued in winding up on the first group of amendments that we should be talking about the Bill and not about the issues raised by the amendments, which seemed a very ill-judged remark. This Bill is about a very wide range of policy areas—economic, constitutional and international—on which the Government are asking us to give them extensive powers, on trust, without telling us what they intend to do. The question for many of us is that we cannot trust the Government so far in giving them all those additional powers, unless they tell us rather more clearly what they intend to do. These amendments deal with the implications of leaving the EU for British foreign, security and defence policy, and with the management of those policies when we withdraw. As we withdraw, which is what this Bill is about, we will also withdraw from the structures of common foreign policy and the common security and defence policy in the Treaty on European Union, as specified in a large number of articles. So what will we do then? The leave campaign never addressed this in the referendum, so there is no way one can say, “Well, it’s the will of the people, we can’t stand in their way”. The leave campaign denied that the EU was ever concerned with anything to do with security, foreign policy or defence. We were told when we joined that it was just about the common market, and now it has turned into something else. Anyone who has read Edward Heath’s 1968 Harvard lectures, what he said when he became Prime Minister and what Sir Alec Douglas-Home said as Foreign Secretary, what Jim Callaghan did as Foreign Secretary and what the noble Lord, Lord Carrington, followed through on, including his London report on strengthening the ​mechanisms of common foreign policy, and what Geoffrey Howe achieved, would know that Britain was absolutely at the heart of forming common foreign policy procedures in the European Union. I remember writing something about it for publication in a Chatham House journal in the late 1970s and being briefed very helpfully in the Foreign Office by the official who co-ordinated our input to common foreign policy, whose name was Pauline Neville-Jones. One or two Members of this House may, indeed, be familiar with the name. I also recall the noble Lord, Lord Forsyth, who sadly is not in his place at the moment, insisting even after the referendum that the EU had nothing to do with British or European security—and I gave him an annotated copy of the 2015 security and defence review with chapter 5, which is entirely about European defence co-operation, marked for his benefit. Last September, the Government finally published a position paper on common foreign and security policy, which said, remarkably, that, “the scale and depth of collaboration that currently exists between the UK and the EU in the fields of foreign policy, defence and security, and development”, is such that we need, “a deep and special partnership”— a familiar phrase— “with the EU that goes beyond existing third country arrangements”. It goes on to point out that the UK was a founding member of the EU’s CSDP and takes part in all 15 common security and defence policy operations and missions and concludes: “The UK would like to offer a future relationship that is deeper than any current third country partnership … This future partnership should be unprecedented in its breadth, taking in cooperation on foreign policy, defence and security, and development, and in the degree of engagement that we envisage”. Well, that was interesting. Nothing was said for months afterwards—and, finally, the Prime Minister last week gave her speech in Munich in which she went into a little more detail about what she at least, if not the rest of her Government, seems to envisage. She said: “The EU’s common foreign policy is distinct within the EU Treaties … So, there is no reason why we should not agree distinct arrangements for our foreign and defence policy cooperation in the time-limited implementation period, as the Commission has proposed. This would mean that key aspects of our future partnership in this area would already be effective from 2019”. In that case, it is about time the Government started to educate the population on what arrangements they propose to make with the European Union. I hope, at least, that someone has told the European Union the sort of things that we might like to envisage. She then goes on to talk about our: joining the European Defence Agency and the European Defence Fund; contributing to the European Union’s common development policy, but on the condition that we also play an active role in formulating future European Union defence policy—I am not entirely sure how we do that, as an outsider—co-operating in cyberspace and space; and dealing with a whole range of issues including, on internal security, a new bilateral treaty between the EU and UK.​

6.30 pm

We need to know, before this Bill is passed, what sort of things that implies. We cannot entirely take on trust what the Government have said, partly because we know that they are confused and contain many disagreements within themselves. The Foreign Secretary made another speech last week. I looked very carefully through it; it is longer than the Prime Minister’s. There is one sentence in it about future co-operation with the Europeans. It says:

“It makes sense for us to continue to be intimately involved in European foreign and security policy”.

After that, he goes on to make a number of jokes about what British tourists do in Thailand, Doggerland and other such places, and does not return to the subject at all. One can conclude only that the Foreign Secretary is not of the same mind as the Prime Minister on how far we should continue to collaborate. I was even more interested to note—I am sure the noble Baroness, Lady Deech, will have noted—that the two-page article in the Sunday Times the Sunday before last about “Brains for Brexit” said that, far from the European Union being an asset in security terms, it has been responsible for more conflicts than any other international institution in the last 20 or 30 years. That is a quite astonishing comment which I think means that the European Union was responsible for various wars in Yugoslavia, among other matters. That at least suggests that the hard Brexiters, of whom the noble Baroness is one perhaps, see the European Union as something with which we should have no security relationship.

The purpose of the amendment is to say that, before the Bill is passed, the Government should be more coherent and clearer—with different Ministers saying the same thing—about what sort of deep and special partnership we wish to have. We will clearly not continue to command EU common deployments, as we have done in Operation Atalanta, but if we are to contribute, there has to be a very clear framework. I am conscious of this from what I had to do as a junior Minister in the coalition Government. There were those then—Liam Fox above all—who were happy to co-operate with the French and others in Europe, provided we did not tell the newspapers about it. When I suggested that we might, perhaps, invite the press up to Northwood to see the rather magnificent joint command for that operation, he agreed that ambassadors from other EU states could be invited but certainly not the British press.

The Government are incoherent on this issue. We therefore have the right to demand clarity before the Bill becomes law. The Bill takes the UK out of the European Union. The Prime Minister has just said that she wants us to stay in many of its foreign defence and development activities. How will that happen and how far are the Government prepared to commit themselves to it? I beg to move.

* Viscount Hailsham (Con)    Share this contribution My Lords, my purpose in adding my name to Amendment 12 is to enable the Government, through my noble friend, to explain what arrangements they intend to put in place before Brexit, in order to ensure that the United Kingdom is a full participant in the formulation of foreign and ​security policies which inevitably will be of great and enduring consequence to us all. The absence of such arrangements would be a conclusive argument against leaving the European Union. Noble Lords should be clear about this: if we wish to punch above the weight that naturally attaches to a country of relatively modest resources, it is because we are part of and not outside the structures of the European Union. For five years, I had the good fortune to serve in the Foreign Office under the overarching authority of Douglas Hurd. It is much to be regretted that he is not able to participate in this debate. His authority within the diplomatic and international community was great. This was due in part to his patience, his personal integrity, the temperate language that he always employed and his willingness to compromise. He never sought to promote himself by appealing to the wilder fringes of any political party. My noble friend was a model of a Foreign Secretary and I commend his example to all his successors. I digress for a moment and say that I very much regret that this House does not have the opportunity of hearing from Mr Jack Straw and Sir Malcolm Rifkind, both of whom would have made a valuable contribution to this debate. When working under Lord Hurd of Westwell, I had immediate departmental responsibility for a number of important areas: the collapse of the former Soviet Union; central and eastern Europe, most especially the war in former Yugoslavia; and the turmoil, then as always, in the Middle East. We did, of course, have distinctive political policies on all these matters and we have distinctive bilateral relations with the relevant countries and institutions. But looking back on my time in the Foreign Office I am sure it is true that we made a real difference when we were able to work with our European colleagues and within the framework of collective European policy. Collectively within the European Union, the United Kingdom was more influential than it would ever have been standing alone. This is not the age of Lord Palmerston or Don Pacifico. If one looks forward to the major international problems that we now face, that judgment remains good. Consider the ambitions of Russia; the ever-increasing power of Asia, especially China; the fact that America is once again detaching herself from the rest of the world and, most notably, Europe; the risk of war on the Korean peninsula; international terrorism; the problems posed by climatic change; the instability in the Middle East and the rise of militant Islam. In respect of all these matters, a collective approach is infinitely more effective than the individual policies of a middling power such as ourselves. There are also some specific problems to consider. What of our permanent seat at the Security Council? As member of the European Union, our permanent seat was less controversial than it might have been. Outside the EU, our status as a permanent member will be under increased pressure and, in any event, the status of France will be greatly enhanced. What about Gibraltar and the Falkland Islands? Outside the councils of the European Union we will not be able to rely on the automatic support of our European neighbours. Further, on any view, our role as America’s principal interlocutor with the European Union will cease. These considerations, by themselves, ​leaving aside all others, are a good and sufficient argument against leaving the European Union: that is my considered position. However, for the purposes of this debate, these concerns should cause this House to put questions to Ministers. We are repeatedly told by the Prime Minister and others that while we are leaving the European Union we are not abandoning our close ties. The noble Lord, Lord Wallace of Saltaire, usefully summarised our position paper, whatever it actually meant. We need more detail. We do not want bland reassurance. “Brexit means Brexit” is a quite meaningless phrase. It is not a policy or even an indication of a policy. Indeed, it is conclusive evidence of an absence of policy. Therefore, I say to my noble friend that this House is entitled to know in detail what arrangements will be put in place before we leave the European Union to ensure that the United Kingdom is a full, active and influential partner in the policy decisions that will certainly affect the lives of our fellow citizens for years to come. I doubt that this House will get a clear answer. I suspect that we will be none the wiser when the Prime Minister makes her long-awaited policy speech at the end of the week. If decisions were made at last week’s meeting at Chequers, that is welcome. It is almost, though not wholly, true that any decision is better than no decision. However, we are entitled to ask why on earth such ***strategic*** decisions were not taken before we triggered Article 50 and not now, with but 12 months or so to go. The absence of any arrangements and procedures of the kind identified in these amendments is by itself a good reason—there are many other good reasons—to reject the policy of leaving the European Union. Therefore, I look to my noble friend to give clear guidance on what procedures and arrangements the Government propose to put in place. This House is entitled to clear and precise answers to these questions, for they are fundamental in character. This is not a time for indecision, fudge, weasel words or lack of clarity. Having our cake and eating it is not an indulgence now available to us.

1. Baroness Deech (CB)    Share this contribution My Lords, I had not meant to intervene but since the noble Lord, Lord Wallace of Saltaire, has speculated on my views, I wish to put some things in context. Obviously one seeks clarity but I think there is a certain note of hysteria going around. Only a few moments ago, we had a question and answer session showing just how impotent the EU, and, indeed, any of us, have been in relation to Syria. The EU does not even manage to pay its subscriptions to NATO and has been impotent in relation to Russia’s behaviour recently. However, our own performance as a permanent member of the Security Council, a position from which we cannot be dislodged unless one entirely rips up the charter, has been admirable. If we want to continue to be an interlocutor between the continent of Europe and America, it is not a good idea to shoot ourselves in the foot by being even more uncivil towards President Trump than is absolutely necessary. As far as foreign policy and security are concerned, we are members of the Five Eyes group, which, from what I have read, is rather more efficient in its actions than what is going on in the EU. While we of course want clarity, there is no need to panic. We have to consider what the EU ​has done historically in relation to foreign policy. Over the last 40 years, it has had as many failures as successes whereas our record has been pretty good.

6.45 pm

* Lord Judd (Lab)    Share this contribution My Lords, like the noble Viscount, I had the privilege of serving in the Foreign Office back in the 1970s. I underline his comment that it is a great shame that Lord Hurd no longer sits in the Chamber as he certainly was a very effective and powerful Foreign Secretary. One of the reasons he was successful was that he listened to people and adopted a reasonable approach to finding solutions. There is no greater responsibility for a Government of the United Kingdom than to look after the well-being and safety of their people. At the moment there is a total dereliction of duty. We are about to abandon ways in which we have worked to protect the well-being of British people, while having absolutely no convincing indication of what is to replace our current methods of co-operation. Defence and security are inseparable and cannot be contained within national frontiers. They both require international solutions and co-operation. We also know, and debate it often in this House, that our armed services are very fully stretched; some would say overstretched. They cannot possibly do all that it is necessary to do on their own; they have to work with others. We have devised means whereby we can successfully co-operate in the interests of the British people. How on earth can we, with any sense of responsibility at all, say that we will withdraw from the existing arrangements without knowing exactly how we will fill the gap and maintain that indispensable co-operation? This amendment, so ably moved by the noble Lord, Lord Wallace, is absolutely crucial and I am therefore very glad to have added my name to it. It does not apply just to this sphere, of course. We are being asked to buy a pig in a poke in too many areas. However, we cannot defend the British people by buying pigs in pokes, but by having absolutely convincing, watertight arrangements in place. There can be no interregnum between one regime and the next; we have to undertake this in time. Will the Government please this evening begin to give us some indication of precisely what the arrangements will be and what resources will be put into them?

1. Lord Hannay of Chiswick (CB)    Share this contribution My Lords, I was urged by my noble friend Lady Deech to be more polite to President Trump, so I will respond to that by thanking him extremely warmly for having brought home to us the value of the European Union’s common foreign and security policy. In the year he has been in office, he has singlehandedly illustrated why our national interests in a number of areas are much closer to those of our European partners than to those of his Administration: for example, as regards the nuclear deal with Iran, the rather unfortunate decision to move the US embassy to Jerusalem, his very lukewarm support for NATO, his withdrawal from the Paris climate change agreements and his trade policy. In all these areas he has brought home to us why this debate and this amendment, which I support, are vital to our ​future national interests. I hope that when the Minister responds, she will be prepared to go a bit further than generalities. As others have already said, there is a complete lack of specificity in what the Prime Minister has said—she has, quite laudably, set out in very firm terms her desire that this should be a major pillar of the new partnership—about what the Government have in mind. It really is time that we saw more. The Prime Minister has spoken about a new treaty. We are in a negotiation. Normally, if you are in a negotiation and make a proposal, you table it. I have not seen the treaty. Has anyone seen it? I do not think that anyone has. Does it exist? I suspect not because, judging from the rather lukewarm attitude of the Foreign Secretary, he might not be able to produce much of an input into it. This really is getting important now. We are only a year away from dropping out of all the complex machinery which makes the common foreign and security policy work. I have to say to my noble friend Lady Deech that her caricature of common foreign and security policy is bizarre. For example, the idea of a nuclear agreement with Iran originated in the European Union, and it was followed up, rather belatedly, by the United States. Therefore, I do not think that we should belittle such co-operation. In any case, the Prime Minister is firmly of the opinion that it matters and that we need to work very closely with the EU. I wonder whether it would not be better to say here and now—perhaps the noble Baroness the Minister replying to this debate could do so—that our co-operation in this area of common foreign and security policy is not subject to the rubric “Nothing is agreed until everything is agreed” and that it is, as we are trying to say but have been rather hesitant about saying, completely unconditional.
2. Lord Cavendish of Furness (Con)    Share this contribution My Lords, is the noble Lord aware that the phrase “Nothing is agreed until everything is agreed” came from President Tusk, not us?
3. Lord Hannay of Chiswick    Share this contribution It was not only President Tusk; it was part of the agreed conclusions of the first part of the negotiations—that is, we subscribed to it too. As that first stage did not cover common foreign and security policy, all I am suggesting is that, now we are moving into that field in the negotiations, we should make it clear that our proposals—including the proposal for a new security treaty—are not subject to “Nothing is agreed until everything is agreed” but will be put forward to the mutual benefit of all parties. That would make a huge difference, because there is a lot of misunderstanding and a certain amount of suspicion that we are approaching this in a spirit of transactionalism—that we are trying to trade off one part of the negotiations against another. That would be a mistake in the field of common foreign and security policy. If it is to be pursued after we have left the European Union, it can pursued on a basis of mutual benefit only and not of a transactional approach. Therefore, I hope that when the Minister replies to this debate she can give a little more clarity on what the Government are seeking and that she can state in absolute terms that the unconditional nature of what we are pursuing here is our policy.

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* Lord Adonis (Lab)    Share this contribution My Lords, I have four amendments in this group, which, following on from what the noble Lord, Lord Hannay, has just said, seek to maintain British membership of the EU’s Political and Security Committee, the EU’s common foreign and security policy, the EU Foreign Affairs Council and the EU Intelligence Analysis Centre. First, I warmly welcome the noble Baroness to the Front Bench and to our debates. We have very high hopes of her and her response to this debate because she is not the noble Lord, Lord Callanan. We regard her as the more accommodating face of Her Majesty’s Government. We think that, while the noble Lord, Lord Callanan, is not on the Front Bench at the moment, she has an opportunity to make all kinds of very sensible statements of government policy which can then go on the record and we can move on from there. This is a golden opportunity for her to do so in respect of foreign policy. The noble Lord, Lord Wallace, made a very powerful speech on why it is important that we remain thoroughly engaged in the security apparatus of the European Union and he spoke about the big dangers that face us as we leave. I do not think there is any point in my repeating those remarks or those of the noble Lord, Lord Hannay. I just want to make two comments. The first relates to the only speech that the Prime Minister gave, on 25 April 2016, in the debate on the referendum, where she weighed the arguments for remaining in the European Union. What is so remarkable about that speech is how much emphasis—it was an almost exclusive emphasis—she placed on the security aspects of the European Union and the dangers to our security of leaving. Clearly, given her experience in the Home Office, she was particularly concerned about some of the Home Office dimensions of that, and we will cover those in a later group. However, she also raised the broader security issues. If one looks at the words that she used in that speech, it is very clear that she regarded membership of the multilateral institutions of the EU, particularly in foreign policy and security co-operation, as being of huge importance to the Government and to this country. She said: “If we were not members of the European Union, of course we would still have our relationship with America … But”— these are the key words— “that does not mean we would be as safe as if we remain”. As the noble Viscount, Lord Hailsham, said, we will be leaving all these institutions in one year, and I believe it is incumbent on the Government to give the House some sense of what their policy will be in respect of those institutions. That is hugely important. My second point is to consider the course that we now appear to be set on. It is what has become known as “hard Brexit”, which is leaving not just the security institutions of the European Union but the economic institutions—the single market and the customs union. I am a novice to international security policy. I have spent most of the last 15 years trying to reform public services at home and, like many other noble Lords, I have had to get to grips with these issues. One of the most important and, for me, influential books that I have read while I have tried to understand what this ​might mean for the future of Britain in Europe and globally is by Professor Brendan Simms at the University of Cambridge. He has written a quite brilliant book called Britain’s Europe: A Thousand Years of Conflict and Cooperation, which charts our whole relationship with Europe during the last millennium. Professor Simms makes a quite obvious point, the significance of which becomes greater and greater as we appear to be heading towards leaving not only the security but the economic institutions of the European Union. The basic but fundamental point he makes is that countries which are engaged in trade conflicts and trade wars find it that much harder to co-operate on security issues. To my mind, in terms of the security of the United Kingdom going forward, the most alarming development at the moment is that, as we appear to be in an ever more tense and potentially conflictual relationship with France and Germany in particular over the future of our trade policy, and if we are to start engaging in tariff wars and setting up rival customs arrangements and things of that kind which could lead to quite significant trade conflicts, that can only weaken our security co-operation with them over the medium to long term. Those of us who are in favour of remaining in the European Union are often accused of carrying out what is called Project Fear, but I recommend to the Minister and to noble Lords the Prime Minister’s speech of April 2016. She draws a direct parallel between the instability of relations between European powers before 1914 and what could happen if we start to fracture those relations today. That came from her, not me. Therefore, what we look for from the Minister while she is able to make positive statements about Europe in the absence of the noble Lord, Lord Callanan, is some indication that she appreciates the need for very close co-operation with our European partners on trade and economic matters, not least because that will tend to promote close alignment in foreign and security policy.

1. Lord Cavendish of Furness    Share this contribution My Lords, does the noble Lord not realise that those of us who advocate leaving believe in free trade, which has been a great source of peace, rather than conflict, throughout history? He belongs to the side that wants tariffs.
2. Lord Adonis    Share this contribution My understanding is that it is the policy of Her Majesty’s Government to put in jeopardy the free trade we currently enjoy in the European Union. If the Government were in favour of free trade, we would stay in the customs union and in the single market. These are straightforward, obvious propositions. The policy of the Government tends only towards reducing free trade with the single biggest set of trading partners that we have at the moment.
3. Lord Lamont of Lerwick (Con)    Share this contribution How is the noble Lord just about the only person in this House who does not know that the Government have stated over and over and over again that they want a free trade agreement with the European Union?
4. Lord Adonis    Share this contribution My Lords, the best free trade agreement to have with the European Union is the one that we are currently in. That is patently obvious. When you ​have an existing set of satisfactory arrangements, the idea that the policy for improving them is to undermine them is total nonsense. I hope the noble Baroness will give us some assurance that she understands the significant security dimension that is at stake in our leaving the European Union and the importance of having close alignment on trade, not least so as not to weaken our collective security with our European friends and allies.

7.00 pm

* Lord Stirrup (CB)    Share this contribution My Lords, I will speak briefly to Amendment 12. The issues which it raises are of crucial importance to a post-Brexit UK, but they have only recently begun to achieve any prominence in the Westminster debate and have had very little visibility at all on the wider national stage. EU Sub-Committee C of your Lordships’ House has recently concluded an inquiry into sanctions policy after Brexit and is currently conducting an inquiry into the UK’s future relationship with the European Union in the fields of security and defence. In both cases, the Government have expressed an intention to act in close concert with our European partners—the Government; not the movers of this amendment—but they have not so far explained how this is to be done. There are some very clear difficulties. The EU’s policy regarding specific sanctions regimes and its common security and defence policy are agreed at ministerial level within the Foreign Affairs Council. However, the arguments through which final proposals are hammered out take place at lower levels, in the engine rooms of the EU. If one is not present in the engine rooms, one has no influence over the formulation of policy proposals. This means that if the UK wishes, post Brexit, to act in concert with the EU in particular sanctions matters, or if it wishes to participate in common security and defence missions—for both of which it has expressed some enthusiasm—it risks having to do so on the EU’s terms. It would have to do so having had no input to the formulation of policy, and with little or no input to subsequent ***strategic*** direction. This is not a position with which I, for one, would feel very comfortable. The question, therefore, is: what arrangement can the UK reach with the EU that would allow it a suitable degree of influence in these matters? Why should the EU be interested in such an arrangement at all? Perhaps because in those areas in particular, the UK brings capabilities which, in scale and nature, are of an order that few, if any, other European countries possess. However, that does not alter the fact that a non-EU member is unlikely to be given the kind of locus in decision-making that is available to a member. The position of current non-members that align with the EU in these matters is not one that, in my view, would be appropriate for the UK. We need to argue for a separate, tailored arrangement. Sanctions policy and common security and defence missions are, of course, offshoots of wider foreign policy. If we wish to have a close relationship with the EU in these specific areas, then we will need some mechanism for discussing and agreeing with it in ​advance the wider international issues and objectives involved. We need an architecture that brings the UK and the EU together to formulate foreign policy in pursuit of shared objectives, and that places UK personnel in those engine rooms of the Union where the specific proposals on individual issues are debated and evolve. We need to agree a modus vivendi for these people that protects the status of EU members while providing for outcomes that are in the best interests of the Union and ourselves. That is a very tall order, and all the more reason, then, for pursuing such an outcome much more vigorously and urgently than has been the case so far. Amendment 12, and indeed several associated amendments, calls for such arrangements to be not just negotiated but approved by both Houses of Parliament before the provisions of the current Bill are implemented. I do not go so far: I do not believe that the amendments as set out should be agreed. However, I do believe that they provide welcome exposure to issues that are of crucial importance to this nation, that have been largely ignored for far too long and that should at last be accorded the priority they deserve. I hope that the Government will now act accordingly.

1. Lord Campbell of Pittenweem (LD)    Share this contribution My Lords, it is always a pleasure to follow the noble and gallant Lord, Lord Stirrup, who speaks with great clarity and directness. It may surprise the noble Baroness, Lady Deech, when I say that I have some sympathy for her in putting forward the notion that the European Union has not really paid up sufficiently for its defence. One of the so-called advantages of President Trump’s arrival and his apparent dismissal of NATO has been to cause a much greater degree of realism. The old arguments about burden sharing now take a very practical effect, and NATO countries have agreed on a minimum of 2% of GDP. As far as I can see, all NATO countries are now moving, as far as they can and as quickly as they are able, towards reaching that level. I support the amendment moved so ably by my noble friend Lord Wallace of Saltaire. I have one advantage over him—as indeed does the noble Lord, Lord Kerr of Kinlochard. We were both present at the Munich Security Conference and heard how the speech was delivered, as much as understanding the content. It was an interesting speech in this sense. The first half was exemplary. The Prime Minister extolled the virtues of the existing security arrangements in Europe and rightly pointed to her role in continuing to ensure that the United Kingdom remained a participant in the application of the European arrest warrant and an active member of Europol when, on the Back Benches of the other place while she was Home Secretary, quite a lot of people in her own party would have departed from both these positions without a backward thought. Munich is regarded, perhaps over-grandly, as the Davos of defence, and there is no doubt that the Prime Minister’s speech got pretty substantial billing. That is why I and many others found the second half so disappointing, provoking as it did an American listener—whom I believe to have had Republican sympathies—to say, “Where’s the beef?”. The truth is that the Prime ​Minister had nothing of substance to say in addition to the paper that was published by the Government last September. There was no hectoring from the Prime Minister, but there was certainly a degree of lecturing. In a sense, what she said can be summed up as: the security regime of the European Union is extremely good, but we are leaving it, we want you to help us replace it with a treaty, and, if you do not agree to what we want—and here is the lecturing to which I referred—you will bear the responsibility. That is hardly the way to ***win*** friends and influence people in a gathering of experts and people with enormous experience in the realms of security and defence. There was one element of the Prime Minister’s speech that has not, so far, received sufficient consideration. She said that, “when participating in EU agencies the UK will respect the remit of the European Court of Justice”. I thought that the whole purpose of Brexit was to have nothing to do with the European Court of Justice. If that is not now the Government’s position, it might be argued that the door of the ECJ has been opened, if only slightly. Perhaps it was too Delphic a sentence to attach much significance to, but it has not been the subject of further explanation. As has already been hinted at, the consequence of leaving is that the United Kingdom will become, in European Union terms, a third country. That is relevant to the issue of participation in Europol and the European arrest warrant. It raises a number of questions—some of which are being legally disputed—about whether or not the kind of arrangement the Government appear to wish to achieve would necessarily involve the role of the European Court of Justice. There are strong arguments on both sides, but the matter remains uncertain. Before I move on to the question of defence, perhaps I may make one last point on security. Everything in these debates seems to end up around Ireland in some way or another. Ireland is a foreign policy issue because the treaty is an international treaty lodged with the United Nations—and it is also an issue to which we must have regard in considering the question of security. As I understand it, the Government are considering the creation of a virtual border based on electronic means. At the same time, they are telling us that cybercrime is on the rise and is one of the principal issues which may have an impact on our security. If people can get inside the computer system of the Pentagon, I doubt they will find it too difficult to get inside any electronic border that we may create between Northern Ireland and the Republic. On defence, it is quite true—unassailable—that NATO is the bedrock of our defence. But it is also true that in NATO and the European Union there is a more considered determination to provide much more co-operation. The two institutions had their head offices at the same time in Brussels and for years they would not speak to each other. Now, at the very centre of the policies of NATO and the European Union, is a determination that there should be a higher degree of co-operation. There has been discussion about the common defence and security policy but, although it now becomes an important element in the consideration of these matters, ​no one has yet mentioned PESCO. This is not a junior form of a place where you can buy your groceries but—I have reservations about the language—Permanent Structured Cooperation. Essentially, it is the countries of the European Union concentrating on co-operation on defence matters so as to ensure that collectively they might make a more substantial contribution to NATO. We are not members of PESCO—recently formed—and if we leave the European Union we will cease to be present at meetings of EU Defence Ministers and Foreign Ministers. We will no longer be involved in the decision making of the common defence and security policy. As a third party, our participation in operations will be at the discretion of the other member states. I see that as a highly deficient alternative to what we presently enjoy. The security and defence consequences of our departure, as has been pointed out, were never properly discussed—any more than the political consequences. But this evening were are concerned with security and defence and there needs to be clarity. If the noble and gallant Lord, Lord Stirrup, had any responsibility for it, I am sure that we would have clarity. The reason there is no clarity is that no decisions have been made. That is why, when the Prime Minister at Munich said that this was an urgent matter and we must get on with it, it did not receive the kind of ready welcome she might have expected. The amendment is essential if we are to cause—to force, if you like—the Government to come clean on what their proposals are: to go beyond the document published last September and to set them out in detail. It is a matter on which the European Union is anxious to have detail and I see no reason why it should not be public rather than private. That is what the amendment is designed to achieve and why it should be supported.

7.15 pm

* Lord Kerr of Kinlochard (CB)    Share this contribution My Lords, I agree with the assessment of the noble Lord, Lord Campbell of Pittenweem, of the Prime Minister’s speech in Munich—it is exactly right—but he forgot one thing: at least the Prime Minister did not set out to insult the conference as the Foreign Secretary had the year before. Things are getting a lot better. I rise to support Amendments 12 and 185 and to say why I cannot support Amendment 166 and therefore Amendments 164 and 165. Amendment 166 states that we should remain in the Foreign Affairs Council after we have left the European Union. We have to be realistic—that is not possible. If we decide to leave the European Union, we will not have a seat in any of the councils of the European Union. That is a fact. We may be able to negotiate some kind of seat in the directing bodies of agencies; if we are operating alongside the European Union in, say, a defence deployment, we may be able to arrange some joint command structure for that particular operation, but the direction of common foreign, security and defence policies and PESCO will be set by the 27 and we will have no say in the decisions they take. This, I fear, is undeniable.

1. Lord Patten of Barnes (Con)    Share this contribution Will the noble Lord concede that at least European Ministers after they ​have had their discussions and made their decisions will be sure to tell us afterwards what they had decided?
2. Lord Kerr of Kinlochard    Share this contribution I suspect we will find out. To me personally, this is an extremely sad moment. When I was ambassador to the European Union I found that the things I was allowed to suggest as policy prescriptions were taken seriously in Brussels, partly because it was assumed that if the EU followed the British prescription, the British would ensure that the Americans came in behind it. When I was ambassador in Washington I found the same. Access to and influence on the President was a function partly of the perception that, on a foreign policy issue, the British could call the shots in Brussels. I am glad that this discussion started with a tribute to Lord Hurd of Westwell, who was the exemplar of how to handle common foreign and security policy. I am glad too that it started also with a tribute to noble Lord, Lord Carrington. The original EPC was, in many ways, a British construct. CFSP as it emerged, with the strong support of the Healeys and the Callaghans, was Douglas Hurd’s construct. The European External Action Service was a British proposal. We punched more than our weight but we have to accept that when we leave the European Union, if we do, that is all gone and we should not pretend that we will have the same influence from outside. What should we do?
3. Lord Cavendish of Furness (Con)    Share this contribution Can the noble Lord explain to us why it is not in the interests of our European partners—100% in their interests—to co-operate as we have always co-operated before?
4. Lord Kerr of Kinlochard    Share this contribution I am coming to that. I agree entirely that co-operation is in everyone’s interests. This is one of the areas of negotiation where we are not talking about a zero-sum game; rather, we are talking about a common interest, so I agree with the noble Lord. The point I am making is that we are in the next room. We are not in the room where the decisions are taken. We need an offer and an architecture for the next room. We need to come forward very soon and say, “We are prepared to consult on everything in the area of the common foreign and security policy. We are prepared to consult before every great debate at the United Nations. We would like to consult about every conflict area where Europe should have a view and possibly a presence. We would like to go on contributing our analysis and our intelligence. We would like you, o European Union, to build an annex to the Council—the room next door where we, who we hope will be your closest partner in co-operation on foreign policy, will be consulted by you and will consult you”. A moment ago the noble Lord, Lord Liddle, made the point that the timing is very important. If we leave the European Union in March 2019, we will leave the Council and there will be no such structure in existence. I should think that something will be invented in the end, but there will be a period of hiatus when we will do the best we can. It would be much better if the United Kingdom were now to put forward an offer and an architecture. It would be much better if there ​had been a third section to the Prime Minister’s speech in Munich in which she had said, “This is how we envisage it working”. I do not see, particularly on the common foreign and security policy, why we should leave it to the European Commission. There is no great expertise on this in the Commission. It seems that it would have been better on a number of the dossiers in this negotiation if we had actually decided to play at home rather than play on their turf. It would have been better if on every issue we had not waited for the other side to make a proposal. This is the locus classicus. This is the area of our greatest reputation in Europe. We invented the existing structures in this area, which we are now going to walk away from. This is the area par excellence where the other countries would like to co-operate with us. Why do we not put forward a proposal now? That is why I can support very happily Amendments 12 and 185, but I fear that there is no point in pretending that we can remain, on particular issues, a member of the club. We will have left the club, so the best we can do is try to be its closest partner on the common foreign and security policy.
5. The Earl of Sandwich (CB)    Share this contribution My Lords, following on from what my noble friend has just said, I should like to ask a favour of the Minister. I am not going to make a speech because I had my chance at Second Reading. My request is that she will respond to the question of international development. The noble Lord, Lord Wallace of Saltaire, mentioned it, but it was not in his amendment. However, it is very connected. I am thinking in particular of Kosovo at the moment as an example of the bridge between security, defence and international development. It is still going on. At this moment the Prime Minister of Kosovo is in the House of Commons seeking our support in the context of the European Union, of which we are still a member. This is something that is happening now. I hope that the Minister can respond on that subject and I will probably table an amendment at the next stage.
6. The Earl of Listowel (CB)    Share this contribution My Lords, we will come to the issue of children’s rights later in the Bill: the right to education, the right to contact with both parents and the right to rehabilitation from abuse and torture. While listening to the debate I recalled my mother’s experience of losing her younger brother when he was one or two years of age. They were in an air raid shelter that was cold and wet. He contracted, I think, meningitis. I was also thinking of the Anna Freud National Centre for Children and Families, which is a centre of excellence for helping children and young people. Originally it was known as the Hampstead War Nurseries. It was set up by Anna Freud during the Second World War to care for children dealing with the trauma of bereavement as a result of losing their parents in war. I hardly need to say to your Lordships that this is a very important matter. We need only to look at what is happening to children in Syria, so we must take the most constructive and proactive course possible. We can keep this country safe, but other countries rely on our strength to keep them safe and secure, and help their children to lead stable and secure lives. I am ​sure that the Minister will want to make a constructive response to this debate and I hope that she will be as sympathetic as possible to the concerns raised.
7. Baroness Hayter of Kentish Town (Lab)    Share this contribution My Lords, I will be brief because most of the points have been made. I am grateful to the noble Lords who tabled this amendment and have thus ensured that this important issue is being discussed today. As has been said, the Prime Minister’s speech in Munich did rehearse the case that, “our security at home is best advanced through global cooperation, working with institutions that support that, including the EU”. We also had a welcome reminder from my noble friend Lord Adonis of the Prime Minister’s earlier, pre-referendum speech on the same issue. In Munich, she went on to outline her desire for an ambitious post-Brexit EU security relationship, talking about a security treaty as part of the “deep and special partnership” with the EU that she wants to see. However, as we have heard from most speakers in this debate, there was a curious lack of detail, or “beef”, in what she said. As with last week’s amendments, these issues are integral to how we leave the European Union and indeed to the vote which will take place in this House in due course over the withdrawal deal, with its framework for our future relationship with the EU. As has also been mentioned, there is clearly a relationship between trade and security, as my noble friend Lord Adonis reminded us. I hope, therefore, that when the Minister answers the various points of the debate, she will do so in the spirit of these being an integral part of what this Bill is looking at, which is the method by which we leave the European Union. Given that our role in defence is most probably the main defence power in the EU and the only one already hitting the 2% target, our departure will have a significant impact on the defence and foreign policies of Europe and will therefore affect our other relationships with it. Indeed, we should be mindful that, while the UK possesses full-spectrum military capability—although a little stretched, as my noble friend Lord Judd reminded us, and no doubt my noble friend Lord West would if he was in his place—and an extensive diplomatic reach across the globe, we should note that our hard and soft power has been greatly enhanced by our membership of the EU. That is why, as we have heard, Mr Callaghan as he was then focused on this and why the last Labour Government helped to launch the common foreign and security policy and the common security and defence policy. So while the Government have rightly indicated that they will seek to continue our participation in, for example, EU missions and interacting with relevant EU bodies, what we need is for the Minister to outline how the Government envisage this happening and on what terms—a point made by the noble and gallant Lord, Lord Stirrup. This is needed with a degree of urgency since, as my noble friend Lord Judd said, there simply cannot be an interregnum or hiatus, to use the words of the noble Lord, Lord Kerr, before something is put in place. We have a year and a month to go. I will take a moment to pose a different question to the Minister. Given the demands at the weekend by Spain’s Foreign Minister for joint management of Gibraltar’s airport after Brexit, could she confirm that ​at every step of the way the Government of Gibraltar are being informed and consulted on the Government’s evolving position on these and other issues, and that nothing will be agreed to jeopardise Gibraltar’s future—mindful, of course, of its worries arising from paragraph 24 of the EU’s negotiating mandate?

7.30 pm

I recognise that some of these amendments are probing at this stage. Nevertheless, we strongly support the principles behind them, particularly their call for greater detail and specificity from the Government, as was called for and demanded by the noble Viscount, Lord Hailsham, and by others, and even for the clarity required by the noble Baroness, Lady Deech. Continued co-operation with the EU is vital for our security and our wider interests, and to ensure that we can continue to make a positive impact abroad, as well as maintaining our reputation as an outward-looking nation. These issues are important, and we look forward to hearing what I hope will be a positive and detailed response from the Minister.

* Baroness Goldie (Con)    Share this contribution My Lords, I thank you all very much indeed for contributing to a genuinely extremely interesting and useful debate. I thank the noble Lord, Lord Adonis, for his very warm words of welcome. I fear that it is inappropriate to say this to someone bearing the name Adonis, but I fear I may be doomed to disappoint him. I will try to deal as best I can with the various points that have been raised. The Government share with this House the objective of building a close and co-operative relationship with the EU on issues relating to defence and security, as referred to by the noble Lord, Lord Wallace of Saltaire, or to foreign affairs, security and intelligence, as referred to by the noble Lord, Lord Adonis. These are indeed vital matters. The continued security of Europe and of our citizens is paramount to us. It would just not be in our interests to see that co-operation diminish. The purpose of the Bill is, I suppose, mechanical and rather tedious, but it is a mechanism to try to ensure that the UK statute book continues to function after we leave the EU and that it is not riddled with gaps and holes. That is what this Bill is all about. Amendment 12, as proposed by the noble Lord, Lord Wallace of Saltaire, is about the future relationship with the EU and securing it. That is vital—nobody disputes that—but it is of course inevitably, and I am sorry to use the platitude, subject to the current negotiations. Given that the Government have already committed to providing Parliament with a meaningful vote on any final deal, I respectfully suggest to the noble Lord that perhaps this Bill is not the appropriate forum to raise these concerns. I still think that the debate is an appropriate forum in which to articulate them.

1. Lord Kerr of Kinlochard    Share this contribution Could the noble Baroness reassure me that there is a negotiation going on on the future relationship between the UK when it has left and the common foreign and security policy of the EU? Is there a negotiation going on? I have the impression that there is not. I was trying to say that we should start one by making a proposal now.

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* Baroness Goldie    Share this contribution The noble Lord will understand that I am a very lowly mortal and that I am not privy to the detail of the negotiations. What is clear from what the Prime Minister has said is—just as the noble Lord, Lord Adonis, very helpfully identified—how extremely important these issues are to the Prime Minister. I am absolutely certain that, within the holistic forum of the negotiations, these matters are certainly being discussed and looked at.

1. Baroness Hayter of Kentish Town    Share this contribution The noble Baroness has said, and it keeps being implied, that these are not issues for this Bill. I am sure that she knows the Bill far better than I, having read it more often, but I remind her that on page 7, Clause 9(1) says that the use of regulations is, “subject to the prior enactment of a statute by Parliament approving the final terms of withdrawal of the United Kingdom from the European Union”. We know that, under Article 50, those final terms of withdrawal have to include the framework for our future relationship, which is almost bound to affect and comment on issues such as this. Although on many occasions Ministers may not want to answer, there is reference in the Bill to the withdrawal deal and surely it is appropriate for us to bring to the Government anything that might be in that.
2. Baroness Goldie    Share this contribution Yes. My position that I advance to the noble Baroness—I was just going to come to this in my speech—is that there will be a subsequent opportunity for Parliament to look closely at whatever the withdrawal agreement is and its implementation. In addition, the Government have committed already to providing Parliament a vote on the final deal. Parliament will be given the opportunity to scrutinise the future relationship between the UK and the EU. That is why I submit that the Bill before us is essentially of a mechanical nature. That is what it is: it is trying to ensure, as we leave the EU, that we make sense of transferring the necessary laws, enactments and regulations, whatever they may be, into the statute book of the United Kingdom. The noble Baroness is quite correct that Parliament should have that right to scrutiny, of understanding what the agreement is and questioning how the implementation will take place; I am pointing out that these opportunities will be there. Parliament will not be denied that opportunity.
3. Lord Campbell of Pittenweem    Share this contribution Will the noble Baroness give way? I shall be very quick.
4. Baroness Goldie    Share this contribution My Lords, I would be happy to give way later, but I am quite anxious to make progress. Important points have been raised. I want to try to keep the theme running as to how I will respond to them. The noble Lord, Lord Adonis, referred to the Prime Minister’s speech in Munich. She gave a very important speech because she detailed further how the UK envisages future collaboration with the EU on internal and external security. She reiterated our unconditional commitment to European security. I turn to a very important point raised by the noble Lord, Lord Hannay, and echoed by the noble Lord, Lord Adonis. I say without equivocation that we remain absolutely committed to ensuring European security and developing this ​deep and special partnership. Our desire for a close working relationship on foreign and security policy is not conditional on other areas of the negotiations. I hope that that reassures the noble Lords.
5. Lord Campbell of Pittenweem    Share this contribution We have, effectively, a willing buyer and a willing seller when it comes to security and defence. Why not take the opportunity of concluding that bargain? It would be much easier to do than, for example, the trade agreements that we hope to deal with in the future.
6. Baroness Goldie    Share this contribution This is like the fair in Paisley: things coming from one side, interventions coming from the other side and voices from behind me. I am not sure that I entirely agree with the analogy. It is the case that explorations are taking place, if you like, between a buyer and a seller—that is what a negotiation is—but these are sensitive negotiations. I am trying to make clear in the course of my speech—perhaps if I can make a little progress it might become more apparent—just how committed the Government are to addressing the issues raised by your Lordships. They are issues of real concern and are certainly of vital importance. That is because our shared values—those values between the United Kingdom and the EU—are manifest and universally acknowledged. I hope that universal acknowledgement understands that we do not need the text of the Bill to explain to everyone that it is there. I hope that everything that we have done as a member of the EU and all that we are doing in the conduct of the negotiations, particularly as made clear by the Prime Minister’s remarks, will reassure all just how serious we are about these matters. We have proposed a bold new approach to security co-operation with the EU, including a comprehensive framework for future security, law enforcement and criminal justice co-operation, and for future co-operation on foreign and security policy. I say to the noble Lord, Lord Wallace of Saltaire, that, as we leave the EU, of course our consultation on the CFSP will change, as it inevitably has to do. With considerable justification, many of your Lordships—the noble Lords, Lord Wallace of Saltaire, Lord Judd, Lord Hannay and Lord Campbell, my noble friend Lord Hailsham and the noble Baroness, Lady Hayter—were anxious to get some idea of what the post-Brexit position would look like in relation to these issues of critical importance. I say by way of preface to all of this that, as a Government Whip for the Foreign and Commonwealth Office and for Defence, I have regularly found myself at this Dispatch Box outlining positions on foreign affairs and defence which are UK derived. They are positions that we have reached by ourselves and as a consequence of our NATO membership—which is very important, as acknowledged by the noble Lord, Lord Campbell—as part of our P5 position on the United Nations Security Council or as a consequence of discussions with our global allies. We do that now on our own account. I make that point to explain that, while we value the relationship that we have had with the various agencies in the EU, there is another territory out there that is also extremely important to the future security not just of this country and the EU but of our global partners.

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* Lord Browne of Ladyton (Lab)    Share this contribution It is crucial that we understand that the Prime Minister proposed in Munich a treaty for what was referred to as “internal security”, which is internal security within the European Union. It would be a treaty which had plenty of detail and clearly reflected co-operation with the existing institutions of the European Union—that is where we get into discussion about the European Court of Justice. But for external security, there would be co-operation. Why this difference? Why a treaty for internal security, and why just co-operation on global security, with a clear indication that we would leave the European Union’s foreign policy on the date of Brexit?

1. Baroness Goldie    Share this contribution There seems to be an inescapable distinction between these two positions. In relation to the internal security of the EU, there can be a meaningful discussion about what we can do to assist and support that, but when it comes to external security and just as I have outlined, there is a multiplicity of other positions, agencies, alliances, relationships and partnerships which govern what we do. I can see that what would be appropriate to deal with one scenario might not be appropriate to deal with another, but I say that without prejudice to whatever the negotiations are currently covering. I am not privy to the detail of the negotiations, but there seems already to be evidence that constructive dialogue is taking place. From what we have heard from the Prime Minister and her absolute and unqualified commitment to security and to trying to embark on as close and harmonious a relationship as we can get with the EU post Brexit, there is no doubt about her conviction on these matters. We have to work as closely as we can with the EU post Brexit. The Prime Minister has made that crystal clear and is right to do so. The UK is not without influence. As the noble Baroness, Lady Deech, noted, it enjoys a status in relation to these matters—I refer again to our P5 position on the United Nations Security Council. One area in which people have been sceptical is in their asking why the UK should be treated differently from other third-country partners as we try to negotiate new arrangements with the EU. Taskforce 50 noted in its presentation on external security that the EU would lose one of its two permanent members of the Security Council when the UK leaves. Taskforce 50 recognises that this could merit a specific dialogue and consultation mechanism with the UK. Perhaps I may return to a very legitimate question posed by a number of your Lordships: what is all this going to look like and is there any sort of shape to it?

7.45 pm

* Lord Davies of Stamford (Lab)    Share this contribution The Minister has just mentioned the matter of our withdrawing from the permanent membership of the United Nations Security Council and that our withdrawing from the European Union will mean that there will be only one EU permanent member. Will that not be a wonderful day for France, which will be able to speak in the councils of the United Nations as representing the EU as a whole, and will no doubt do so?

1. Baroness Goldie    Share this contribution I am sorry, I think that I may have been misunderstood. I did not talk about the United Kingdom withdrawing from being a P5 member of the ​United Nations Security Council. I said that when we withdraw from the EU, the EU will be left with only one member, which is France. The position of the UK in that respect is powerful and influential, and I am pointing out that Taskforce 50 thought that it could certainly merit a specific dialogue and consultation mechanism with the UK. It is pretty clear, particularly when there are many in this Chamber much more knowledgeable than I am about these important and technical matters, that to underpin our future co-operation we will seek regular institutional engagements, including specific arrangements on secondments and information sharing—that would seem to be at the heart of constructing any relationship. The nature of the threats that we face mean that we should seek a framework that could be scaled up in times of crisis. One needs a relationship which can be tested against need if situations arise when the partnership, agreement or whatever it is to be has to swing into action. The United Kingdom intelligence community already works closely with other members of the EU. The heads of the German BND, the French DGSE and the UK secret intelligence services issued a joint statement at the Munich security conference committing to close co-operation and stating that cross-border information sharing must be taken forward on themes such as international terrorism, illegal migration and proliferation of cyberattacks after the UK leaves the EU. We want to do all that. I am trying to explain to your Lordships that there is straw with which to make my bricks. I am not just clutching it out of the air; I am trying to indicate that there are substantive matters that can be the foundation for something very firm and enduring. Perhaps I may try to deal with one or two particular points raised. The noble and gallant Lord, Lord Stirrup, raised the important matter of sanctions. We have just passed a sanctions Bill which will provide the UK with the powers to implement our own independent sanctions regime, but we would delay these powers coming into force if we could agree arrangements with the EU concerning sanctions co-operation during the implementation period. On sanctions, as with co-operation on foreign and security policy more generally, we seek to consult and develop a co-ordinated approach before decisions are made. To enable such co-operation, we will need consultation mechanisms; for example, regular sanctions dialogues. I was very struck by the contribution from the noble Earl, Lord Listowel, who raised real and poignant issues. Nobody would disagree with that, which underlines why we need close co-operation on these vital issues. On Amendments 164 and 166 tabled by the noble Lord, Lord Adonis, the political and security committee and the Foreign Affairs Council are of course bodies of the EU. They are attended by member states and are intended for the development of the EU’s policy. We are leaving the European Union and are not seeking to participate in these meetings on the same basis as EU members. The noble Lord, Lord Kerr of Kinlochard, identified these problems. But, given our historic ties and shared values, we are likely to continue sharing the same goals and we will therefore want to co-operate closely on a common foreign policy. The noble ​Lord, Lord Kerr, said very cogently that we are not talking about a zero-sum game. It was racy language for the noble Lord, Lord Kerr, but I totally agree with him. We are not talking about a zero-sum game: well established and good relationships already exist which will not just evaporate. We will seek to bind these and tie them in to our new post-Brexit relationship. We want to establish an enhanced partnership with the EU that reflects the unique position of the UK. This will include close consultation in a variety of fora. Attending the Political and Security Committee and the Foreign Affairs Council, however, is not the only means by which we can achieve that. Amendment 165 was also tabled by the noble Lord, Lord Adonis. This amendment seeks to bind the UK—“bind” is the important word—to follow the EU’s foreign policy objectives regardless of our own views. This would limit the UK’s ability to respond independently to developments in the world post Brexit, and such a restriction would be profoundly undesirable. Of course, on many foreign policy issues the UK and EU will continue to share the same goals and will want to co-operate closely, whether that is by continuing to support the Middle East peace process or by tackling the threat of piracy off the Horn of Africa—but, again, I do not think we need texts and primary legislation to underline what are already our shared values and beliefs. Amendment 185 was also tabled by the noble Lord, Lord Adonis, and refers to the EU Intelligence Analysis Centre. I reiterate the Government’s unconditional commitment to European security. In the exit negotiations we will work closely to ensure that the UK and EU continue to co-operate closely, including through the sharing of information, to safeguard our shared values and to combat common threats, including threats of terrorism, organised criminal groups and hostile state actors. The precise modalities and arrangements to enable this partnership will be decided in the negotiations. I do not expect this to satisfy the noble Lords, Lord Adonis and Lord Wallace of Saltaire, but I hope that it will provide them with sufficient reassurance of the Government’s commitment to continue close co-operation with the EU and its agencies and that, in these circumstances, they will see fit not to press their amendments. I will say in conclusion—I reiterate it because the noble Lord, Lord Hannay, raised the point—that the Government have been clear that the UK remains unconditionally committed to European security. In the exit negotiations we will work to ensure that the UK and EU continue to co-operate closely to safeguard our shared values and to combat common threats, including terrorism. A partnership where we can build on the existing structures and arrangements—because it is not a zero-sum game—to improve processes will enable us to go further to respond to the reality of these. I hope that this will provide your Lordships with sufficient reassurance of the Government’s commitment to continue close co-operation with the EU and its agencies.
2. Lord Kerr of Kinlochard    Share this contribution Before the Minister sits down, perhaps I may say to her that she will have responded to this debate admirably if she can think of ​a way of conveying to the Foreign Secretary—it might be relatively easy since he is here—that there are at least some in this House who believe that the right way of advancing the dossier of co-operation with the EU that we have left on a common foreign and security policy would be for us to put forward a draft treaty now—not waiting for the other side, not waiting for the Commission, the expertise of which is not on foreign policy, but putting forward a treaty drafted by the Foreign Secretary, with all his detailed, forensic skills.
3. Lord Wallace of Saltaire    Share this contribution My Lords, of course I shall withdraw the amendment, but I shall make a couple of comments. It is clear that we will have to return to this at the next stage if the Government do not provide any more detail. First, on the role of the Lords in considering Bills such as this, the noble Baroness said—as the noble Lord, Lord Callanan, said on a couple of occasions—that this is a largely mechanical Bill. Well, it is a mechanical Bill that gives very wide discretion to the Government to design our future relationship with our most important security, political and economic partners. So a House that concerns itself not with whether the principle of the Bill is correct but with the detail is entirely in accord with its role to ask for detail on what that discretion will be used for. It would be easier to accept that this is a mechanical Bill and not to raise these difficult questions one after another if we had some confidence that the Government actually know what they want in these areas. Part of our problem is that many of us have no such confidence. I do not think that the Foreign Secretary has a clue about what he wants by way of a future relationship with Europe: I doubt whether he has really thought about it for more than three or four minutes. He is too busy thinking about the next anecdote he is going to tell or the next joke he is going to make. His speech last week was a disgrace for a Foreign Secretary: the Prime Minister’s was of an entirely different quality. For a Conservative Party that has always prided itself on its commitment to a strong foreign policy, it must be a real embarrassment that we still have someone in place who is incapable of giving a serious speech on foreign policy. So this House is fulfilling its proper role in asking for detail on the implications of the Bill. Secondly, I take up what the noble and gallant Lord, Lord Stirrup, said: the engine room is important.
4. The Minister of State, Ministry of Defence (Earl Howe) (Con)    Share this contribution My Lords, I think it is against the rules and the spirit of this Chamber to criticise a Member of another place by name. I hope that the noble Lord will see fit to moderate his comments accordingly.
5. Lord Wallace of Saltaire    Share this contribution I apologise for being perhaps a little stronger than I should have been in this respect. On the engine room—I wanted to return to the noble Earl, Lord Howe, on this—much of the business of multilateral organisations, be it NATO or the EU, is done in working groups and committees. The common foreign and security policy structure has some 40 working groups and committees, including a military committee that has ​been chaired by a British officer. If we are not in any of those working groups, we will miss out on formulating policy. There are other details that matter a great deal. I remember the noble Earl, Lord Howe, saying on one occasion, when some of us were following the noble Lord, Lord West, and asking, “Where are you going to find the frigates to make up the carrier groups that we need?” The noble Earl said, if I remember correctly, “They do not necessarily have to be British frigates”. I took him as meaning that they might be Dutch, French, Belgian or whatever. Well, that also needs a certain structure, with certain training mechanisms and certain multilateral commands.
6. Lord Hamilton of Epsom (Con)    Share this contribution Would the structure not be NATO?
7. Lord Wallace of Saltaire    Share this contribution The noble Lord may not know, but, as I have quoted, we have been involved in some 15 EU operations, some of which have been naval. Had he visited Operation Atalanta at Northwood, he would have known that that is an entirely naval operation, commanded by the British with ships from a number of different nations. Operation Sophia in the Mediterranean has also involved British frigates working with others on the whole question of migration. So some operations are NATO, some are the EU. I have said quite enough. Of course I am going to withdraw, but we, along with many others, do not know enough about this area to be able to give the confidence to the Government that we want—that is the whole problem with this “mechanical Bill”. I beg leave to withdraw the amendment.

Amendment 12 withdrawn.

8.00 pm

Amendment 13

Moved by

* Baroness Ludford    Share this contribution

**13:**Clause 1, page 1, line 3, at end insert—

“( ) Regulations bringing into force subsection (1) may not be made until the Secretary of State has laid before both Houses of Parliament procedures agreed with the EU for continued UK participation in measures to promote internal security, police cooperation and counter-terrorism and these procedures have been approved by a resolution of each House of Parliament.”

* Baroness Ludford (LD)    Share this contribution My Lords, the Prime Minister’s speech in Munich 10 days ago, which was cited in the previous debate, was encouraging as far as it went. The Prime Minister spoke of wanting to participate in Europol, the Schengen Information System, the European arrest warrant and the European investigation order, which is a sort of European arrest warrant for evidence. But aspiration is not enough. Cross-border co-operation on law enforcement is premised on an assumption that all member states share similar standards of fundamental rights protection. Mutual recognition is rooted in mutual trust. I am afraid that successive British Governments have not really understood this sufficiently and have been more or less reluctant to sign up to the protective measures alongside the measures on police powers.​ It is really strange that the UK has had such an ambivalent relationship with EU justice and home affairs over the past 20 years because it is possible to say, without being arrogant, that our record on the rule of law and the quality of our lawyers, judges and police stand comparison with any other in Europe and should have put us at the centre of EU developments in civil as well as criminal justice. But successive Governments have insisted on opt-outs and optional rather than full-hearted participation. That has not stopped the merits and value of our weight and experience and our personnel in justice and home affairs being recognised. We have the director of Europol—I think he has been there for the best part of 10 years—Rob Wainwright, who is on the brink of retiring. Of course, the European Commissioner for Security, Sir Julian King, is British. Two former presidents of Eurojust are British. That is the body of prosecutors which ensures that cross-border investigations and prosecutions are carried out smoothly. Indeed, the noble and learned Lord, Lord Thomas of Cwmgiedd, was president of the European Network of Councils for the Judiciary—the network of judges—which supports and encourages an independent and qualified judiciary. You cannot do cross-border co-operation unilaterally. It has to be a reciprocal arrangement based on legal agreements which are enforceable in respecting individual rights as well as the rights of national authorities. There are two foundations of mutual trust within the EU: first, the possibility of recourse to the European Court of Justice to ensure a level playing field in the application of EU law; and, secondly, the rights and principles in the European Charter of Fundamental Rights, the right to protection of personal data being of particular relevance in this context. On the resolution of legal disagreements, in her Munich speech the Prime Minister proposed two principles: first, respect for the sovereignty of the UK’s legal order; and, secondly, respect for the remit of the European Court of Justice, at least when participating in EU agencies. I think there is a lot of head-scratching about how those two principles are going to be reconciled. I am hopeful that the Minister will be able to explain to me precisely how that is going to work. Can he also flesh out what a security treaty would look like in incorporating what the Prime Minister called a mechanism for, “independent dispute resolution … in which both sides can have the necessary confidence”? How will the full exchange of data be secured under the auspices of such a treaty? About three years ago Denmark voted to leave Europol. Since then, it has negotiated very limited access to data in Europol—and it is a full member of the EU, the Schengen area, the European Court of Justice and the Charter of Fundamental Rights. What makes the Government think we will get better access to Europol than Denmark? We might well get observer status but we will have no vote on the work programme or the direction of Europol’s work. We will discuss the Charter of Fundamental Rights fully later but it is highly relevant to the exchange of data so I must mention it now. The relevance of the Charter of Fundamental Rights is why the trade body of the British tech industry, techUK, has urged the ​retention of the charter in domestic law. It is interested mainly in the commercial exchange of data for the digital economy but the same applies to the exchange of personal data for the purposes of law enforcement. The tech sector is very well aware of the long-running problems over transatlantic data transfers after the Snowden revelations in 2013, leading to years of political wrangling and litigation, including the ECJ blocking the so-called safe harbour agreement before the privacy shield was agreed—and there had to be changes in US data protection law to achieve that. Whether or not the UK seeks a formal adequacy decision in the context of our future trade and security relationship, we can be sure that there will be a wide and deep assessment of data protection in this country, not least by the European Parliament, and the possible invalidation by the ECJ of any agreement which fails fully to adhere to EU standards. It seems ill judged for the Government to prejudice that trade and security relationship with the EU by jettisoning the charter. The fact that they insisted on weakening the privacy protection for immigration data in the Data Protection Bill may also turn out to be unwise. The Prime Minister wanted continued participation in the European arrest warrant and the European investigation order. The extradition agreement with Norway and Iceland took 13 years to negotiate, is still not in force three years after agreement, and does not include surrender of own nationals. How do the Government propose to do better than Norway and Iceland? The 1957 Council of Europe convention would be a step backwards in extradition practice and in any case would require not only the UK but individual European countries to change their legislation. What prospect is there of them doing that? On the European arrest warrant, the Government will of course be aware that the Irish courts have refused the extradition of a person to the UK and have referred the case to the Luxembourg court because they are afraid that if they return someone to the UK and they are in detention beyond March next year, they will not get the protection of the European Charter of Fundamental Rights. So it is already affecting extradition co-operation. The European investigation order—the other measure the Prime Minister mentioned—has been implemented in UK law, as I have had cause to raise with the Government, by substituting reference to the charter with a reference to the European Convention on Human Rights, which of course is not an EU measure. That seems a rather petty thing to do and, again, does not seem very sensible if it is a flagship measure mentioned by the Prime Minister but it has not been properly implemented in UK law. To conclude, can the Government tell us, given their limited acceptance of ECJ jurisdiction and their rejection of the charter, exactly what terms—and under what structures, as was just mentioned—they expect to get in a security treaty, and will they submit a draft for our enlightenment before too long? I beg to move.

1. Lord Cormack (Con)    Share this contribution My Lords, I added my name to the noble Baroness’s amendment for two reasons. The second was that I was encouraged by what the ​Prime Minister said in Munich and I very much hope that we are going to have the closest possible co-operation for all our security. But the first reason that I put my name on the amendment was that I had the honour, until the unfortunate general election of last year, of serving on the EU Home Affairs Sub-Committee of this House. After the general election I was summarily dismissed because I had not voted with the Government during our debates on the triggering Bill last spring. But there we are: it did not shut me up and certainly will not shut me up tonight because we took evidence from Rob Wainwright, the head of Interpol. On that committee, I used to sit next to Lord Condon. I am very sorry that he has retired from your Lordships’ House because he made an extremely important contribution, based on vast knowledge. I was impressed by his pride in what Rob Wainwright had achieved as a Brit leading that extremely important organisation. I was impressed, too, by the searching questions that Lord Condon asked of not only Rob Wainwright but a number of other expert witnesses who came before us. The conclusion that one had to come to after those various evidence sessions was that the measure of success of our negotiations would be determined by how close we had come to replicating what already existed. There is no point in rehearsing all my misgivings about where we are, because we are where we are. But I hope that my noble friend on the Front Bench can reassure the Committee that the Prime Minister, following her Munich speech, really is committed to coming to close arrangements with our European friends and neighbours to ensure that the measure of security which we enjoy—and which the people of this country enjoy—will not be damaged by an imperfect relationship with Interpol. I would like to see a proper membership of Interpol and, frankly, I am not persuaded that it could not happen. I hope it will because what matters more than anything else to the people of our country, almost a year away from the terrorist outrage which hit us here in Westminster last March, is that they feel secure. That feeling of security is encouraged if they know that there is the closest possible co-operation and exchange of information with our European friends and neighbours. One other thing that came out during our evidence sessions was the very real importance of the European arrest warrant. I hope that in building upon what the Prime Minister said in Munich, we can ensure that there is again a similar arrangement after we leave the European Union. Those were the reasons why put I my name to the amendment and I am glad to support it. I do not want to sound offensive in any way because I have a high regard for my noble friend, who has a very difficult job to do, but I hope we will have a reply to this debate of real substance, in view of what the Prime Minister said in Munich a couple of weeks ago.
2. Lord Hannay of Chiswick    Share this contribution My Lords, perhaps I might carry on after the noble Lord, Lord Cormack, because I too served on your Lordships’ Home Affairs Sub-Committee. I chaired it some years ago, when we were going through what could be described as a dry run for our debate tonight. That dry run was on protocol 36, the opting out and then opting back in; ​the current Prime Minister played a notably positive role in that, particularly so far as the European arrest warrant was concerned. The first point, which cannot be made too often and which I hope the Minister will recognise, is that in this area of EU policy there is no safety net. It is not like trade where the WTO rules are, I would argue, inadequate but nevertheless are there as a safety net if all else fails. There is no safety net for justice and home affairs. If we do not make watertight arrangements by 29 March next year, we will be walking on thin air. On this, I would like to ask a specific question: are the Government confident that the arrangements for a standstill transition or implementation—whatever they like to call the period that immediately follows 29 March 2019—will be applicable to these justice and home affairs matters when we are a third country? It would be good to have that answered.

8.15 pm

Secondly, while I welcome very much what the Prime Minister said in Munich, which was remarkably positive on this matter, can the Minister just confirm that we are all talking about the same things: the European arrest warrant; the European Criminal Records Information System; the Schengen Information System; the passenger name recognition directive; the Prüm convention; Europol, Eurojust and the European investigation order? I apologise if I have left anything out but the list is rather long anyway. Is that what the Prime Minister was talking about when she said that she wanted effectively to remain in replicas of these matters? The question then is: how on earth is that to be done and structured?

The Prime Minister also said some slightly delphic but nevertheless helpful things about the jurisdiction of the European Court of Justice in this field, which I welcome because that could be a major obstacle if it is treated as a no-go area. But it is particularly important in this field because the European arrest warrant is not about the dealings between one Government—that of the United Kingdom—and the European Union of 27. It is about the rights of individuals to due process and is therefore a crucial issue.

Lastly, there is an Irish dimension to this debate and we really must not forget it. The introduction of justice and home affairs legislation was one of the things which enabled issues such as extradition and other matters on the island of Ireland to be depoliticised. For many years, as everyone in this House knows, those matters were highly politicised and it was almost unthinkable that we could have extradited somebody from Ireland to face justice in Northern Ireland for crimes committed there. That has changed but this puts all that at risk, so there is a really serious Irish dimension here. It is quite different from the trade matters we have discussed—although those are crucial, too—because if we found ourselves walking on thin air, then I am afraid the re-politicisation of those issues on the island of Ireland would follow quite quickly. We should just remember that when the Irish ratified the European arrest warrant, they removed their link with the extradition provisions of the Council of Europe, so there is nothing there.

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I hope the Minister will be able to say something at the end of this debate about these points. Above all, the call is for greater specificity regarding the Government’s plans. The Prime Minister seemed to set out down the right road towards that in Munich, but they remain shrouded in a good deal of mystery.

* Baroness Kennedy of The Shaws (Lab)    Share this contribution My Lords, there cannot be anyone in this House who does not agree that the security of this country is vital and that collaboration in fighting crime is really important. We have to remember that international cross-border crime is one of the real challenges that we face. It has been made easier because of developments in recent times, such as the electronic transfer of money, the ease of travel and the whole business of communicating by cell phones, email and the like. Just as that makes it possible for us to trade, it makes it much more possible for illicit trades to take place, too, so international cross-border crime is something that we really have to contend with in a way that was not the case 50 years ago. Countering cross-border serious crime, whether it is terrorism, the transportation of drugs, the importation of firearms or all manner of illicit products or trading in human beings, involves incredibly important collaboration and co-operation, so like other noble Lords I welcome the fact that the right noises are being made about future co-operation in policing and security matters, particularly because of the real complexity of this stuff. I was with a group of recently retired senior counterterrorism police officers and someone who was about to retire last Thursday talked about the invaluable nature of these collaborations and the ways in which the European arrest warrant, Eurojust and the things on the list that was read out by the noble Lord, Lord Hannay, are so vital in countering this really serious level of crime. If you can penetrate the dark web, it shows just how active this criminality is. I strongly support Amendment 13, tabled by the noble Baroness, Lady Ludford, and other noble Lords, but it raises an issue. The issue is that, if we are going to use something like the European arrest warrant, it involves something different from the need for arbitration or for some supranational tribunal to deal with trading disputes, as the noble Lord, Lord Hannay, said. This is of a different order. When we are dealing with something like the European arrest warrant, we are talking about the liberty of the subject. We are talking about people being arrested, kept in custody and transported from one place to another. The rights of the individual there are so significant that we have to have a court with highly trained judges at the apex of any legal system because people resist the possibility of being transferred for criminal trials to proceed. I want to reiterate what the noble Lord, Lord Hannay, said about the old days. It would be a frequent occurrence that attempts would be made to extradite people and it took years. People were able to resist extradition for years. I see the noble Lord, Lord Thomas of Gresford, in his place. Once, many years ago, he led me in a case that involved lengthy extraditions and had gone on for years. The arrival of the arrest warrant put paid to that. The difference it has made has been considerable. The UK has extradited 1,000 people to other parts of Europe to be prosecuted for serious ​crimes and has received some 200 individuals from other places for serious crimes. I urge the Committee to think through the consequences of that. We need to have a court at the apex of this, and the court that is sought by the rest of Europe is the European Court of Justice, which already exists and knows and understands the nature of these processes. What do we do? Do we create some new court which has all the same powers and just give it a different name in order to appease those who do not like the European Court of Justice, or do we recognise that for this area there has to be the jurisdiction of the European Court of Justice? A number of amendments in this group are tabled in my name, and I want to refer the Committee to them. Amendment 99 relates to the protection of “protected persons”. This may be something that noble Lords are not really aware of, but we adopted the European protection order directive in 2014. This relates to difficulties which are faced mainly, but not exclusively, by women who are stalked or victimised, often by former partners, and who go to live in other parts of Europe. Across Europe we have developed victim protection orders which involve mutual recognition so that, if someone stalks someone to somewhere else but we have created a protection order in the UK, it can be immediately made effective in another country where someone has pursued the person who is the obsession at the end of their malign intent. Such victims orders are used not just in relation to domestic violence and the stalking that happens in relationships but in relation to other forms of stalking, for example, in witness protection issues or in trafficking. It is an area in which I have particular experience, and these orders are going to be vital in providing protection for people in different jurisdictions. I really hope that, in seeking to create the right kind of regime for us to operate across Europe in relation to these criminal matters, we also protect the victim protection order regime—the European protection order regulations—as well. The other matter on which I have put forward an amendment, in which I am supported by the noble Lord, Lord Paddick, and my noble friend Lord Judd, relates to justice and home affairs measures. I know it is the Government’s objective that some of these processes continue after departure. We are most concerned that there is a serious understanding of what mutual recognition means. There is some concern being expressed in other parts of Europe that we do not use the terms mutual recognition and harmonisation in quite the way that is intended when it comes to this collaboration on criminal and civil matters. I have spoken about this before in the House. It is about the fact that it is not enough to introduce European law into the UK, as some of these regulations require reciprocity of a very deep kind. It means that we will respect orders made in other countries and that they will respect orders that we have made here. Think of the difference that it makes to a woman whose family are in Germany and who takes her children there to visit them, but who after a divorce is being harassed and stalked by her previous husband. She can get an order in her local court and know that when she goes to visit her family in Germany, the ​order will operate there too if she is pursued by her former—abusive and violent—partner. We know that this also happens in relation to matters such as access to children, where people can get maintenance orders in the local court: you can go down to the court in Bromley, get your order and it will be made effective in another country in Europe. It is so important that people do not have to instruct lawyers in other places, when they could ill afford to do so and thereby secure justice in the circumstances they find themselves in. The mutuality there is of a very deep kind. Just introducing European law into our system and legislating for it will not be enough. What we really require is something that creates a regime that continues what has been established with great care over very many years.

1. Baroness Massey of Darwen (Lab)    Share this contribution My Lords, Amendment 209, which is in my name, follows directly from the remarks of my noble friend Lady Kennedy, so I thank my noble friend Lord Adonis for allowing me to slightly skip the order. The amendment echoes the concerns of others, notably the noble Lord, Lord Hannay, and my noble friend Lady Kennedy about the UK’s access to and participation in Eurojust, Europol, ECRIS and the European arrest warrant. This also includes the database of the Schengen Information System II and the European protection order—I think we must have covered them all between us. I want to look at this from the perspective of child protection. This amendment has implications for a huge area that includes child trafficking, child abduction, forced migration, sexual exploitation, criminal proceedings, online abuse and missing children—a long list of concerns, also mentioned by my noble friend and the noble Lord.

8.30 pm

In the many excellent House of Lords committee reports on the impact of Brexit on our systems, we have tended to refer to children’s issues mainly just in passing, if at all. I want to focus on the importance of considering children at the heart of our discussions. I was involved in several of those reports, including the Home Affairs Committee report on crime and police co-operation mentioned by the noble Lord, Lord Cormack, who was much missed after his—what shall I say?—disappearance, removal or whatever. In that report, the committee concluded that the UK has been a leading protagonist in shaping the nature of co-operation with the EU in police and security matters. The fear is that we will lose the platform from which we have been able to influence and help set agendas.

I am aware that the Prime Minister has made reassuring statements, but concerns still remain, and the impact on children could be enormous. We need collaboration and co-operation on matters affecting children. We must speak out for children who cannot, or have not been asked to, speak out for themselves. We have limited detail on these implications. This amendment would require the Government to put a strategy before Parliament to ensure that children, among others, are kept safe and supported when it comes to cross-border crime. This strategy should be subject to parliamentary approval, as set out in Clause 9. ​I salute the many children’s organisations, both in the UK and in Europe, that have formed a coalition to ensure that children are considered in Brexit arrangements. They point out that many crimes affecting children are increasingly complex and have international implications—for example, child trafficking, where there is often a crossover with the transportation of refugees.

Crimes conducted online also cross borders. Child abuse material and pornography are produced and disseminated across borders, and research shows that 60% of such material is hosted in Europe. Being able to tackle such crimes effectively demands that police forces, the National Crime Agency and legal professionals need a structure for cooperation. About 40% of Europol’s work is linked to initiatives that are either provided or requested by the UK. Will joint investigation teams continue to exist post Brexit? In 2016 the UK received the most funding of all EU member states to set up these teams—32 of them in total. Operations include Operation Golf, which tackled child trafficking and was highly successful in identifying and investigating a Romanian organised crime network which had links in the UK and other EU countries. A joint investigation team of the Metropolitan Police, the Romanian national police and Europol used personnel and databases to deal with the problem successfully.

As my noble friend Lady Kennedy said, the European arrest warrant was used nearly 200 times between 2010 and 2016 to extradite suspected child offenders. Before the introduction of the arrest warrant, it took an average of 12 months to transfer offenders across the EU. It now takes less than two months. What assessments have been made of the UK’s need to remain part of these cross-border agencies for the purposes of safeguarding children? What assessment has been made of the impact which the loss of co-operation with such agencies would have on safeguarding children? We cannot leave children across Europe vulnerable to crime and exploitation, which can destroy young lives and divide families.

* Lord Deben (Con)    Share this contribution My Lords, one of the themes that has come through in the debates on many of the amendments so far is that the Government are enthusiastic about where we are, keen on continuing the links and determined that we shall not in any way fall out from those, but unwilling to commit themselves to the obvious solutions. We have heard in this debate tonight an exact repetition of what we have had before. In other words, some of us are saying that these things were achieved with great difficulty. The European arrest warrant caused enormous argument and could be a really dangerous thing if it were not properly protected by the European Court of Justice. Like everyone else, when I became a Member of your Lordships’ House I was asked what subjects I was particularly going to speak on. The first was the environment, the second was Europe and the third was human rights. Therefore, when the legislation that we are now part of was going through in its various forms, I was very concerned that it was properly protected. However, I was very aware, as is the House, that crime does not know any borders, particularly the type of crime that the noble Baroness, Lady Massey, was talking about.​ We need the protection that the warrant gives. When we were kids and we read stories of derring-do, we all knew that the first thing that people would try to do was to get across the channel because then they would be out of the reach of British law, and indeed of the law in many ways. I believe strongly that first of all we have to recognise that what we have we did not get easily and did not arrive simply. To suggest that somehow or other we can produce a different system and call it something else, because that would be convenient to the people who are ill informed enough to want to leave the EU, seems extremely dangerous. We should recognise that this took a lot of doing. The second point, which has been made very interestingly, is about the nature of mutual recognition. Very often we are divided by not understanding the words that we use. There is an attitude in Britain that suggests that we get it right and other people do not, and therefore they had better do it our way because we know best. That has been our besetting sin throughout the period of our membership of the EU and, if we leave, we will get even worse at it. In other words, we are very keen at teaching other people but not frightfully good at learning from them. One of the things that we have learned—I think by accident; certainly not by design—in having to co-operate on these issues is that we have understood much more clearly the problems, difficulties and solutions that others have had in our European home. We have to recognise that understanding mutual recognition is not easy, and the idea that we can suddenly create a different mechanism for doing it is very far-fetched. On my third point, I have great admiration for the Prime Minister. I do not understand how every morning she wakes up and thinks, “God, I’ve got another day of this”, and deals with some of the people that she has to deal with—I will not list them but we all know which ones I mean. However, it is not good enough to have good intentions and show generalised support. My noble friend who is answering for the Government has given us a great deal of good intentions and noble views but no actual support for real policies and actual determinations. This is not something that we can pass off by merely having good intentions because it is very hard and we have to be tough about it. We have to say to our friends, “We actually want, and will have, exactly what we have today on these matters because there is no alternative that is better and there is no way that we are going to invent one”, because crime will not wait. This is a rather important amendment. All it says is that the Government have to move from intentions to reality before they can move. That is not an unreasonable thing for the House which is responsible for our constitution to ask. I hope that my noble friend is not going to say how important all these things are, how valuable they are, how much the Prime Minister is in favour of them, but that just at the moment, because it is all part of the negotiation, he cannot go further than that. If he does, perhaps for all our debates he might just turn on the recording. That is evidently the answer we are going to have on everything, because that is the answer we have had so far today on everything. If it goes on like this, this House will have to ask whether the Government ​intend to have a debate or discussion about things that matter, about the future of our nation and our people. Are they going to have a discussion about the things that protect our people, the policing which has to cover areas beyond our borders? Above all, are they going to have a discussion about how this affects Ireland? We have for too long taken for granted the fact that the Irish situation is, at least to a large extent—much less so than the newspapers would have us believe, but still to a large extent—peaceful. We must none of us forget that. I have to tell my noble friend that it will become increasingly difficult for the Government to uphold their position unless they are prepared to take seriously this House’s demand that they tell us what they want. How can you negotiate with people unless you can say very clearly what you want on crucial issues, and what could be a more crucial issue than this?

1. Lord Judd    Share this contribution My Lords, at the end of all these proceedings, some months down the road, there will be a vote in Parliament. At that time, it will be essential that we know exactly what we are voting for. That is why the speech by the noble Lord, Lord Deben, is so important. There is a fundamental difference between good intentions and concrete policy, there to be implemented. As in our previous debate, the issues are too big; there is no room for an interregnum or period of doubt. We must be able to move from what we have to what is necessary overnight. We must have firm policies and firm decisions that follow from them. I served on the Home Affairs Committee under the chairmanship of the noble Lord, Lord Hannay, when we were having that dry run, and very interesting it was, too. What I found very telling was that virtually every witness working in the field, when the question, “Will your work become more difficult if we leave the European Union than it is at the moment?” was put directly, said unequivocally yes, they needed the European Union to meet the challenge of the job. Forgive me if I repeat myself, but it is terribly important. Crime is international; it does not recognise frontiers. That is true of trafficking and, as my noble friend said, of drugs. It is true of terrorism. These things do not know national frontiers. Therefore, you must co-operate and work closely with others who face the same difficulties. The other point I want to make is that, more recently, serving on the Justice Sub-Committee under the chairmanship of my noble friend Lady Kennedy, it has become very clear that we have underestimated—it is rather tragic that the British people have not understood, or begun to understand—how much British lawyers and British legal expertise have been contributing to the strength of European law, which is in all our interests. British lawyers have made a terrific contribution and they are very much respected. In taking evidence from practitioners in this sphere—the chairman is here to strike me down if I am misquoting—they told us over and over how the law is improving under the present system. The overriding authority of the European Court is crucial, however, because it provides a context in which everyone can have confidence in the necessary reciprocity. These amendments are very important, and I hope the Government will take them seriously.​

8.45 pm

* Lord Inglewood (Con)    Share this contribution My Lords, it is two or three years ago now, but I had the privilege of chairing a House of Lords ad hoc Select Committee on extradition law. Of course, extradition law, as far as the European Union is concerned, is the question of the European arrest warrant. I can say with confidence that the conclusions we reached, on the basis of the evidence before us, is that the system seemed essentially to satisfy all the parties concerned. It was working well, not only from this country’s point of view but from the point of view of other countries in the European Union. Of course, the reality is that a deep and special relationship will not inhibit criminals coming to this country. In a world where there is ever greater mobility, we will have our fair share of criminals from elsewhere and no doubt other countries will have their fair share of our criminals. We have to deal with that problem. The other thing that was pretty apparent from our work was that most of the criticism of the system was hung up on the European Court of Justice. It was a criticism not of what the European Court of Justice on the whole decided was appropriate, but of it not being exclusively comprised of British citizens. We need to be absolutely clear about that. We are talking about a system, the generality of which worked extremely well and in everybody’s interests. Therefore, I ask my noble friend the Minister whether he can give the Committee an assurance that, whatever arrangement may come into being after Brexit, they will work as well as the existing arrangements. We have heard a number of speeches this evening that have been a trifle philosophical in tone, and I do not want to criticise anybody for that. I want to make a purely pragmatic point: if the system is not as effective as the one we have now, there will be more criminals on the streets of this country. Do the Government wish to bring that about? Equally, more of our criminals will no doubt be enjoying their ill-gotten gains in relative security on the Costa del Sol. Is that what the Government want to bring about? We have heard about Ireland and I need say no more about that. It is terribly important to be clear about the pragmatic, nuts-and-bolts, on-the-ground implication of scrapping this procedure because there is every risk and likelihood, if we are not careful, that we will degrade the system of justice in this country.

1. Lord Thomas of Gresford (LD)    Share this contribution My Lords, I follow the noble Lord, Lord Inglewood, in a plea that we do not go back to the system before the European arrest warrant was introduced. The noble Baroness, Lady Kennedy, referred to the case that we did together some years ago when the extradition proceedings, which lasted some four and a half years, were ended by the 12th application for habeas corpus being turned down by the noble and learned Lord, Lord Woolf, which he may remember. What he may not remember is that my client went back to the country demanding his extradition, where the prosecution accepted a plea of guilty to one out of 32 charges, and was given a sentence that resulted in his immediate release. That was the old system; the system we have had since the introduction of the European arrest warrant, with all the agencies that have come into being, started I think ​by Mr James Callaghan when he was Prime Minister, developing under the European Union banner, has been extremely good and effective. In the Queen’s Speech debate on 27 June last year, it will not surprise your Lordships to know that I asked the Government what they were going to do about this whole area—about all the agencies to which the noble Lord, Lord Hannay, referred. What was going to happen? After that, there was complete silence. I wondered what was happening. These discussions and negotiations are as urgent as any to do with trade. They deal with the security of this country and the possibility that, if nothing is put in place, this country will become a haven for criminals, as opposed to somewhere the law is properly administered. But nothing happened—and so it was with considerable interest that I read the speech of the Prime Minister in Munich a week last Saturday. What was she going to say? She proposed a treaty. Who is negotiating that treaty? Who is in charge? Is it Mr Johnson? That is a bit unlikely. Is it Mr Fox or Mr Davis? Who are they negotiating with? The noble Baroness, Lady Goldie, in her reply to the last debate, said that she knew that there was a dialogue going on. What dialogue? I have not heard of any dialogue, and I am interested in this subject. Where are we? The noble Lord, Lord Hannay, also asked the very pertinent question of what happens after March next year. Do the extradition warrant system and all the other bodies concerned with co-operation in criminal matters continue, or not? If they do not continue, the treaty to which the Prime Minister referred must be in place. As the noble Lord, Lord Judd, said a moment ago, we cannot have an interregnum—a period when nothing is happening. Something has to be put in its place, and nothing I have seen or read suggests that there is a dialogue or treaty in any form, draft or anything else ready to come into operation when we leave the European Union. So specific questions on this issue can be asked of the Minister. What negotiations are happening? Who is doing them? When will there be a result? What is in the treaty? How are you going to put all these things together in a period of months to ensure the continuation of co-operation in this extremely important field? If there are no answers to those questions and the Minister just chuckles his way through, as he occasionally does—if he will forgive me—the security of this country is at risk, and we risk becoming that haven for criminals that would be a blight on our whole country.
2. The Earl of Listowel    Share this contribution My Lords, my name has been added to the amendment in the name of the noble Baroness, Lady Massey of Darwen, and I support every word that she said. Of course, she was chair of the All-Party Parliamentary Group for Children for many years, and had to give up that job because of her new responsibilities in Europe for the welfare of children. So I am sure the Minister will want to pay very close attention to what she has said. I have a specific question for the Minister. Many foster carers in this country are from continental Europe. We do not know exactly how many, but the European Criminal Records Information System is very useful in ensuring that those interested in preying on children do not move from one country in Europe to another ​or from continental Europe to this country. The Minister will be aware of recent concerns that people interested in preying on young people in the developing world have been joining charities, for instance. Will he provide the Committee with as much information and detail as possible, given the concerns raised around the Committee this evening on these issues? I was pleased to hear of the Prime Minister’s speech in Munich. I also recall that two or three years ago, as Home Secretary, she brought in the human trafficking Act, which was an important step forward. I look forward to the Minister’s response.
3. Lord Hogan-Howe (CB)    Share this contribution My Lords, until a short time ago I was Commissioner of the Metropolitan Police, having served for nearly 40 years making arrests and prosecuting people, which I quite enjoyed. I will say a few words about the importance for police officers, in particular in the investigation process, of some of the things that Europe provides and which need to be accommodated in the new arrangements. I worked in South Yorkshire, Merseyside and London and also served as one of Her Majesty’s inspectors looking at serious and organised crime. The Met led the extradition process for the United Kingdom—and still does—and also counterterrorist units, both in this country and with an international dimension, with 50 officers based in embassies around the world. Many things remained constant in the 40 years that I was an officer, but some things have changed. One of the big changes is the mobility of people across our borders. In London particularly, a high number of foreign national offenders were arrested. The Met still arrests around 225,000 times a year. That is not 225,000 people, because many are arrested more than once. That is probably about 1 million people around the country and one in three of them is a foreign national offender—a very significant proportion of those arrested. Not everybody who is investigated and prosecuted is arrested. Of those in London, 55% are Europeans and 45% are from elsewhere. Both proportions are significant and have to be accommodated. The ratio which I have described for London differs around the country. In some of our more rural areas there is a very high percentage of foreign national offenders. It varies by part of the country and seasonality. Different times of the year lend themselves to different types of migration. The police investigate very serious offences and more minor ones, but all demand the same level of proper investigation. The process that follows arrest or any investigation is usually similar. The first part is to confirm the identity of the suspect and the second to gather the available criminal intelligence about them. The third is to gather their criminal convictions, where they are recorded, and the fourth is to check on any forensic evidence that might be available for them. Together with the evidence, this forms a substantial part of the case. One challenge for any investigating officer is that, where there is an arrest, an investigation is time limited. Some 90% of investigations are concluded within 24 hours of an arrest. This can be extended to 36 hours by a superintendent, but the majority of offences are investigated and concluded in the first 24 hours. It is, therefore, vital to gather the four things I have just ​mentioned fairly quickly. The arrangements we have had with Europe have been substantially better than those we had in the past. When you are investigating an international suspect it is not always easy to gather all that information quickly, but it is often vital that it is gathered before they are released. For example, if someone has been arrested for rape and has on three previous occasions been arrested for rape in another country but not charged, you would want to know that information before you came to a conclusion about whether there had been consent as regards this particular offence. That is just one example of why this is important.

9.00 pm

In terms of the DNA, fingerprints and, increasingly, the facial recognition that is now available through Prüm—it has been available only more recently; for many years it was not available through Prüm—again it is vital that the samples are checked not only against the known database but against samples from scenes where the offender was not identified to find out whether the arrested person is linked to any previous offence. Therefore, the system obviously has to be efficient and effective.

I speak as someone who supports Brexit. I was misquoted during the previous debate, when it was said that I did not support the European arrest warrant. That is not what I said. I believe that the new arrangements the Government will make will have to replicate the best of what Europe offers us now. Noble Lords may not necessarily support that view and they have explained why, but clearly we have to strive to get these things in place. Clearly, the European arrest warrant is vital, as is the exchange of criminal intelligence and conviction data. The extradition warrant needs to replicate the existing provisions and to be simple, consistent and quick. The existing system is not perfect but it has led to some notable achievements in the past. Noble Lords will remember that after 7/7 one of the suspects was found in Italy and quickly returned. That is just one example of how these things can work well.

In conclusion, there are probably two major reasons why I think that we ought to achieve this agreement with Europe. First, examples were given of where there is not a perfect arrangement—Denmark was mentioned. However, Norway is not a member of the European Union but is a member of Europol and seems to enjoy many of the benefits that European Union members obtain. Secondly, although it is true that we do not want to become a Costa del Sol for criminals, neither does any other country want to receive our criminals. There is no great benefit for our country in seeing our rapists walk free in other countries, or in seeing their armed robbers walk free in the UK—so it would be hugely mutually beneficial to achieve speedy transit between all countries, and it ought to be possible to achieve some kind of reciprocity that would at least mimic the benefits of our present system. That is vital for the operational work of police officers in the ways that I hope I have described.

* Baroness Kennedy of The Shaws    Share this contribution How do you make that effective if you do not have the European Court of Justice at the apex?

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* Lord Hogan-Howe    Share this contribution The noble Baroness is in a far better position than I am to talk about the law, so I am not sure that I am able to say that. We have an extradition treaty with America and many other countries where that type of arrangement is not in place, so I would need to understand why the American model and that of other countries works without the arrangement mentioned by the noble Baroness, and why it has to be in place in Europe. There may be a reason, but I am not aware of it.

1. Lord Hamilton of Epsom    Share this contribution My Lords, before my noble friend the Minister winds up this debate, I would like to address the problem of him being constantly accused of not spelling out the Government’s position. We are mid-negotiations. Surely, if you are negotiating with the EU, it is very difficult to reveal your negotiating position. Our experience of dealing with the EU is that when we start to reveal our negotiating position, it immediately laughs at us and tells us that it is absolutely ridiculous for us to think that we are going to get these concessions, and that we are cherry-picking and want to have our cake and eat it and all this sort of thing. It seems to me that the Government are in a very difficult position. They have to hold this debate because we are processing the Bill through Parliament, but simultaneously we are trying to negotiate with the EU. We cannot reveal our position. The overall position is that nothing is agreed until everything is agreed.
2. Lord Lamont of Lerwick    Share this contribution I totally agree with what my noble friend is saying. It is very important that that point is made: it is not made often enough and could be made every time on every amendment. Does he agree that the most absurd question of all, which we have had several times on previous amendments, is for the Government to be asked what their fallback position is? How on earth can someone in a negotiation say what their fallback position is?
3. Lord Hamilton of Epsom    Share this contribution My noble friend is absolutely right. Of course, the EU is watching all this extremely closely because it is desperate to try to snarl up the whole process so that we cannot leave. The fact that a referendum involving a democratic vote was held on this is regarded by most people in the Commission as a sign of weakness. I think it was President Macron who said the other day that if a referendum were held on whether France should pull out of the EU, the leavers would ***win***, but of course he was not going to allow a referendum. I am sure that that will go down in history along with other French expressions such as “Let them eat cake”.
4. Lord Adonis    Share this contribution My Lords, I have six amendments in this group. They refer to the United Kingdom having continued access after withdrawal to passenger name records, to the Schengen Information System, to the European arrest warrant, to membership of Europol, to the European Criminal Records Information System, and to the fingerprint and DNA exchange with the EU under the Prüm Council decisions. The questions put to the Minister by the noble Lord, Lord Thomas, went to the heart of the matter—that is, given that the Prime Minister said in her Munich speech that she wishes to see a treaty replace all these ​elements of the existing arrangements, the Minister should simply tell us the process by which we will be negotiating the treaty. This debate, as with many others, gives the complete lie to the ridiculous assertion that no deal is better than a bad deal. Let us be clear: if there is no deal on 29 March next year, the current arrangements to which the noble Lord, Lord Inglewood, referred, painstakingly negotiated over many years, for the European arrest warrant and the very high levels of engagement between the member states of the European Union—which the noble Lord, Lord Hogan-Howe, said were so important to his work as Commissioner of the Metropolitan Police—all fall. Is the Minister going to tell us that the security of this country will be as safe as it is now if all those arrangements fall? I assume that he is not, in which case the United Kingdom leaving the European Union with no deal at the end of March next year would be a complete abdication of the national interest. We need to get that firmly established. As we have more of these debates and see the precise benefits of the EU—which, after all, are the reason we went into the European Union—it becomes clearer and clearer that leaving with no deal would be a dereliction of the national interest.
5. Lord Deben    Share this contribution Before the noble Lord leaves that point, does he also agree that asking the Government to explain how this treaty is being discussed and by whom cannot have any effect whatever on the negotiations between the Government and the European Union? Is it not true that several of the questions asked have had nothing to do with the negotiations? We would just like to know where the Government are on matters which are unconnected with those negotiations.
6. Lord Adonis    Share this contribution I entirely agree, and I hope that the noble Lord will say that to the noble Lord, Lord Lamont, who is sitting right next to him. It provides a devastating response to the noble Lord’s intervention just a moment ago. We are asking the Government simply to declare the policy of Her Majesty’s Government in the negotiations that are taking place. Since one assumes that our European partners are being told what we are seeking to negotiate—it is quite hard to negotiate something if you do not tell the other side what you are seeking to negotiate—I cannot see that there is any damage to the public interest in telling this House and the public. These are very straightforward questions. The noble Lord, Lord Hamilton, says that we should not declare our hand midway. Are we or are we not in favour of keeping the European arrest warrant after 29 March next year? If we are, that is a clear negotiating objective of the Government. It will require a straightforward continuation of the current arrangements, and people like me will say all the way through that it is yet another argument as to why we would be much better off staying in the European Union in the first place and not having to go through this hugely complex and difficult process of attempting to replicate arrangements so that we do not end up with a worse situation, when there is every likelihood that we will. The devastating response to and commentary on all these matters come from the Prime Minister herself—both in her Munich speech, in which she made it very clear ​that she would regard it as damaging to the national interest not to have a treaty at the end of March, and in her speech on 25 April 2016 before the referendum, in which she was even clearer on these matters. In that latter speech, in which she sought to argue why we should stay in the European Union, she went through in great detail the benefits that the European arrest warrant, the Prüm arrangements and so on gave to the security of the United Kingdom. Those are all points that the noble Lord, Lord Inglewood, has raised. The noble Lord, Lord Hogan-Howe, seems to want to will the ends without the means. I understand that he has not had to negotiate these issues himself, but just says, on a wing and a prayer, that he wants these objectives to be secured and is sure that our negotiators in Brussels will be able to do it. If the noble Lord had had any systematic engagement with the Ministers responsible, I do not think he would necessarily have so high a degree of confidence in their capacity to negotiate his objectives. The Prime Minister herself gave the devastating response to the question of why we should stay in the European Union in respect of these security and justice issues. In her speech of 25 April 2016, when referring to the European arrest warrant and the passenger name record directive, she said that these show, “2 advantages of remaining inside the EU … without the kind of institutional framework offered by the European Union, a complex agreement like this could not have been struck across the whole continent, because bilateral deals between every single member state would have been impossible to reach”. Let us be frank: that is why we are in the European Union, why it serves our national interest and why we have a very high degree of co-operation when it comes to justice and home affairs. We are talking about very large numbers. The Prime Minister herself gave the figures, saying that in the five years prior to her speech—2011 to 2016—5,000 people had been extradited from Britain to Europe under the European arrest warrant, and 675 suspected or convicted wanted individuals were brought to Britain to face justice. She said: “It has been used to get terror suspects out of the country and bring terrorists back here to face justice”. Just as the noble Lord, Lord Thomas, gave his extraordinary statistics about how long it used to take to get extradition proceedings under way, the Prime Minister said: “In 2005, Hussain Osman—who tried to blow up the London Underground on 21/7—was extradited from Italy using the Arrest Warrant in just 56 days. Before the Arrest Warrant existed, it took 10 long years to extradite Rachid Ramda, another terrorist, from Britain to France”. These issues are of the utmost gravity and we need an assurance from the Minister that, in the negotiations for the treaty that the Prime Minister referred to in Munich, we will seek to maintain arrangements that are in every respect as good as those we currently have. If we do not have those in the treaty she presents to Parliament at the end of the year, many of us will say that this whole Brexit process has seriously damaged the security of the United Kingdom.
7. Lord Liddle (Lab)    Share this contribution Does my noble friend accept that the reason the Government will not disclose their negotiating objectives is not that this would somehow ​prejudice their position but rather that they do not know what those objectives are? The truth is that this is an issue of real sensitivity to the Brexiteers. The question is whether these arrangements are intergovernmental or involve the institutions of the European Union and the supervision of the European Court of Justice. I know all about this because, as an adviser to the then Prime Minister, I went through many iterations of this issue. When justice and home affairs first became a subject of the European Union, and a pillar of the Maastricht treaty, it was all at an intergovernmental level. Gradually, it became more communitised, as it were, for the simple reason that that was the way to make it work. We could not make it work as an intergovernmental mechanism. We could not get the degree of co-operation needed to make something like the European arrest warrant work without having some judicial supervision mechanism, so the Labour Government agreed to it—somewhat reluctantly because some of the people involved were not the greatest supporters of civil rights in many respects, but they agreed to it. What is happening in Brussels at the moment is that the member states are discussing among themselves what framework they are going to set for the negotiations for the rest of the year. That will be coming out at the end of March.

9.15 pm

* Baroness Goldie    Share this contribution Is the noble Lord, Lord Liddle, making an intervention? I want to be clear what the order of speaking is.

1. Lord Liddle    Share this contribution I was responding to my noble friend’s point.
2. Baroness Goldie    Share this contribution I think your noble friend thought that he had been usurped.
3. Lord Adonis    Share this contribution My noble friend’s intervention is excellent and gives the Minister more to respond to. I know he is short of points to deal with at the end of this debate.
4. Lord Liddle    Share this contribution This is Committee stage. We are allowed to go back and forth. What are the Government saying to other member states at the moment about the nature of the agreement on this that they are prepared to contemplate? Are they saying to our current partners that they are prepared to see judicial supervision in these arrangements or not? I hope the Minister will answer that very simple point.
5. Lord Paddick (LD)    Share this contribution My Lords, I apologise for not speaking at Second Reading; I took the view that I was unlikely to add anything new, bearing in mind the number of speakers. However, I have a few new things to add as a result of today’s debate. I had more than 30 years of service in the Metropolitan Police Service—which pales into insignificance when you consider the experience of the noble Lord, Lord Hogan-Howe—but I have also been briefed by the National Crime Agency lead on Brexit and by the director-general of the National Crime Agency on these issues.​ It might be considered a technical point, but there is a difference between counterterrorism intelligence exchange and law enforcement. The counterterrorism intelligence tends to be of such a sensitive nature that it is exchanged on a bilateral basis and therefore is nothing to do with the European Union. When sensitive data, for example, are shared by the United States with the United Kingdom, the United States would not do that if it was on the basis that the United Kingdom would then share all that intelligence with the EU 27. However, there is a technical difference between counterterrorism in terms of intelligence and counterterrorism in terms of bringing terrorists to justice, and here we are talking about bringing people to justice using these various mechanisms. My noble friend Lady Ludford referred to the European Court of Justice and the Charter of Fundamental Rights as two important mechanisms which allow this co-operation to take place within the European Union. In her Munich speech, the Prime Minister tantalisingly mentioned the European Court of Justice and the potential for a role for it after the UK had left the European Union in relation to things such as the European arrest warrant. The noble Baroness, Lady Kennedy of The Shaws, made the point that this is not about relationships between two sovereign nations, it is about individual rights in terms of whether an individual is going to be moved from one country to another. Perhaps the Minister can give us some clarity on the Government’s position on the European Court of Justice by explaining what the Prime Minister meant in her speech. The noble Lord, Lord Cormack, talked about the need for the closest possible co-operation, which is what the National Crime Agency would say, and that the measure of the success of the negotiations would be how closely we can replicate the existing arrangements. I believe that the Government’s position is that they want to replicate all of these things as far as possible, and that is what I took from what the Prime Minister said. So to say that the Government cannot give away their negotiating position by saying what the objective is going to be is not, I think, true in this particular case. Perhaps the Minister will tell us that what the Government seek to achieve is as close as possible to the arrangements we have, but that is not the question. The question is how the Government are going to secure those arrangements; that is the critical question, not what they are seeking to achieve, but how they are going to do it. That is because there seems to be a contradiction between not wanting to have any jurisdiction of the European Court of Justice on the one hand and yet wanting to participate in things such as the European arrest warrant on the other. The noble Baroness, Lady Kennedy of The Shaws, helped the House to introduce the very important issues around protected persons. For example, the victims of domestic violence have the protection of orders that are made in one country enforced in another, which brings a new dimension to the importance of these arrangements. The noble Baroness, Lady Massey of Darwen, and the noble Earl, Lord Listowel, talked about the importance of the protection of children through the European arrest warrant and the other measures, in particular the European Criminal Records ​Information System, which enables law enforcement to quickly check the antecedents of people who are suspected of these sorts of offences. These are extremely important issues in terms of bringing people to justice and in terms of protecting citizens not only of the United Kingdom but of other European states. We have heard from my noble friend Lord Thomas of Gresford how extradition can take years—four and a half years in the case he mentioned—whereas under the European arrest warrant justice can be brought far more swiftly. For me, the essential question is not what the Government want the end position to be, because that is quite clear—and it is certainly what the National Crime Agency and other law enforcement officers want, and indeed what the noble Lord, Lord Hogan-Howe, has also said. The question that the Government need to answer is this: how on earth is this going to be achieved, bearing in mind their apparent contradictory stances on other issues such as the European Court of Justice?
6. Baroness Hayter of Kentish Town    Share this contribution My Lords, as we have heard, these amendments relating to reciprocal issues are key to continuing to protect and assist British citizens after Brexit, including children and protected persons, in ways that hitherto our EU membership and cross-border agreements have provided. In particular these are the European arrest warrant, the mutual recognition of family court judgments, information exchange, Europol and Eurojust. The Government’s approach to these issues must be agreed in principle with the EU in time to be included in the framework part of the Article 50 requirements and form part of the withdrawal agreement, so a satisfactory approach to these will be key to the future vote on that deal. However, as we have heard from speakers tonight, there seems to be an extraordinary lack of urgency, especially if there is any chance—I am not sure whether this is what the noble Lord, Lord Hannay, hinted at—that a standstill transition agreement could not cover these issues. That would make it even more urgent. I ask in particular about the Government’s urgency, or lack of it, as I began asking Written Questions on this a year ago. The noble and learned Lord, Lord Keen, will remember it very well: it was on St Valentine’s Day last year—I do not think he chose it to be that day, but never mind—that he answered some of my questions on matrimonial and maintenance proceedings. It was very reassuring: he said that the Government, “recognises the importance of the issues”. Wow. There was no more than that then, nor indeed on civil judicial co-operation and cross-border disputes and family law when he replied to a similar Written Question in August. I worry about the lack of progress since then. As the Prime Minister has remarked and others have repeated, keeping our citizens safe is the first mission of any Government. Therefore, like others, I welcome that she used the Munich speech to reiterate her desire to negotiate continued, and in some cases enhanced, co-operation with EU nations and particularly with these bodies and schemes. As we have heard, the amendments cover the Schengen Information System, ​the European arrest warrant, the European Criminal Records Information System, Europol and Eurojust. Given what we have heard today and in earlier debates, the Minister will recognise the importance of our continued participation in all of those, but also the challenges that that will bring to them in negotiating. While we heard from Munich the desire for this comprehensive agreement, it is time for the Minister to offer a bit more detail and clarity sooner rather than later. It is about the direction of travel or the objectives. It does not undermine any negotiations for us, not just our Parliaments, to know what the Government want to do. As the noble Lord, Lord Deben, said, it is time for the Government to move from intention to reality. These issues, as has been touched on just now, are partly held up by an obsession with red lines around the ECJ. They cannot be allowed to stand in the way of some logical and sensible solutions to these problems. These issues are too important to be left to a divided Cabinet. At the moment I see a pantomime horse, or Dr Dolittle’s pushmi-pullyu, being pulled in two different directions, mostly about red lines that are immaterial to the issues we have been discussing. I hope we can hear about some direction and some practical steps from the Minister, particularly on how these negotiations are taking place.
7. The Minister of State, Department for Exiting the European Union (Lord Callanan) (Con)    Share this contribution I thank all noble Lords and noble Baronesses who have contributed to what has been a fascinating debate. I reiterate the Government’s commitment to ensuring that the outcome of our negotiations with our partners in the EU delivers continued close co-operation on internal security matters. There are parallels between the effect of Amendment 13 in the name of the noble Baroness, Lady Ludford, and that of Amendment 12 in the name of the noble Lord, Lord Wallace of Saltaire, which was debated previously, in so far as they both seek to discuss the future relationship with the EU, which is, of course, subject to the negotiations. The noble Baroness’s amendment seeks to prevent the Government from bringing regulations into force until agreed procedures for continued participation in EU internal security measures have been approved by both Houses. The Government have already committed to providing Parliament with a meaningful vote on any final deal. This will give Parliament the opportunity to scrutinise the future relationship between the UK and the EU in all these areas. For this reason, it is our view that the amendment is not needed. I must come back to the points made by my noble friends Lord Hamilton and Lord Lamont. Many noble Lords have pushed me and asked for further detail and clarification on the negotiations. This Bill is negotiation agnostic; it is not concerned with the negotiations. I understand why people want clarification in all those areas, but, of course, when we have reached an agreement, it will be the subject of future legislation that noble Lords will no doubt want to comment on in great detail. However, I will attempt to answer as many questions and go into as much detail as I can. I suspect that the noble Lord, Lord Adonis, may be a little disappointed yet again, but I will do my best.​

9.30 pm

I turn to Amendments 207 and 209, tabled by the noble Baronesses, Lady Kennedy and Lady Massey. In our view, both these amendments are unnecessary. They would place in the Bill objectives that the Government are already committed to pursuing and compel them to lay before Parliament a strategy which is already available, and which I will come to later.

Amendments 175 to 180 in the name of the noble Lord, Lord Adonis, would prevent the Government making regulations under the power in Clause 9 in relation to a range of internal security tools until they had laid before Parliament a strategy for reaching agreement with the EU on continued co-operation across a range of internal security measures. The future partnership paper that we published on 18 September 2017 set out how we aim to go about securing those aims and, therefore, it is the Government’s view that this group of amendments is not needed.

As many noble Lords have referenced, the Prime Minister has proposed a bold new security partnership with the EU, including a comprehensive agreement on our future security, law enforcement and criminal justice co-operation. She elaborated on the Government’s proposals in this area in her speech in Munich earlier this month, making it clear that Europe’s security is our security and that the United Kingdom is unconditionally committed to maintaining it. Her speech built on the future partnership paper that the Government published on 18 September 2017, which set out how we are seeking an overarching treaty that provides for practical operational co-operation and facilitates data-driven law enforcement and multilateral co-operation through EU agencies such as Europol and Eurojust.

* Lord Adonis    Share this contribution Can the Minister answer the question put by the noble Lord, Lord Thomas, as to which Minister is taking the lead in the security negotiations?

1. Lord Callanan    Share this contribution I will come to that later in my speech, but I will answer that question. In that same paper, we made it clear that we value the operational benefits that we derive—I was struck by the comments on this from the noble Lord, Lord Hogan-Howe, and on how valuable many of them are. The noble Lord, Lord Hannay, referred to many of them, too, including the passenger name record directive, the second generation Schengen Information System and the European arrest warrant. There is also ECRIS, referred to by the noble Earl, Lord Listowel, and all the various acronyms that go with many of these JHA matters. They are all to do with the systematic exchange of information with our EU partners—for example, on criminal records—which helps to deliver fair and robust justice. I hope that reassures the noble Lord, Lord Cormack. He referred to Interpol. I assume that he meant Europol, but, for the avoidance of any doubt, I should say that we continue to co-operate in the same way with Interpol. We made it clear that we want to agree future arrangements in this area that support co-operation across a range of EU measures and agencies, and to avoid operational gaps for law enforcement agencies and judicial authorities in the UK and the EU. The level of co-operation that we want to sustain goes ​beyond the specific tools and measures highlighted by the noble Baronesses, Lady Kennedy and Lady Massey, and the noble Lord, Lord Adonis. We have described the legal instruments here as a “toolkit” that can provide cumulative benefits. We have also indicated that we want our future partnership with the EU in this area to be dynamic, allowing us to co-operate if necessary in new ways in the face of evolving threats. The amendment tabled by the noble Baroness, Lady Kennedy, highlights the respective roles of domestic courts and the CJEU. We made it clear in our future partnership paper on security, law enforcement and criminal justice that a future agreement in this area would need to provide for dispute resolution. Let me give a little more detail on that. On leaving the EU we will bring to an end the direct jurisdiction of the CJEU in the UK. There are a number of existing precedents where EU agreements with third countries provide for close co-operative relationships without the CJEU having direct jurisdiction in those countries. The UK will engage proactively to negotiate an approach to enforcement and dispute resolution that meets the key objectives of the UK and the EU. We also published a separate future partnership paper on enforcement and dispute resolution last August, addressing many of those points and setting out the Government’s approach to these issues. The House has of course debated this issue on a number of occasions, particularly earlier this month, on 8 February, in the debate on the EU Committee’s report on judicial oversight of the European arrest warrant. The withdrawal agreement and implementation Bill will implement the withdrawal agreement in our domestic law. In addition, the Government have already committed to provide Parliament with a meaningful vote on any final deal. This will give both Houses of Parliament the opportunity to scrutinise again the future relationship between the UK and the EU. We need to be able to work with the EU to respond quickly and effectively to the changing threats we face from terrorism and serious organised crime. In negotiations, we will be seeking to agree the best possible way to continue our work alongside our European partners in support of our common goals and shared interests. We are absolutely committed to securing the close relationship that the noble Baronesses, Lady Ludford, Lady Kennedy and Lady Massey, and the noble Lord, Lord Adonis, want to see—and on that basis I hope that they will not press their amendments. Amendment 99, also tabled by the noble Baroness, Lady Kennedy, would prevent regulations made under Section 7(1) of the Bill from diminishing the protections in relation to “protected persons” set out in Part 3 of the Criminal Justice (European Protection Order) (England and Wales) Regulations 2014. As I understand it, the amendment seeks to ensure that the relevant authorities in England and Wales will continue to recognise and act upon European protection orders made in remaining member states after exit day, whether or not those states act on ours. The EPO regime, established by an EU directive of the same name and implemented in England and Wales under the cited regulations, which came into force in 2015, is essentially a reciprocal regime. It requires the relevant designated authorities in the different ​member states involved to act and to communicate with each other in the making of an order and in its recognition and enforcement—and also, indeed, in any modification, revocation or withdrawal of one. It is not possible for us to regulate from here to require the relevant authorities of remaining member states to act in any particular way. As such, if we are not in a reciprocal regime we will no longer issue EPOs to remaining member states, since it would be pointless to do so, and nor will the authorities in those member states issue them to the UK, for the same reasons. In short, absent our continued participation in the EPO regime, or in some proximate reciprocal arrangements in its place, these regulations will be redundant; they do not work unilaterally. This amendment therefore pre-empts the outcome of the negotiations, potentially requiring the retention of redundant legislation. It would not be right to create a false impression by retaining redundant legislation. I am happy to be clear, however, that if the forthcoming negotiations produce an agreement to continue access to the regime established under this directive, or something like it, appropriate steps and legislation will be brought forward to implement it at that time. This will encompass the protections for protected persons. We will, of course, consider that at that stage. Meanwhile, for now, there is no practical point or purpose in having such an amendment or these provisions. I shall answer some of the other points that were made. The noble Baroness, Lady Ludford, asked me about the O’Connor case and about extradition to the UK from Ireland. I am sure that the House will understand that I am somewhat limited in what I can say on this matter; it is a live case at the moment. Suffice it to say that we are monitoring it closely, but it would be wrong to speculate on its impact before the case is concluded. Once it is, we will be happy to do so. The noble Baroness, Lady Ludford, and the noble Lord, Lord Paddick, I think it was, asked how we could reconcile the principles set out in the Prime Minister’s Munich speech, first on UK sovereignty and secondly on the ECJ. As the Prime Minister said: “The Treaty must preserve our operational capabilities. But it must also fulfil three further requirements. It must be respectful of the sovereignty of both the UK and the EU’s legal orders. So, for example, when participating in EU agencies the UK will respect the remit of the European Court of Justice. And a principled but pragmatic solution to close legal co-operation will be needed to respect our unique status as a third country with our own sovereign legal order”. The noble Lord, Lord Hannay, asked about justice and home affairs in the implementation period. We welcome the EU’s position that the UK should continue to participate in existing justice and home affairs measures where it has opted in. We also want to ensure that the UK and the EU can take new action together against unforeseen incidents and threats during that period. For those reasons, we want to be involved in new measures introduced during implementation where that is appropriate. He also asked about the Prime Minister’s speech in Munich. I confirm that she was talking about all the justice and home affairs measures he mentioned—the EAW, ECRIS, Europol and all the other appropriate acronyms.​ The noble Baroness, Lady Ludford, asked about the European arrest warrant and about the chance of a successful outcome compared with Norway. We value our co-operation through the EAW as it provides a faster and cost-effective way of handling extradition and helping us tackle cross-border criminality. With regard to Norway, our starting point for negotiations on future co-operation will be different from that of either Norway or Iceland, where a bilateral agreement is also in place. Of course, our starting point is different from theirs in so far as our extradition arrangements will be fully aligned with those of the EU at the point of our exit since we operate the same tool. That was not the case with Norway and Iceland when they joined. The noble Lord, Lord Thomas, asked where we are in the negotiations and who is doing them—which the noble Lord, Lord Adonis, was also interested in. The Secretary of State for Exiting the EU is responsible for conducting negotiations in support of the Prime Minister. He is supported by the core negotiating team, which is made up of senior officials from a range of government departments. In response to his question about contacts, officials are engaging now and constantly with EU counterparts on a range of issues—but I come back to my earlier point that it would not be appropriate to give a running commentary on these discussions. We approach the next round of negotiations with optimism.
2. Lord Thomas of Gresford    Share this contribution Can the Minister tell us if the European Union has appointed anybody to represent the 27 other countries in conducting the other side of treaty negotiations?
3. Lord Callanan    Share this contribution Michel Barnier is the EU chief negotiator. I thought that that was fairly obvious. Finally, the noble Lord, Lord Adonis, asked about no deal. Of course, we approach these negotiations not expecting failure but anticipating success. We are confident that continued practical co-operation between the UK and the EU on law enforcement and national security is very much in the interests of both sides, so we approach these negotiations anticipating success. We do not want or expect a no-deal outcome. However, a responsible Government should prepare for all potential outcomes, including the unlikely scenario in which no mutually satisfactory agreement can be reached. That is exactly what we are doing across the whole of government. The UK uses and benefits from a range of international information-sharing tools in the area of security and law enforcement, which are by no means limited to EU mechanisms but include bilateral and multilateral channels, including Interpol and the Council of Europe. I hope I have answered all the questions—
4. Lord Thomas of Gresford    Share this contribution Do I understand the Minister to be saying that the people conducting the trade negotiations will deal with the security stuff as well? Is that what he is saying? Are there no lawyers on the other side to conduct the negotiations on behalf of those 27 other countries? What is the situation?
5. Lord Callanan    Share this contribution There are lead negotiators on each side but they are supported by a whole range of officials and Ministers from various departments. ​David Davis is our negotiator, Michel Barnier is the EU’s negotiator, and they have different members in each of the teams—
6. Lord Thomas of Gresford    Share this contribution But is the withdrawal agreement the same thing as the treaty or are they separate?
7. Lord Callanan    Share this contribution No, the treaty will be a separate piece of legislation when we negotiate it. I hope I have tackled most of noble Lords’ questions and they will be able to withdraw or not move their amendments.
8. Lord Pannick (CB)    Share this contribution May I just ask the Minister about his comments on the European Court of Justice? Is there anything in the case law of the ECJ that justifies the Government’s reluctance for it to continue to be the dispute resolution procedure for the matters we are discussing?
9. Lord Callanan    Share this contribution We have been clear that respecting the Brexit vote means delivering on having control of our own laws. Our Supreme Court will be the ultimate arbiter of our own laws and it would not be appropriate to submit ourselves to the jurisdiction of a foreign power.

9.45 pm

* Baroness Ludford    Share this contribution I should briefly like to thank all speakers in this extremely valuable debate, especially the co-signatories to my amendment, the noble Lords, Lord Cormack and Lord Judd, and my noble friend Lady Smith of Newnham. It was evident that, almost without exception, there was very strong support for staying in these crucial law enforcement measures. I am not so sure we got what the noble Lord, Lord Cormack, asked for, which was a reply of real substance. We certainly did not get the clarity that my noble friend Lord Paddick asked for on the ECJ. Quite honestly, that was an extraordinary response to the noble Lord, Lord Pannick. As the noble Lord, Lord Hannay, said, there is no safety net in this area. The WTO is not much of one but it exists.

1. Lord Mackay of Clashfern (Con)    Share this contribution Is the noble Baroness talking of the European Court of Justice as though there would be no change in its constitution as a result of our leaving the European Union?
2. Baroness Ludford    Share this contribution There obviously will be a change, in that there will not be a British judge or British Advocate-General. What we want to know is how we will plug into what the Prime Minister asked for in Munich: to have respect for the sovereignty of the UK’s legal order—the Minister really emphasised only that—but also respect for the remit of the ECJ, at least when participating in agencies. That raises the question: will we also respect the remit of the ECJ when it rules on the individual rights of people who challenge, for instance, a European arrest warrant? We have no answer to that question but the people who are nationals of those countries will want to know exactly what the jurisdictional regime is. I am afraid we are no closer to knowing that. As my noble friend Lord Paddick said, however, we do have clear negotiating objectives in this area—this is perhaps unique in Brexit—as the ​Prime Minister has set them out and the Minister has just confirmed them. What we are utterly in the dark about is how the Government propose to secure the arrangements, structures and mechanisms for continuing effective and efficient cross-border law enforcement co-operation. The Minister said that we will have a meaningful vote on the withdrawal agreement, which is supposed to give us an opportunity to scrutinise at the end of the process, and hence that this amendment is not needed. But that is not enough; we want a purchase and input into those negotiating objectives. The Prime Minister makes a speech in Munich and tells us, “These are the objectives”, but the Government do not deign to tell us how on earth those objectives are to be secured. Like me, the Minister is a veteran of the European Parliament. We found there that the European Commission, the member states and the Council learned the hard way that unless you bring the European Parliament, in that case, into your confidence about your negotiating objectives and how you are going to secure them, the danger is that at the end of the process the deal will be rejected because it has not been kept informed along the way. The lesson in Brussels was to front-load the process by keeping the people who might be in a position to block the deal informed of how it was to be secured. I am afraid the Minister did not convince me, at least, that we are any further forward than we were with the future partnership paper, because that paper did not set out how we are to achieve these objectives. It said what the Government wanted to achieve. That has been repeated by the Prime Minister and the Minister, but we are none the wiser about how these measures will be replicated when we no longer have the structures and mechanisms of the EU. I fear that we will have to come back to this in all seriousness at future stages but, for the time being, I beg leave to withdraw the amendment.

Amendment 13 withdrawn.

Amendment 13A

Moved by

* Lord Goldsmith    Share this contribution

**13A:**Clause 1, page 1, line 3, at end insert—

“( ) Regulations bringing into force subsection (1) may not be made until the Secretary of State has laid before both Houses of Parliament proposals for arrangements for the continued application of the Charter of Fundamental Rights to retained EU law under sections 2, 3 and 4.”

* Lord Goldsmith (Lab)    Share this contribution My Lords, we now come to the first group of amendments that deals with the exclusion from the Bill of the European Charter of Fundamental Rights. A number of amendments relate to the exclusion of the charter and to its specific provisions, so this may be a convenient place to debate the general principle of what the Government are proposing and the issues to which that gives rise. I shall therefore speak also to Amendments 14, 20, 25 and 34. Amendments 46, 47, 333 and 347 are consequential and I apprehend that there will be no need to say anything more about them.​ The starting point for these amendments is the Government’s decision to exclude the European Charter of Fundamental Rights from the carryover into domestic law of existing EU law that the Bill is otherwise designed to achieve. As noble Lords know, and as the Government have been at pains to point out, the purpose of the Bill is to maintain legal continuity, certainty and stability for businesses and individuals by incorporating EU law as it stands into UK law. As the Prime Minister said in her foreword to the White Paper, the purpose is to ensure that: “The same rules and laws will apply on the day after exit as on the day before”. The White Paper goes on to explain that it will then be for democratically elected representatives in the UK, in this Parliament and the devolved Administrations, to decide whether to change that law after full and proper scrutiny and debate. This decision to bring EU law into UK law at the moment of exit is an essential part of the plan to provide clarity and is necessary, it is said by the Government, to bolster confidence and planning as the Brexit process comes into effect. The noble Baroness the Lord Privy Seal said at Second Reading that this is, “about ensuring that people’s rights are maintained. It is vital to a smooth and orderly exit from the EU”.—[Official Report, 30/1/18; col. 1374.] However, there is one glaring and deeply troubling exception to the proposal to bring EU law into domestic law so that it is the same the day after exit as it was the day before: the exclusion of the charter, in its entirety, from this exercise. In another place, the Solicitor-General described the exercise as downloading EU law into domestic law, but what is not being downloaded is the charter. In another place, Sir Keir Starmer noted that although thousands of provisions of EU law are being converted into domestic law, and may have to be modified in some sense after that exercise, only one provision in the thousands on thousands of provisions of EU law is singled out for extinction, and that is the charter. That gives rise to a conundrum.

1. Lord Lamont of Lerwick    Share this contribution Is the noble and learned Lord going to come on to explaining why it was, when he was Attorney-General and working with Tony Blair, he worked so hard to try to get the charter excluded from the Lisbon treaty? Indeed, they thought they had achieved such an opt-out from the treaty until it was overruled subsequently by the European Court of Justice. Surely what we are doing now is trying to fulfil the objective that he himself had in mind.
2. Noble Lords Oh!
3. Lord Goldsmith    Share this contribution I can see noble Lords ***opposite*** are all very well briefed. I predicted this at Second Reading. I will come on to that, but let me make some progress on the arguments which matter.
4. Noble Lords Answer!
5. Lord Goldsmith    Share this contribution No, I will make some progress on the arguments which matter. As the Constitution Committee of this House said at paragraph 119 of its report, the conundrum is this:​ “The primary purpose of this Bill is to maintain legal continuity and promote legal certainty by retaining existing EU law as part of our law, while conferring powers on ministers to amend the retained EU law. If, as the Government suggests, the Charter of Fundamental Rights adds nothing to the content of EU law which is being retained, we do not understand why an exception needs to be made for it. If, however, the Charter does add value, then legal continuity suggests that the Bill should not make substantive changes to the law which applies immediately after exit day”. I want to examine the reasons that are put forward for not including the charter. The more I look at the arguments, the more convinced I become that the Government have got it wrong. I will not deny that there are issues as to the best way to bring the charter into effect in domestic law, and there are other amendments which will debate that, but Amendment 13A would require the Government to bring forward proposals for its continued application and the route by which the charter can be given effect.
6. Viscount Hailsham    Share this contribution Would the noble and learned Lord tell the Committee whether he is contemplating that the charter should be incorporated into domestic law as a statute, and as such be capable of amendment?
7. Lord Goldsmith    Share this contribution I am suggesting that the charter is brought into domestic law in the same way as all the other provisions of EU law will be brought into domestic law by this Bill, if it is passed. That means that they will be subject to the powers in the clauses that will be passed for amendment through orders, if this House and the other place approve that way of doing it. They will also, of course, as always, be subject to amendment by primary legislation. I will come on to this, but it is interesting that special protection is given to the ECHR through the Human Rights Act to protect it as we go forward, but there is no protection provided at all for the rights which underlie the charter. That is one of the deficiencies that are not taken account of in the Government’s proposal.
8. Baroness Deech    Share this contribution Does the noble and learned Lord accept that perhaps we are being tied in knots by his argument? The nub of the charter, and why it is different from the European Convention on Human Rights and our Human Rights Act, is that the charter says that judges can set aside, invalidate or nullify our Acts of Parliament. That is the nub of it and is why it does not sit with the rule of law and parliamentary sovereignty. If you incorporate it in domestic law, you are in a real tangle, because if you try to repeal it, judges could set that aside. You end up in a vicious spiral.
9. Lord Goldsmith    Share this contribution I am grateful to the noble Baroness for the intervention. Of course it is not the charter which provides that, in certain circumstances, our courts have the ability to disapply domestic law; it is EU law and its ability to override Parliament. That is not what the charter has created; it is EU law that has created it. That is something which this Bill is intended to remove. I want to get back on to the reasons why. The first reason put forward—this is the nub of the question put to me by the noble Lord, Lord Lawson—is that the charter merely codifies existing rights and principles.
10. Noble Lords Lamont!​

10.00 pm

* Lord Goldsmith    Share this contribution I apologise to both noble Lords. The proposition is that the charter does no more than codify existing rights and principles, so it is not necessary to bring it in. It has been said, for example, by the very distinguished and independent Bingham Centre for the Rule of Law that that proposition is demonstrably not correct. It sets that out in a detailed report that I commend to noble Lords. An opinion of Queen’s Counsel obtained by the Equalities and Human Rights Commission concludes that in fact this would lead to a significant weakening of human rights protection in the United Kingdom. Against those independent statements, it is no wonder that many NGOs and many members of civil society are deeply troubled about the exclusion of the charter. It is not just civil society that is concerned about that, as the noble Baroness, Lady Ludford, noted in the last debate, but industries such as the tech industry. One can find examples of rights that are not protected in the report, which I also commend to noble Lords, by the Joint Committee on Human Rights. In its right-by-right analysis it identifies which rights are already included in our law and which are not. For example, on the very first item in the charter—Article 1 on the protection of human dignity, which many people would regard as the most fundamental human right and the basis of all others—the Government’s right-by-right analysis gives two reasons for saying that that would be continued: first, an unincorporated treaty, the Universal Declaration of Human Rights, which does not have enforceable effect in this country at all; and, secondly, as a general principle of EU law—but, as noble Lords will know, this Bill seeks to prevent general principles of EU law being given effect or creating any enforceable rights. That is an aspect that we will have to come back to later in the debates on the Bill.

1. Lord Faulks (Con)    Share this contribution The noble and learned Lord identifies the fact that certain rights are no longer protected adequately because the charter contains rights that are not there in the European convention or, presumably, otherwise provided for by law. Could he tell the House why the Human Rights Act was not expanded to take into account the protection of these laws? At no time from 1998 to the time when the Labour Government lost power was there any attempt to include these rights that he now says are a central part of our law.
2. Lord Goldsmith    Share this contribution They were, because the charter provided for them. The Human Rights Act incorporated one set of provisions only, the European Convention on Human Rights, which goes back to just after the Second World War and which provides the classic political and civil rights. The other rights that we find in the charter, which is a much longer document and refers to socioeconomic rights, were not included in the Human Rights Act because they were not included in the European Convention on Human Rights. The right-by-right analysis demonstrates which of these rights are not included. Given that the Government’s objective, as stated by the Prime Minister, is to ensure that the protections for people in this country are ​the same the day after exit as the day before, I respectfully suggest that it is not for me to identify why that is not right; it is for the Government to demonstrate why it is. When we have substantial independent bodies such as the Bingham Centre and independent opinions from QCs demonstrating that actually it is not the case that the protections remain the same, the Government need to explain. I shall come on to that further. Obviously there are examples of rights in the charter that reflect precisely other rights that we have within our law. In particular, there are a number of rights in the charter that are explicitly based on the European Convention on Human Rights; they are the same. Indeed, during the negotiations I went to some pains to try to ensure that they were phrased in the same way so as to prevent lawyers from saying, “It’s written differently so it must mean something different”. However, those are not the only rights that are there. As I noted at Second Reading, the charter is based not just on the European Convention on Human Rights but on principles of EU law and on principles that are commonly accepted by the member states, and those are in a different position from the ECHR rights.
3. Lord Brown of Eaton-under-Heywood (CB)    Share this contribution Just take one of the rights that is precisely mirrored in the convention. Is it suggested that henceforth, the wise complainant who faces primary legislation here which is incompatible with that right should therefore sue under both the charter and the convention because, lo and behold, under the convention, despite the constitutional arrangement whereby the court’s powers are limited to a declaration of incompatibility, he can disapply the primary legislation? Is that to be the consequence: that in a case where it matches, the convention trumps the constitutional settlement we arrived at, to which the noble Baroness, Lady Deech, referred?
4. Lord Goldsmith    Share this contribution That will depend on the shape of the Bill when it is completed—in particular, what is said about the provisions which deal with primacy of EU law—but at the moment, as the noble and learned Lord will know well from the cases he sat on, people have been bringing cases by reference to both the charter and the convention. One reason for that is that the protection under the charter is more powerful. In future, if people want protection of human rights, they will want the more powerful protection, and if that remains available after the Bill is enacted, they will look to it.
5. Baroness Deech    Share this contribution So if that protection is more powerful, the entire British structure relating to human fertilisation and embryology, which is very liberal and go-ahead, could be wiped out by the application of Article 3. It is very fortunate that the bodies opposed to our progress in reproductive rights have not cottoned on to that. It talks about the prohibition of eugenics, whatever that is, and selection of persons. By interpretation, it would stop us doing mitochondrial research, selection of embryos to screen out disease and a whole host of other things. Another article ensures continuing freedom of movement. Surely we do not want that.

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* Lord Goldsmith    Share this contribution The noble Baroness raises two different points. Some of the rights in the charter plainly do not continue after exit because they are dependent on our membership of the EU. Those include freedom of movement, which is based, as the explanations of the charter plainly show, on the rights that currently exist. There are others, such as the right to vote in European elections, which will not apply. Let me make this point now, because it is one of the objections raised to keeping the charter in. As with many other provisions of EU law, there will need to be changes—I think they are described as deficiencies in the Bill; defects. For example, other provisions of EU law refer to bodies to which we will no longer belong or to supervising agencies with which we will no longer be concerned because we will have left the European Union. That is what the provisions of the deficiency orders are intended to deal with. So, too, they can deal with matters under the charter which no longer have effect for that reason. The noble Baroness’s first point was a different matter, which was to do with the ambit of Article 3. I am sure that she has it clearly in mind, but the explanations of Article 3 make it clear that: “The reference to eugenic practices, in particular those aiming at the selection of persons, relates to possible situations in which selection programmes are organised and implemented, involving campaigns for sterilisation, forced pregnancy, compulsory ethnic marriage among others, all acts deemed to be international crimes in the Statute of the International Criminal Court”. I do not doubt that the noble Baroness would be as opposed to those provisions as the rest of us would be. In relation to reproductive cloning, which may be what she had in mind, the explanations talk about being against reproductive cloning, but that is not the same as therapeutic cloning. We can have debates about that if need be. Let me move on, if I may, because I have only started to deal with one aspect of the issue. In terms of the substantive protections that the charter provides but the ECHR does not, although it covers many of the same, reference has been made already to the case of Mr David Davis himself and Mr Tom Watson. I say this not because it is amusing to point the finger at Mr Davis, in his current position, having relied on the charter, as we know he did, but because it is illustrative of something significant. As a Back Bencher, he and Mr Watson brought a case against the provisions of the Data Retention and Investigatory Powers Act—DRIPA. Mr Davis was concerned that they would impinge on the ability of MPs to have confidential communications from their constituents. In his argument, he and his lawyers relied on the charter, and they were successful in doing so. The court agreed that the charter was relevant. Another example of new rights, developed rights or rights that have emerged through the dynamic approach of the charter is in the Google Spain case in which the right to be forgotten arose as a result of an examination of Articles 7 and 8 by the Court of Justice of the European Union. So, there are a number of examples where the substantive protections will be different. I have made it clear that there are many examples where the substantive protections are the same, but the purpose ​behind the Bill is to make sure that the protections for people are the same the day after leaving as the day before. It is not just the substantive protections. There are different remedies, one of which has been referred to already—the ability to disapply legislation if that is where the Bill ends up at the end of the day. That is a more powerful remedy than the Human Rights Act. That was demonstrated in the Benkharbouche case when the State Immunity Act was disapplied so that foreign employees of an embassy could bring claims, which they would not otherwise be able to bring, so as to produce a more just situation. The Government’s position on the substantive protections appears to have changed. I understood that the Government said that the protections would be the same, but now the formula that appears to be being used is that there will be no significant loss of substantive protection. That is not the same thing. No significant loss of substantive protection means that there is some loss of substantive protection, though someone takes the view that it is not significant. That is not the same as the principle the Prime Minister’s foreword set out. Will the Minister respond to the following questions? First, will he confirm that the Government no longer contend that disapplying, excluding the charter, will lead to all the same existing substantive protections, or do they accept that some of them will not exist? If so, will he tell the Committee either now or subsequently what those are? Secondly, I referred to the phrase “no significant loss of substantive protections”. Does the Minister agree that that leaves aside the question of whether procedural or other protections will be excluded as a result of excluding the charter from this protection? I ask the Minister to identify what the differences are and whether he accepts that there will be a loss of protection, even though the Government wish to say that it is not significant, so that the Committee can judge. Also, he will need to say, please, why that meets the objective the Prime Minister set in her foreword to the White Paper.

10.15 pm

The second objection that is put forward to including the charter is that there are provisions that cannot apply. I have already dealt with that point, because there are provisions such as the right to participate in the EU elections, which, of course, will not apply because we will not be a part of the European Union—but there is nothing dangerous in including them because, as is the case with many other EU instruments which are brought over, there will need to be adjustments or they simply will not apply.

The third argument that is raised is a reference to the fact that the scope of the charter is spent because it applies to member states only,

“when they are implementing Union law”.

With respect, that argument does not prevent the charter being important; on the contrary, it makes it invaluable. Although we will cease to be bound by new Union law after we leave, we are bringing on to the statute book, through this Bill, the existing Union law—and our country will be acting within the scope ​of that Union law and implementing it or, to put it another way, the charter will apply to retained law. There is a series of retained laws in Clauses 2, 3 and 4 of this Bill, and the charter will have an important and invaluable role to play, not just interpreting those but in ensuring that they are applied in a way that satisfies human rights considerations.

There is a further problem—

* Lord Brown of Eaton-under-Heywood    Share this contribution I promise that I will not intervene again—I loathe intervening. But does the noble and learned Lord agree, although he proposes the domestication of the charter, it will still be necessary in future to decide what is within the ambit of what used to be EU law, because that is where the operation of the charter is presently confined—or does he suggest that now it opens up and encompasses all UK law, so that it is a wider application than it was originally? Are we going to have to go again through the impossible exercise, notoriously uncertain in application, of having to decide what is specifically and directly within the ambit of EU law in future as well?

1. Lord Goldsmith    Share this contribution I am grateful to the noble and learned Lord and I know that this is a point that troubles him, but he should bear in mind that what we have in Clauses 2, 3 and 4 of the Bill are provisions to bring specific aspects of EU derived legislation and EU direct effect legislation into UK law. That is the Union law that will continue, and that is what is defined as retained EU law—and it is to that retained EU law that the charter will continue to have effect under the scheme that I advocate to your Lordships, not to anything else or more broadly UK law.
2. Lord Brown of Eaton-under-Heywood    Share this contribution So the right to dignity would exist in the context of EU law, but not otherwise? Is that really how it is intended to work? Can the noble and learned Lord give an illustration of a case that will succeed under the right to human dignity in future—I mean, there has not ever been one in the past that has succeeded under that—when otherwise it would fail?
3. Lord Goldsmith    Share this contribution The noble and learned Lord knows that I took Article 1 as an example only because it is the very first article in the charter. I have respectfully invited noble Lords to look at the Joint Committee on Human Rights report, where the committee goes through each of the articles and through what the Government have said in relation to them, and identifies where they find place already in existing, enforceable UK law, and where they do not. It is where they do not that we are concerned with, and where they do not that there will be the very gap that the Prime Minister has said should not exist. There is the further problem that, even if the rights survive, they will survive without the enhanced status and protection that they currently have. They have an enhanced status at the moment because of the 1972 Act and because of EU membership, but from the date of this Act they will only survive in a delegated form and ​be amendable by delegated legislation. They are not protected from being amended or removed by delegated legislation. Compare the position in relation to the ECHR and the Human Rights Act. The Bill says in three places—in Clauses 7(7)(e), 8(3)(d) and 9(3)(d)—that the Human Rights Act is protected from amendment or revocation. The classic civil and political rights, but no more, which are, rightly, protected by the HRA, are protected from being amended other than by primary legislation to which this House and the other place have specifically agreed after proper scrutiny. However, none of the rights underlying the charter will be protected in that way, unless they find themselves within the ECHR, which is only some of them. That is unacceptable for many people.
4. Lord Hope of Craighead (CB)    Share this contribution I find this very difficult to understand. If you look at the charter, you find reference to the Union in item after item. It begins with a series of rights, but as soon as you penetrate further you find that it is closely related to membership of the Union and things that are guaranteed by its law. If I understood the noble and learned Lord correctly, he wants the charter to be brought in and protected against that kind of amendment in the same way as the Convention on Human Rights. This charter will have to be largely rewritten if we introduce it into our law, but it is not designed for the kind of situation we are facing after Brexit. It is designed for use within the Union and to be interpreted by the CJEU. I simply do not understand how the system is intended to work if it were brought into our law in the way the noble and learned Lord is suggesting.
5. Lord Goldsmith    Share this contribution The noble and learned Lord will recall that, whenever he opposed me with that argument from his position in the House of Lords or Supreme Court, I did my best to try to explain why there is an error in his thinking. With respect, I do the same here. If one takes, for example, one of the rights in the charter which does derive from Union law, is it to be said that although it is going to be transposed into our law as an EU retained law, it will no longer be subject to any of the protections that it has at the moment through being subject to the charter? It does not mean, as the noble and learned Lord, Lord Brown, suggested, that all UK law will be subject to this protection. It does mean that that law which is currently subject to that protection will continue to be so unless and until it is amended. That is the way that one gives effect to the intention that the law should be the same the day after Brexit as the day before. I want to underline that we are talking about the extent of substantive protections; other protections and their extent; and the lack of enhancement of rights. These are all distinct points. I will also refer to the loss of the effect of charter principles. Noble Lords who have studied the charter will know that as well as rights there are principles. The principles are more aspirational, but they guide the legislator and that is a useful thing to have. Even leaving that aside, the other items I identified—the substantive protections, their nature and their enhancement or lack of it—are all things which mean we will not have the same protections after exit day as we have at the moment.

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* Lord Faulks    Share this contribution Is the noble and learned Lord telling the House that these principles are going to be actionable on their own?

1. Lord Goldsmith    Share this contribution The noble Lord knows that that is not the position in relation to the principles: they are guidance and aspirational. I am not spending a lot of time on them, although some of the NGOs have. I will give one example. There was a case in which the EU’s proposed legislation in relation to plain packaging of tobacco products was challenged in the courts on the grounds that it contravened freedom of expression. One of the things that the court looking at that noted was that the charter provided for a high degree of public protection in terms of health. I hope that all noble Lords agree with that sentiment, whether or not they agree with the result of the case. That is an example of where the principles come into effect.
2. Lord Lamont of Lerwick    Share this contribution I apologise for interrupting the noble and learned Lord a second time. We have listened to what he has said with great care. He has spoken for 34 minutes. He said that he would answer the question I posed at the very beginning of his speech—namely, why he had altered his mind when previously he had tried to keep the charter out of the Lisbon treaty, when he then said that it ought to have no direct domestic effect. Why has he changed his mind?
3. Lord Goldsmith    Share this contribution My Lords, I was about to come to that and I am grateful to the noble Lord.
4. Noble Lords Oh!
5. Lord Goldsmith    Share this contribution I said that I would come back to it, and that is what I intended to do. A number of things have happened since the charter was drafted, as I said on Second Reading. The courts have referred to provisions of the charter and have given them effect. The decision was made to give the charter legal effect, which was not the way we started the negotiation. That is what happened in the Lisbon treaty, but that was not the original intention. That is what we argued against at the time, precisely so as to avoid the situation in which the courts were in a position to give effect to rights that we had not expected them to give effect to. That is what changed. That is why we now have a situation, where, as I have said, in a number of cases the courts have said that the charter has an effect and provides enforceable rights to individuals. I conclude. The Joint Committee on Human Rights considered that the Government’s decision to exclude the charter, while effectively retaining nearly all other EU law, was taken without having undertaken a comprehensive analysis of the implications for the protection of rights. I cannot say whether that is right, but this amendment would require a focus to be given to that so that we can see what the correct analysis is and what the right way to proceed is. I beg to move.
6. Viscount Hailsham    Share this contribution My Lords, I wish to speak to Amendments 14A, 20A and 25A in this group, which stand in my name. I apologise for the absence of my noble friend Lord Bowness, who has put his name to a number of amendments but cannot be here because of weather conditions. He has asked me to apologise to your Lordships for his absence.​ The purpose of the three amendments standing in my name is to ensure that the terms of the charter, if incorporated into domestic law, are capable of amendment by Parliament. This may be implied by the other amendments, but I think not. I listened very carefully to the noble and learned Lord. While there is a capacity to remedy deficiencies by regulation, there is no capacity to enable Parliament to mount a careful scrutiny and amendment of the charter. Therefore, the purpose of my amendments is to make it explicit that the charter, if incorporated into domestic law, is subject to parliamentary scrutiny and amendment. I do not want to say very much by way of a general justification for the need to incorporate the charter; I am conscious that the noble and learned Lord who has spoken has much greater expertise than I. I know that the noble Lord, Lord Pannick, will probably speak. He, too, has much greater knowledge of this than I. I am but a journeyman lawyer and I have never had to wrestle with the charter’s significance in domestic terms. However, I noticed last week in the Times that Professor Bogdanor made a very powerful case for not scrapping the rights. The important thing that your Lordships need to keep in mind is that the charter provides a number of rights and remedies not found elsewhere in our domestic law. That point was made by the noble and learned Lord.

10.30 pm

I am deeply concerned at the growing strength of what I regard as the extremes of political debate on the left and right of the spectrum. It seems that the centre ground, where I have always tried to position myself, is giving way and is in retreat, and I believe that we need all the reinforcement we can get. Some of your Lordships will know that my father wrote about the elective dictatorship—a view that I have always shared. I do not believe and have never believed that Parliament is a sufficient protection for the rights and liberties of the citizen. If a political party is captured by extreme elements, is elected into office and can retain the loyalty of its MPs, it can do very much what it pleases. The damage that could be done to our rights and liberties in short order could be very great and might be irreversible. That is why most sophisticated democracies—in this context the United States is probably the most significant—have incorporated protection for rights and liberties in Bills of rights. The charter, if incorporated into domestic law, would go some way to fill the void. It goes beyond the rights and protections afforded by the European convention, as the noble and learned Lord rightly said.

Perhaps I may give a concrete example that may trouble your Lordships. As I understand the policy of Mr Corbyn and his colleagues, it is to nationalise a number of public services and utilities, and he asserts that this can be done at nil cost. This implies either no compensation for the owners of the assets or compensation that is calculated in a wholly derisory way so as to produce nothing or near to nothing.

* Lord Lamont of Lerwick    Share this contribution The reason that the Labour Party says that nationalisation of the railways would cost nothing is that the shadow Chancellor thinks that financing things by bonds is costless. That is what he has said.

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* Viscount Hailsham    Share this contribution Yes, I know that is what he has said but I ask noble Lords to think about the impact on those who will lose their assets. That is the point I am making. I agree with my noble friend but my point is: what about the position of those who lose their assets?

1. Lord Faulks    Share this contribution My Lords—
2. Viscount Hailsham    Share this contribution I am just going to finish this point and then I will give way. It is at that point that Article 17 of the charter comes into play. As the Committee will know, Article 17 provides that property is to be protected and, furthermore, that rights of compensation are to be paid. This is the protection that this House would be very chary about giving away. I give way to my noble friend.
3. Lord Faulks    Share this contribution My noble friend will know that Article 1 of the first protocol of the European convention does precisely the same thing.
4. Viscount Hailsham    Share this contribution So there is an overlap, and the question is one of remedies. As my noble friend will know, the remedies under the charter are probably more effective than the remedies under the convention, and that is the point that the noble and learned Lord was making.
5. Lord Blencathra (Con)    Share this contribution My noble friend seems to be saying that we need to incorporate this into British domestic law to protect ourselves from an extremist, wicked Government, but surely if such a Government were elected, one of the first things they would do would be to scrap this law using their parliamentary majority.
6. Viscount Hailsham    Share this contribution That would have to get through both Houses, which would be at least some check on the process. The point I am making is not quite the point that my noble friend has interpreted. I am saying that, if the charter is to be incorporated into domestic law, it has to be the subject of parliamentary scrutiny and amendment, and that is the only basis on which the charter should be incorporated into domestic law. I accept the noble and learned Lord’s point that a number of aspects of the charter are entirely irrelevant and are hinged on our membership of the Union. Articles 44, 42, 43 and 39 are examples of that. There are also articles in the provision of the charter that many of us would disagree with. The noble Baroness, Lady Deech, has indicated that she does not like many of them, and I happen to agree with her. I heard my noble friends Lord Howard, Lord Lamont and Lord Blencathra chuntering away, and I agree with them: there are many things in the charter with which I disagree. But I am saying that if it is to be incorporated, it should be incorporated in such a way as to enable this House to scrutinise each and every one of its provisions and amend as appropriate. I remind the Committee that one reason many noble Lords and others wish to withdraw from the European Convention on Human Rights is that the judge-made interpretation of the text is incapable of amendment by Parliament. I wish to avoid that criticism being made of the charter if it is to be incorporated. ​The suggestion in my amendment to make the charter, if incorporated, subject to parliamentary scrutiny and amendment is perhaps the only example in this sorry business of being able to cherry pick, or to have your cake and eat it.
7. Lord Pannick    Share this contribution My Lords, may I respond to some of the objections that have been raised to the points made by the noble and learned Lord, Lord Goldsmith, with whose speech I agree entirely? Many of the objections—those raised by the noble Lord, Lord Lamont, are typical—are to the content of the charter or to its implications. The Committee should appreciate that that is not the Government’s position. The Government’s position is not that they seek to exclude the charter because its contents or implications are objectionable. Their position is very clear indeed. If noble Lords read the debates in the House of Commons or look at the report of the Constitution Committee, they will see that the Government’s position is simply that we do not need the charter in this Bill because its contents and implications are already contained in the retained EU law that is being read across through this Bill. So many of the objections that the Committee is listening to are simply beside the point: they are not the Government’s objection to the charter. The Government’s objection to the charter—it is unnecessary because its contents are already part of retained EU law—is, I am afraid, simply unsustainable. I will not take up time on this, because the hour is late, but if any noble Lords are doubtful about it, I simply suggest they read the helpful opinion by Jason Coppel QC, in which he clearly sets out the equality and human rights position. That is the first point. Turning to the second point, I am always reluctant to disagree with my noble friend Lady Deech, because she taught me law at Oxford, but I have to disagree with her on this occasion. Her objection, as she explained it, and I hope I do not misrepresent her, is that she is concerned that the charter will enable the courts to overturn legislation enacted by Parliament—she is nodding. But I am sure she appreciates that that is inherent in this Bill. The whole point of the Bill is to read across as retained EU law the content of existing EU law that is applicable to this country and to give it—see Clause 5—supremacy. Supremacy means that it takes priority, as in the Factortame case, over anything enacted by Parliament which is inconsistent. So the suggestion that we must oppose the charter because it gives courts that power is simply inconsistent with what the Bill does. Turning to the third objection, my noble and learned friend Lord Brown of Eaton-under-Heywood was concerned about whether the inclusion of the charter would, in some way, give a power that expands the role of the charter further than under EU law. My simple answer to that is no, of course it does not. The charter is being read across only because it is part of existing EU law, and it comes across as retained EU law. It will not have any greater force than it already has as part of EU law.
8. Lord Brown of Eaton-under-Heywood    Share this contribution In those circumstances, does my noble friend agree that the result of that is that we are henceforth, instead of ​treating retained EU law as part of domestic law—having discarded the separation and shed the notion that it is a distinct body of law—still going to have to wrestle with all the difficulties inherent in distinguishing operations or actions pursued in the ambit of EU law from those that are not? Will that problem continue into the distant future?
9. Lord Pannick    Share this contribution My answer is very simple: yes, of course. The whole point of the Bill is to read across the EU law which currently applies to this country and for it to continue to apply. That is the Government’s objective. It is their objective because they—very sensibly, in my view—wish to ensure legal certainty and clarity on exit day. That is exactly the legal position. It is not my idea; it is the Government’s intention in this Bill. As to all the concerns about what the charter might or might not do, one should bear in mind that the charter has been applicable in the courts of this country for many years. No one has suggested that there is some case or principle which is so objectionable that we need now to make an exception for the charter, when the Government’s intention in the Bill is to read across all retained EU law to ensure a functioning statute book that preserves the legal position and ensures clarity, certainty and continuity. That is what this Bill is about.
10. Lord True (Con)    Share this contribution There is, I think, a fourth question. As a layman, I have been listening for 51 minutes to extensive legal argument on these questions—and who am I to judge, in a sense?—and I was persuaded by the distinguished arguments of two former Law Lords that I heard. The noble Lord, Lord Pannick, referred to three arguments but there is surely a fourth argument which has not been adduced by any of the noble and learned Lords who have spoken, and that is that 17.4 million British people voted to leave the European Union, and that means coming out from under the jurisdiction of entities which are not subject to the Crown, Parliament and UK law. The noble Lord, Lord Pannick, smiles and laughs. All the arguments that we have heard in this Chamber over the past two days in Committee come from those who do not wish that to happen, but the fact is that the British people sought a future in which they and their Parliament will make UK laws, and UK judges, under the Crown, will judge those. We have no need of any charter which has been made outside, something that the noble and learned Lord, Lord Goldsmith, argued for repeatedly when he was Attorney-General.
11. Lord Pannick    Share this contribution I am grateful to the noble Lord. The reason I am smiling is that he clearly has not read this Bill. The Government’s Bill reads across the entire content of EU law that applies as at the exit date; it becomes part of our law. It is the whole point of the Bill.
12. Lord True    Share this contribution If I may—
13. Lord Pannick    Share this contribution I am sorry; let me complete the point. The noble Lord has made a point and he is simply wrong. The Government’s Bill reads across the whole of EU law. It removes the jurisdiction of the European Court of Justice—I do not suggest to ​the contrary—and the amendment of the noble and learned Lord, Lord Goldsmith, has absolutely nothing to do with the role of the European Court of Justice. It will be the role of our courts and our judges to decide from now on the meaning and effect of the retained EU law which this Bill reads across. It will then be in later legislation for Parliament, as it sees fit, to amend or repeal that law. But as the noble and learned Lord, Lord Goldsmith, indicated, the Prime Minister said that this Bill is not an occasion for changing the law, it is an occasion for ensuring that on exit day we have a workable, certain, continuing system of law. The real question is why this Bill should make an exception for one element of European Union law, the charter. There is no justification for that whatsoever.

10.45 pm

* Baroness Deech (CB)    Share this contribution My Lords, it does the ***opposite*** of what my brilliant former pupil the noble Lord, Lord Pannick, has said. The inclusion of the charter brings with it uncertainty. It is a Trojan horse because if you carry on applying it, its meaning depends on the evolving case law of the ECJ, which has an objective of bringing further integration and other objectives to do with Europe that are not our objectives. Our judges have said that they want certainty after Brexit, but to include the charter, which is evolving all the time, without our scrutiny will give our judges sleepless nights because they will have to follow the twists and turns in EU law. I come back to the fact that the nub of this is that it will plainly give our judges the right to set aside and invalidate UK law. The noble and learned Lord, Lord Goldsmith, mentioned with approval the Benkharbouche case, where part of our sovereign immunity law was set aside by the Supreme Court on the basis of charter supremacy. That was actually dangerous because if other countries start setting aside immunity law when dealing with our diplomats, we will be in a very difficult situation indeed. I would not assess the Supreme Court by the outcome of what it says; we assess courts by the way they are appointed and the integrity of our judges. The retention of the charter is a recipe for confusion, uncertainty and the setting aside of British law according to ECJ judgments.

1. Lord Pannick    Share this contribution I am sorry to say to the noble Baroness that that is exactly what this Bill achieves in relation to all other retained EU law which is read across. This will be under the control of British judges. Under the Bill it is entirely a matter for them what weight, if any, they choose to give to judgments of the European Court of Justice. The charter of rights is no different from any other provision of EU law in that respect. The noble Baroness mentioned certainty. What I think provokes uncertainty for judges is the approach in this Bill. It is not simply that the charter of rights is excluded by Clause 5; the clause goes on to say that undefined, “fundamental rights or principles which exist irrespective of the Charter”, are retained. There is a conflict in the approach taken on this issue. I suggest to noble Lords that the correct approach is that which has been recommended to the Committee and to the House by your Lordships’ Constitution Committee: that there is no justification ​whatever for distinguishing between the charter of rights and all other aspects of retained EU law. I support the noble and learned Lord, Lord Goldsmith, in what he said.
2. Lord Wigley (PC)    Share this contribution My Lords, I rise to speak to Amendment 35 standing in my name and that of the noble Baroness, Lady Jones of Moulsecoomb, which would leave out subsections (4) and (5) and insert the words as set out in the amendment. The objective of Amendment 35 is to retain the charter rights in UK law and afford them the same level of protection as those in the Human Rights Act. It has similar objectives to some of the other amendments that have been proposed. I must admit that I address the House on these issues with some trepidation because I am not a lawyer, although I have taken the advice of lawyers in drafting this amendment. The amendment provides for what I hope is a sensible and responsible approach to Brexit that respects the referendum decision but does not sacrifice rights and protections on the altar of ideology. Removing the European Charter of Fundamental Rights from EU retained law runs counter to the stated purpose of the Bill, which is to facilitate the wholesale transfer of EU law into the domestic statute book. It also contradicts the Government’s assurances that the same rules will apply on the day before exit as on the day after. The Government’s justification for this anomaly is to claim that the charter is unnecessary and that its omission will not result in any loss of substantive rights protections. In an attempt to support their public assurances to that effect, the Government have since published a right-by-right analysis that they say demonstrates that each right can be found in domestic law. The analysis is unpersuasive. According to Liberty and Amnesty International, it is perfectly possible to retain the charter and deal with any redundant sections after exit just as with the rest of retained EU law, as has already been mentioned. The Equality and Human Rights Commission has obtained the opinion of senior counsel Jason Coppel QC on the Government’s analysis of the charter. His advice is that the loss of the charter will lead to a significant weakening of human rights protection in the UK. This is because, first, there will be gaps in protection, for example in relation to children’s rights, data protection and non-discrimination. Secondly, many rights will no longer be directly enforceable, leading to further gaps in protection. Thirdly, many remaining rights could be removed by Ministers exercising delegated powers. A particular concern that I would like to highlight is that Brexit will remove any children’s rights and safeguards currently offered by the European Charter of Fundamental Rights, which imposes a constitutional obligation on member states to adhere to children’s rights standards when implementing EU law. The EU’s Court of Justice now routinely refers to the charter when adjudicating on cases involving children.
3. Baroness Deech    Share this contribution I am reluctant to interfere. My noble friend Lord Listowel, who is sitting next to me, knows more about child law than anybody. I must point out that the protection given to child law in the charter is very crude indeed compared with decades-old ​jurisprudence in this country. Very recently, the Children and Families Act 2014 and the Children Act before were a nuanced and balanced approach to the protection of children, their education and their rights to contact with both parents. They are infinitely more subtle and pay more attention to their welfare than this kind of sledgehammer approach from the charter.
4. Lord Wigley    Share this contribution I hear what the noble Baroness says. All I would say is that by ensuring that we incorporate things into UK law, we then have an opportunity, democratically and in an accountable fashion, to make modifications as may be necessary. The danger is that we will throw out babies with bathwater. Again, the Government have stated that the removal of the European Charter of Fundamental Rights from UK law, “will not affect the substantive rights from which individuals already benefit in the UK”. The White Paper notes that many of the rights protected in the charter are also found in UN and other international treaties that the UK has ratified, including the UN Convention on the Rights of the Child. However, in a centralised context there is no specific statutory provision requiring respect for children’s rights in lawmaking, nor a general requirement to safeguard and promote the welfare of children in the UK. Furthermore, this particular argument has a specific Welsh angle. Stronger protection for children’s rights exists in the devolved nations, specifically in Wales. The Rights of Children and Young Persons (Wales) Measure 2011 imposes a duty on Ministers to have due regard to children’s rights as expressed in the UNCRC when exercising any of their functions. To achieve that obligation, since 2012 the Welsh Government routinely undertake child right impact assessments on proposals for Welsh law or policy that will affect children directly or indirectly. The withdrawal Bill will limit the scope of the devolved nations to alter law within the current devolution settlement and brings competence on matters that have been arranged under EU law back to Westminster. This would prevent the devolved nations from exercising their powers to withstand or amend legislation from Westminster, even where this contradicts their own commitments to children’s rights. I submit the amendment to the Committee as a contribution to the debate on these most important considerations.
5. Baroness Jones of Moulsecoomb (GP)    Share this contribution My Lords, I rise as a co-signatory to Amendment 35. I usually come to these debates feeling that I understand all the issues involved and, within minutes, I am confused by contradictory legal opinions and by arguments from across the House on issues that are not even relevant to the Bill. So can we go back to basics? I feel like the woman on the Clapham omnibus who is just seeing common sense. The fact is that the Government promised to bring over all EU law and are choosing to exempt this aspect of it. I do not understand that; they break a promise at their peril, because people out there will not understand. I could not do better than repeat some of the things said by the noble and learned Lord, Lord Goldsmith, about the Equality and Human Rights Commission. Let me read again what it says:​ “The simplest and best way of achieving the Government’s intention that substantive rights should remain unchanged and ensuring legal certainty is to retain the Charter rights in UK law”. I do not understand why the Government do not see that as well. The legal opinion produced for the Equality and Human Rights Commission by Jason Coppel QC, which we have heard of already, states that failing to keep the charter will result in, “a significant weakening of the current system of human rights protection in the UK”. Why is that not accepted? It is a legal argument. Have the Government read that opinion? If so, will they re-read it and give us a considered response to it? It clearly has a validity that I doubt the Government’s position has. The noble Viscount, Lord Hailsham, spoke about being on the centre ground, which I did not entirely agree with. I feel that I am on the centre ground; I feel that I, here, can at least express things that I hear out on the street. Out on the street, people think that the Government are going to keep all EU law and then amend it when it comes. That was the promise, so why are the Government refusing to fulfil it?
6. Lord Kerslake (CB)    Share this contribution My Lords, I want to speak in favour of Amendment 34 and in support of the other amendments in this group that seek to retain the EU Charter of Fundamental Rights in UK domestic law. I did not speak at Second Reading, in good part out of recognition of a long list of speakers. I hope that the Committee will accept my apologies and my contribution this evening. The key question here is not whether one was for or against leaving the European Union, nor is it whether one agrees with every aspect of the charter; neither of those points is relevant to this debate. It is whether there are sufficient grounds to exclude the charter from being transposed into UK law in exception to every other law being so transposed. In my view, there is no argument that, if we exclude it, we will see a weakening of our rights. That is very clear from the analysis that we have had from the commission and others. There is no doubt that excluding the charter will lead to confusion and uncertainty in the law—that, too, is made clear in the analysis by other lawyers. So the question one has to ask is: are the grounds for excluding the charter compelling? I have not been persuaded that they are. When Ministers say that something is not necessary, I get nervous. It usually means that it really is necessary but they do not want truly to state the reasons why. That is the reality here. The hard truth is that people speaking against the charter’s inclusion do not like it. That is a perfectly reasonable position to take but, if they do not like the charter, that is a debate for further legislative change in the future; it is not a reason for accepting it now. The public expect us to act with integrity and to do what it says on the tin in relation to this Bill. The two things that have been very clear right from the off on this Bill are that it will not see a diminution of rights and it will not try to change legislation from the EU but will transpose it, followed by a proper debate in this House about where change is needed. Unless ​those advocating the charter’s exception can come up with compelling reasons why it cannot be incorporated, the balance of argument must be for it to stay and be transposed into UK law. I say to the Government: when you are in a hole, stop digging. This should be agreed; it is a straightforward amendment that we can make in this Parliament. It does not, mercifully, await the outcome of the deal or anything related to it; it is a simple matter of integrity in the process that we are carrying out through the Bill. We should support the amendment.

11.00 pm

* Lord Cashman (Lab)    Share this contribution My Lords, I speak as a co-signatory to Amendment 63A, which is also in the name of the noble and learned Lord, Lord Wallace of Tankerness. I will be very brief, especially in a room full, it seems, of Law Lords and lawyers. I come to this in perhaps a very different way from others. As a 67 year-old man, I have spent most of my life not having equality before the law or the equal protection of the law; that is, as a gay man. Most of my rights—the equality I now enjoy—have been achieved largely by dragging legislative changes forcefully from Governments who did not want to give them to us or to many other misrepresented and defamed minorities. When it comes to human rights and civil liberties, you can never have enough belt and braces. Therefore, I do not understand why the exception to the carryover of EU law is solely in relation to the European Charter of Fundamental Rights and the general principles. I promised to be brief and brief I will be. Tonight has illustrated to me more than any arguments that have come from a swathe of NGOs, such as the Bar Council, the Law Society, the Royal College of Nursing and others, that we cannot bring forward a change of such magnitude as this in a Bill that is supposed to retain all the EU law and then amend it afterwards. If we are to change the European Charter of Fundamental Rights, it should be done with full public scrutiny by both Houses, through primary legislation and the full engagement of civil society. Let me finish on this. I talked about the rights that I and others have achieved that have had to be dragged. I want people to have easier access to the courts. If the Charter of Fundamental Rights in some way, through one clause or another, achieves that, I will go to wherever I go when I lay my head finally with great peace and rest. Why? Because the European Union was born out of the ashes of the Second World War—the ashes from crematoria that were dotted across Europe because people were taken there because of their difference, their perceived difference. Homosexuals were worked to death in concentration camps alongside trade unionists and many others. Yes, it is emotional but when you are denied and deprived of your human rights, it strikes at the very core of your being. When you are not given the equality that others have under the law, it strikes at your very existence. These rights have been achieved and enumerated not only in conventions. Sadly, I have heard laughter rained upon people who have tried to defend the charter and the concept of human rights tonight, and I do not take that lightly. These rights that have been achieved have often been forced back against those ​who have sought them. They have been achieved, often, against the will of Governments and across the sacrifices of generations. Do not put them aside lightly. I urge noble Lords to support this group of amendments. If we are to change anything, let us do it through primary legislation or, at the very least, in the same way that we amend other retained EU law.

1. Lord Faulks    Share this contribution My Lords, I am sure that the Committee will be greatly moved by what the noble Lord, Lord Cashman, has said. Everyone is concerned to protect human rights but we must not fall into the trap of saying rights are good and therefore, more rights are better. The role of the Charter of Fundamental Rights in our law has been an uncertain one. The noble and learned Lord, Lord Goldsmith, has had a great deal to do with it and knows a great deal about its creation; he played a part in its drafting. He got his retaliation in first at Second Reading and today, knowing that it was going to be pointed out to him that he was not initially an enthusiast for the charter because of the apparent disorder it might create in the rights architecture of our law. There is nothing wrong with changing your mind. It is quite a fashionable course for the party ***opposite*** to take at the moment. My difficulty is not with the change of mind but the fact that I agreed with his original stance, which was that adding the charter, which was designed for an entirely different purpose, ran the risk of undermining the clarity and cogency of our law. I have some experience of the way rights are played in court. I was part of the Commission on a Bill of Rights, together with the noble Baroness, Lady Kennedy, who is in her place. I was also a Minister with responsibility for human rights. I have considerable experience over the past 20 years, following the incorporation of the European Convention on Human Rights by the Human Rights Act, of acting for public authorities which have been sued for alleged violations of those rights. Rights are very difficult to interpret, whether they come from a declaration, a charter or a convention. Inevitably they tend to be expressed in general terms and leave a great to individual judges to interpret and try to make practical sense of. Most of the rights contained in the charter—obviously, some of them are inappropriate—are not controversial in what they seek to protect. What is far more controversial is how these rights should be interpreted. My right may be in conflict with your right. The protection of my right may have to be sacrificed or modified by the need to protect others’ rights or the powers that the state may inevitably have which affect or modify those rights. Of course we need to protect children, the disabled and the vulnerable in society, as a number of noble Lords have pointed out. Most of what we do in Parliament is concerned with the definition of circumstances in which individuals’ rights should be protected. A number of noble Lords have identified the right to dignity as being important since it is not reflected precisely in the European convention. We can all agree that it is important that citizens are treated with dignity but how does one translate that into anything meaningful in terms of the courts providing remedies?​ The difficulty is that rights are now regarded as trumps and if we are to retain the charter, as seems to be the purport of the amendments in this group, we will have the rather strange situation of existing domestic law, whether it comes from the Human Rights Act or elsewhere, being supplemented by the charter, which will have a particular status. As the Government have made clear, the charter was never supposed to be a source of rights per se but a reflection of the rights that are generally protected by the European Court of Justice. It would be peculiar for our courts to continue to rely on the charter, which was designed to apply to EU institutions in interpreting the scope of EU law, after we have actually left the European Union. The Advocate-General has occasionally made remarks about the charter. At its highest it has been described as “soft law”. If we need to protect or further protect rights, is that not a matter for Parliament or even judges interpreting the common law? Are we really so impotent as a Parliament that we have to rely on the relatively recent EU charter to provide such protection? Some of the amendments seek to turn soft law into hard law with application after we have left. This Bill is surely to provide clarity and coherence in the law after we have left the EU. Retaining the charter will do precisely the ***opposite***. I regret that I do not agree with various observations made at Second Reading that the Human Rights Act provides only for declarations of incompatibility. It does in fact provide damages for violations of the convention. I suspect the reason the charter has attracted such vigorous support is the rather egregious way it has been singled out for attention in the Bill. The reason it has been so singled out is the uncertainty of its application by the courts so far, and the Government’s desire to be absolutely clear that in the difficult task of interpreting the law that the judges will face, the charter can safely be ignored. My amendment, which I come to in conclusion, is an attempt to provide some clarity as to what role, if any, the charter may have in the future. In so far as the charter is part of retained law—I appreciate that the definition of retained law is also the subject of debate—there seems no harm in it having some continued existence, in so far as it is necessary for the interpretation of that retained law; hence my amendment. What I find wholly unconvincing is the argument that it should somehow remain, as a non-native species, providing a free-standing source of rights—as in the Goldsmith amendment—or that it should be grafted on, subject to amendments to the Human Rights Act, as in the Wigley amendment. Who will benefit if the charter remains part of our domestic law after exit day? I fear it will not be those whom we rightly wish to protect; it will be the lawyers, and surely we do not want that.
2. Baroness Kennedy of The Shaws    Share this contribution My Lords—
3. Lord Wallace of Tankerness (LD)    Share this contribution My Lords, may I speak to Amendment 63A?
4. Baroness Kennedy of The Shaws    Share this contribution I stood up before the noble Lord, Lord Faulks, sat down as I knew he was coming to an end. He mentioned, and I accept entirely, his position that the Government may have excluded the Charter of Fundamental Rights because ​of uncertainty. But for many people it is an indicator of something else: that Conservative Party manifestos over a number of years have promised that the Human Rights Act would be removed. On many occasions, we have heard leading Conservatives say that we should remove ourselves from the European Convention on Human Rights, too. The absence of the Charter of Fundamental Rights from the Bill suggests to many that this is part of a journey taking us out of any international arrangements dealing with the protection of human rights, and that that is the real purpose.
5. Lord Faulks    Share this contribution The Government’s position has been made quite clear: they have no intention of repealing the Human Rights Act. It is perfectly true that the previous Government said that they would consult on the question and bring in a British Bill of Rights, which would not mean departing from the European convention. Of course, I understand that there are those who are suspicious of this Government’s motives—I do not speak for the Government—but if a Government were hell-bent on getting rid of human rights, they would of course be able to get rid of the charter as well. I do not accept the sinister interpretation of the noble Baroness. The intention is simply to achieve clarity; that is what the Bill is about.
6. Baroness Lister of Burtersett (Lab)    Share this contribution The Conservative manifesto said: “We will not repeal … the Human Rights Act while the process of Brexit is underway but we will consider our human rights legal framework when the process of leaving the EU concludes. We will remain signatories to the European Convention on Human Rights for the duration of the next parliament”. When the Minister replies, can he give us an assurance about the long-term commitment of the Conservative Party to the Human Rights Act?
7. Lord Faulks    Share this contribution No Parliament can bind its successor; one would expect every Government to consider human rights as an ongoing process, and how best to protect them.
8. Lord Wallace of Tankerness    Share this contribution My Lords, I will speak to Amendment 63A, which is in my name and has already been spoken to with great passion by the noble Lord, Lord Cashman. He gave an excellent antidote to a debate that has otherwise been an important but nevertheless cerebral examination of the legal position of the European Charter of Fundamental Rights.

11.15 pm

In his immediate response to the remarks of the noble Lord, Lord Cashman, the noble Lord, Lord Faulks, said that we should not fall into the trap of thinking that more rights are always better. It is important to make it very clear that what my amendment does and what I think the other amendments seek to do is not to give more rights but rather to ensure that the rights that are already there continue after exit day. My amendment makes it very clear that the Charter of Fundamental Rights has the same effect in relation to the interpretation and application of retained EU law on and after exit day as it had immediately before exit day.

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As the noble Lord, Lord Pannick, made perfectly clear, we are trying to help the Government. The Government said in their Explanatory Notes to the Bill that Clause 5(5),

“makes clear that, while the Charter will not form part of domestic law after exit, this does not remove any underlying fundamental rights or principles which exist, and EU law which is converted will continue to be interpreted in light of those underlying rights and principles”.

That is the Government’s stated aim in the Explanatory Notes, but we have already heard that by expressly excluding the Charter of Fundamental Rights the Bill does not deliver what the Government say they want to do. We have heard reference to the opinion for the Equality and Human Rights Commission of Jason Coppel QC, which identifies some ways in which it fails to deliver on that. There is also a position where, as I understand it, for example under convention rights and the Human Rights Act, it has to be the victim who brings a case, whereas, under the charter, others who can establish an interest but who are not necessarily victims can bring forward a case. There are other situations where there is reference to the charter in existing European Union law—and if we have expressly excluded the charter, how are those provisions going to be interpreted?

We know full well that quite properly the courts will look at what is in the Act and not at what is in the Explanatory Notes, and the Act will have expressly excluded the charter. It will not be unreasonable for the courts to ask what Parliament really meant by that and say that it must have had some intent if, when everything else was continued into retained EU law, the charter was expressly excluded. That is why it is important that we hold the Government to what they say in their Explanatory Notes. As the noble Lord, Lord Pannick, indicated, the Prime Minister indicated that she intended that there should be continuity. The provisions we have before us in the Bill do not produce that continuity and this set of amendments tries to ensure that that happens.

The specific amendment that I have tabled—I am grateful to the noble Lord, Lord Cashman, for signing it—ensures that the provisions which the noble and learned Lord, Lord Goldsmith, proposed, which relate to Clauses 2, 3 and 4, extend to Clause 6(3) and (6), encompassing EU case law and retained general principles. We believe that applying the amendment to Clause 6 neatly fits in with the purpose of Clause 6, which is about the interpretation of EU retained law.

There is no reason why the United Kingdom should not be able to continue to apply the rights in the charter to retained EU law. If, as has already been said in this debate, at any future stage it is thought that the rights go too far, that is a matter for Parliament, in the normal process of primary legislation, to change. What we seek to do in this case is to ensure that on the day after exit the law is the same as it was on the day before exit. It is what the Government say they want to do, and that is why I encourage the Government to accept the spirit and the letter of these amendments.

* Lord Lamont of Lerwick    Share this contribution My Lords—

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* Lord Davies of Stamford    Share this contribution My Lords, I do not think I am going to give way to the noble Lord because I have been trying to speak. In the course of this debate, we are not actually going—I shall give way to the Chief Whip.

1. Lord Taylor of Holbeach (Con)    Share this contribution It is the turn of my noble friend.
2. Lord Lamont of Lerwick    Share this contribution My Lords, I shall speak to Amendment 14, the effect of which is to retain the charter as part of domestic law and to retain EU law under which claimants would be able to have domestic legislation struck down on the basis of incompatibility with the charter. Some noble Lords have expressed the view that they were baffled by the exclusion of the charter from this legislation, but I felt that the arguments were put very simply and cogently by the noble and learned Lord, Lord Brown of Eaton-under-Heywood, at Second Reading when he simply pointed out that the charter is only one part of our extensive framework of human rights, that there would be a risk of confusion because of conflict with the ECHR and that what this was doing was complicating the situation to no good purpose. Furthermore, the Secretary of State for Exiting the European Union has produced a memorandum showing how existing rights are being provided for in the legislation and in retained law. He has also gone further and said that if anyone can provide specific examples of rights that are not provided for, he will give the matter due consideration. Various people have suggested various things that may or may not be suitable for inclusion, but they will no doubt be considered by the Secretary of State and could be considered for primary legislation. I asked the noble and learned Lord why he had changed his mind about the incorporation of the charter, which he and Prime Minister Blair strongly opposed in the Lisbon treaty. I do not want to go over that, as I think I made my point, but I suggest to the noble and learned Lord that he had very good reasons for excluding it, and that now is an opportunity—
3. Lord Goldsmith    Share this contribution In fact, this country accepted that the charter would become part of EU law in the Lisbon treaty—it is the ***opposite*** of what the noble Lord said.
4. Lord Lamont of Lerwick    Share this contribution Against the noble and learned Lord’s will. There was also an attempt to get an opt-out, which the European Court of Justice said was not valid. I see that the Minister is agreeing with me. I believe that is a correct account of what happened. It was struck down. The case in which it happened was, I think, Aklagaren v Hans Akerberg Fransson.
5. Lord Pannick    Share this contribution Would the noble Lord accept that there are many areas of EU law which this country has opposed but which have nevertheless become part of EU law? This Bill seeks to exclude none of them from retained EU law, other than the charter. Why is that?
6. Lord Lamont of Lerwick    Share this contribution That is very much my argument. For reasons that I wish to develop, I agree very much with the noble Baroness, Lady Deech, and ​what was said by my noble friend Lord Faulks about the confusion and conflict that this will cause between the role of the European Court of Justice and our own courts. The President of the Supreme Court has already called for further clarification of the relationship the Supreme Court will have with the European Court of Justice. It seems to me, for reasons I am about to give, that this would be made even worse if we incorporated the charter into the Bill and into UK law. The retention of the charter would lead to real problems of uncertainty and confusion. Above all, retaining the charter would give the ECJ even more continued influence over our courts. I accept what the noble and learned Lord has said, that there is going to be a relationship for a while with the jurisprudence of the ECJ, but incorporating the charter will give much more opportunity for what people have called judicial adventurism from the European Court of Justice, as it continues to expand the interpretation of the charter. This is not an obsession of Conservatives. I draw the Committee’s attention to what the late Lord Bingham, I think, said in evidence to the House of Lords EU Committee in 2016. He said that although, “the European Court of Human Rights is a very benign institution … the European Court of Justice in Luxembourg has predatory qualities to it that could be very inimical to some of our national practices”. That is a reference to the expansionist activities of the ECJ. The charter, as many people know, is extremely loosely worded. The risk of leaving the charter in place is that it allows the ECJ, while it still has jurisdiction over us and our Supreme Court, to expand the charter into new areas. I am not suggesting that the rights we have are frozen for ever or should not be expanded, but merely that that is something that should be decided in this country by our Parliament. I am also concerned, because of this and the expansion of activities of the ECJ, that if the charter were incorporated our courts would acquire the power to strike down statute on the basis of incompatibility with the charter, which is the point that the noble Baroness, Lady Deech, was making. The noble Lord, Lord Pannick, referred to the Factortame case, which was a notorious example where an Act of Parliament was actually struck down. We do not want to create another situation in which domestic courts can strike down Acts of Parliament. It is the European Court of Justice that interprets what the charter means within the European Union, so if the charter is incorporated into law, what relationship is then going to exist between the Supreme Court and the ECJ? As the ECJ continues to develop its interpretation of the charter, we would be on a road where we had to take it more and more into account. On the basis of what has been said, we must avoid that confusion. If there are gaps in the rights, we have an opportunity to incorporate them with primary legislation. For example, people have been saying in some of the debates that there are various matters relating to the environment that are not covered. However, we will have a new environment Act and a new environment agency. That seems to me to be the way to cope with any rights that are not fully covered, and it is far better to avoid the confusion of incorporating the charter into UK law.

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* Lord Davies of Stamford    Share this contribution My Lords, I am being persistent this evening because I want to point out the glaring contradiction in the views that have been put forward in support of the Government and of the Bill as it currently stands. The noble Baroness, Lady Deech, says the Charter of Fundamental Rights is a pernicious and dangerous document—“dangerous” was her word—that would lead to courts in this country setting aside laws that they did not like, which would be scandalously contrary to British traditions of constitution and law. On the other side, we have had people, and the noble Lord, Lord Lamont, is the latest example of this, saying the reason why we cannot have the Charter of Fundamental Rights in the Bill and transferred into English law is that it is unnecessary and would be confusing because all the rights are there and some of the rights are already in the corpus of British law. Noble Lords must make up their minds: they cannot say something is a radical and pernicious measure with substantial negative consequences but at the same time say that it has no effect at all and is merely otiose. There is a fundamental contradiction there. The noble Lord, Lord Pannick, noticed the same thing but was not quite so explicit about it as I have been.

1. Lord Pannick    Share this contribution I did my best.
2. Lord Davies of Stamford    Share this contribution There is a confusion in this country that comes up quite frequently. We like to think—we are brought up to think it—that we do not have a written constitution in this country and we do not have constitutional laws. That is totally untrue: the Bill of Rights is a constitutional law; in my view the Bill that we are now trying to repeal, the European Communities Act, is a constitutional law; and the Human Rights Act is certainly a constitutional law. By “a constitutional law”, I mean a law that is generally regarded as foundational and is prayed in aid before the courts and referred to in court judgments across a whole range of subjects. Because of that contradiction, we do not really recognise what is going on and we get ourselves into a frightful confusion. Unlike the noble Baroness, Lady Deech, I am not shocked and offended by the idea that a court could put aside a Bill that was contrary to existing law. The remedy, of course, is quite simple: Parliament can change either the existing law or the previous one. The noble Viscount, Lord Hailsham, my Lincolnshire neighbour, came out with the right solution when he said that the check and the important constitutional protection against a Government with a parliamentary majority acting entirely irresponsibly or even tyrannically is that any Bills they put forward would have to go through both Houses. In that context, one hopes that the House of Lords would act as a guardian of the constitution and be prepared to stand up to the Government and wait for them, if necessary, to bring in the Parliament Act to override it. That would be a considerable check and balance, and it is a very important role of this House that we are there as a long-stop in such circumstances. The noble Viscount, Lord Hailsham, came up with the right solution and I am sorry that I did not sign his amendment, but I certainly approve of it very much, and if he comes forward with something like it at Report, I shall be happy to support it.​

11.30 pm

* The Earl of Listowel    Share this contribution My Lords, it is very late and I shall be brief. My noble friend Lady Deech is absolutely right: we can be very proud of the children’s legislation we have in this country. The Children Act 1989 is an outstanding Act for children. We are good at many things: we have great lawyers, great scientists and great soldiers in this country. Unfortunately, we do not do so well at implementing the law. I am particularly concerned here about children’s rights. Let me quickly give some examples. I have talked to families with a disabled child trying to get access to early years education for their child. They get turned away again and again because the setting does not have the right equipment or staff to deal with them. Look at what is happening in the family courts. They are being overwhelmed by children being taken into care. Year on year, the number of children taken into care increases. Lord Justice Munby, the President of the Family Division, recently said that that is accelerating and that the family courts cannot deal with it. The All-Party Parliamentary Group has looked carefully at why that is over the past two years. It is because there just are not the resources in local authorities to support vulnerable families to stop their children being taken into care. It is very interesting for me to read Article 24 on the rights of the child: “Every child shall have the right to maintain on a regular basis a personal relationship and direct contact with both his or her parents, unless that is contrary to his or her interests”. That right is being compromised day by day in this country. Children are being removed from their families because those families have not had the support they needed to make a go of looking after their child. This is very difficult and the Government have very difficult choices to make, but if you talk to social workers and academics, you find that this right is being compromised day by day. I know that the Conservative Party, in particular, is concerned to see that families are strong and integrated. I am sure that the Minister will tell me on this article that there are already strong protections in British legislation to ensure that the best interests of the child are maintained and their families are supported to prevent this happening. What is happening on the ground, however, is that because social workers wish to safeguard the children, and because the threshold of access to a social worker is so high, they are getting to see the family when it is in crisis, when things have got to a terrible pass and they think that the interest of the child lies in removing the child from this terrible situation. If we applied this principle properly, we would be intervening earlier to support those families. We see great examples of that. For instance, the family drug and alcohol court, which is expanding across the country, is supporting parents to get them off drugs and alcohol so that they can keep their children. A number of important protections for children are laid out here: access to education and so on. I will have a look at the Joint Committee on Human Rights report to see what is exempted here. There is lots of good legislation for children in this country, but when I look at what goes on on the continent in terms of ​security of tenure in housing or quality of professional care for vulnerable children, I fear that so often they do so much better. My prejudice is that we need this sort of thing. I worry about the elective dictatorship. We get small groups of very wise and intelligent people leading this country from the way we work constitutionally, and the breadth of experience, the people who get left behind, those just managing families, get forgotten about in the drive to do one or other very good thing which eclipses every other consideration. Being as explicit as one can about the rights of children and the protection for families can be very helpful. We will come back to this, and I look forward to debating it further, but on that specific article, I should be grateful for reassurance as to how it will be protected in future.

1. Lord Newby (LD)    Share this contribution Before the noble Lord sits down, I know how concerned he is about the rights of children, but I wondered whether he had read the joint submission from the Children’s Rights Alliance for England and Together (Scottish Alliance for Children’s Rights), which argues forcefully and at length, with many details, and gives many examples of why they wish to have the fundamental charter retained. Why does he disagree with them and wishes it not to be?
2. The Earl of Listowel    Share this contribution I am sorry; it is late. I would like in principle to retain the charter. The UN Convention on the Rights of the Child is not part of British law, and the charter has been a means of channelling the principles of the UNCRC into British law. We need that. The minimum age of criminal responsibility in this country is 10 years old; we can lock up children of 10 years of age. Even in Turkey—with respect to Turkey—it is 16, and 14 around the continent. We are really harsh with our children and we need such protections.
3. Lord Blencathra    Share this contribution My Lords, as the tail-end Charlie in this debate, I too shall be brief. I believe that there is nothing fundamental about this so-called charter. It was a political wish list cobbled together by the EU in the year 2000, incorporated into the Lisbon treaty in 2009, and opposed by every Labour Government Minister. In fact, Gordon Brown would not even go to Lisbon on the first day to sign it. He wanted to distance himself from it. It includes such meaningless waffle as the right to “physical and mental integrity”, and such wonderful new rights as the right to marry and the right to freedom of thought. As the noble and learned Lord, Lord Brown of Eaton-under-Heywood, so cleverly exposed, my right to freedom of thought seems to apply only to the 20,000 EU laws. If I am thinking about any other UK laws, the charter does not seem to apply. Of course, the charter contains the fundamental right to a fair trial. Well, 803 years ago, this noble House put the right to a fair trial in Clause 39 of the Magna Carta. That is the most important fundamental right of all, which we have had for more than 800 years. The Magna Carta was also known as the “Great Charter of Freedoms” and the late Lord Denning called it,​ “the greatest constitutional document of all times—the foundation of the freedom of the individual against the arbitrary authority of the despot”. That is what our predecessors in this House did—not the King, not a foreign court but this noble House.
4. Lord Davies of Stamford    Share this contribution Does the noble Lord recall that the Magna Carta was in 1214, and that the first Parliaments began to sit in the 1270s?
5. Lord Blencathra    Share this contribution The Magna Carta was imposed on King John by the Barons, as I understand it—the Barons being Members of this noble House. The House did not exist in that form, but it was imposed by the Lords and the Barons. The House of Commons passed the Bill of Rights 350 years ago and imposed it on the sovereign, guaranteeing our rights to free elections, no taxes without parliamentary approval and free speech. The Bill of Rights passed 350 years ago by this Parliament formed the basis of the United States Bill of Rights and Bills of rights of other countries around the world. Then just 70 years ago, we used our unique experience to write the European Convention on Human Rights—largely written by British lawyers. We wrote that for countries which had no history of our fundamental freedoms and had suffered the evils and degradations of National Socialism. What I am saying is that the worst indictment I make of the EU is that it seems to have destroyed the belief among parliamentarians, noble Lords and Members of Parliament that we are capable of governing ourselves and writing our own law. There is nothing of any value in the Charter of Fundamental Rights which is not already covered in UK law or the European convention. If we find some great new right in the future and decide that freedom of thought must become a law, are we incapable in this House, in the other place and as British parliamentarians of drafting that? Are we so enfeebled and incapable that we cannot do it? If the Barons could do it 800 years ago, Members of Parliament 350 years ago and the British Government and parliamentarians did it for Europe 70 years ago, are we so incapable that we cannot do it now? The people of this country voted to bring back control of our laws because they believed that Parliament was capable of making better laws than the EU. They believed that we are better at deciding on our essential rights than an ECJ judge from Bulgaria who has a law degree in Marxist-Leninist law—I have checked on that, and he has got a degree from Sofia on Marxist-Leninist law. I happen to agree with the British people. I see the incredible wealth of talent in this House, with noble and learned Lords and Law Lords, and I trust our courts. We do not need nor want this charter. Let us wear once gain the mantle of our predecessors in the Lords and Commons, who gave us every freedom that has been worth fighting and dying for for the last few hundred years. We need the courage of the electorate, who trusted us to make our own laws once again. We should not let them down.
6. The Advocate-General for Scotland (Lord Keen of Elie) (Con)    Share this contribution My Lords—

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* Noble Lords Minister!

1. Baroness Ludford (LD)    Share this contribution My Lords—
2. Noble Lords This side!
3. Baroness Ludford    Share this contribution There are several more speakers, I am afraid, including me.
4. Baroness Whitaker (Lab)    Share this contribution My Lords, in briefly supporting those amendments that seek to retain the charter, I owe your Lordships an apology. I ought to have declared that I am a member of the advisory board of the British Institute of Human Rights at Second Reading, but I forgot. I am not a lawyer, but I respectfully submit that law is not primarily for lawyers, any more than water is for water engineers—it is for people to implement the central values of our democracy on their behalf, and the deprivation of rights and access to justice causes harm, unfair poverty, unfair unhappiness and, in some cases, unjustly shorter lives. That is the sort of thing we should be thinking of when we look at these amendments. I shall just give three quick examples, much humbler than those of Mr David Davis. The general principles and the charter ensured that Mr John Walker could challenge and end pension inequality for same-sex couples. The charter and the general principles supported the recent case in the Supreme Court, which found employment tribunal fees implemented by the Government were unlawful. And the charter enabled the recognition of the importance of health as a fundamental right—not in our law—when tobacco companies challenged regulations to introduce plain packaging of cigarettes. It seems extremely clear that dropping the charter will do away with protective rights and drop safeguards that have ensured justice in individual cases of injustice. It is individuals who we ought to be thinking about, and rights that would not otherwise exist that we ought to safeguard in the charter.
5. Baroness Ludford    Share this contribution My Lords, the Benches ***opposite*** have been well filled to harry the noble and learned Lord, Lord Goldsmith, about fundamental rights. Sadly, they were not here for the previous debate to speak up for achieving a fundamental right to safety and security. I fear that parts of this debate have displayed a fundamental misunderstanding about the EU Charter of Fundamental Rights. There has been evidence of some quite muddled thinking. The charter is not a tool that extends the remit of EU law or promotes further integration; it protects citizens and businesses from abuse of the powers that EU laws confer on EU institutions and—I have to say to the noble Lord, Lord Faulks—on national Governments when they are implementing EU laws. So it is not just about all the EU institutions that we might leave; it is about achieving legal certainty and continuity. ***Deleting*** the charter means discontinuity by making substantive changes to the EU law that is retained in domestic law.​

11.45 pm

I have to say to the noble Lord, Lord Blencathra, that his was a very entertaining speech but, I am afraid, he fundamentally misunderstood the whole purpose of the Bill, which is to retain EU law. In the Bill’s treatment, not only of the charter but also of the general principles of EU law, which the Government propose to allow no right of action on, human rights laws are an exception—different from any other sector. This is entirely at odds with the stated purpose of wholesale transfer of EU law on to the domestic statute book and completely undermines the government assurance that the same rules will apply on the day before exit as the day after. It is completely at odds with the stated aim of taking a snapshot of the current body of EU law.

The Government have been entirely inconsistent over time about the charter, as the noble Lord, Lord Davies, said. In the context of this Bill, they say: “Oh, it adds nothing”, while at other times they bemoan the fact that it adds an undesirable extra layer of rights. If we keep EU law but not the charter it is like “Hamlet” without the Prince—and I am sure we would not want that. There would, no doubt, need to be some housekeeping on the Bill once the principle of retention had been secured. There has been some support for the amendment in the name of the noble Viscount, Lord Hailsham, but that bridge can be crossed once the principle has been secured.

In response to the noble Lord, Lord Lamont, the Brexit Secretary, David Davis, who was an original party to the so-called Watson case on Dripa, relied on the charter; he must have found something in it that was not in existing data protection law. In one of those “couldn’t make it up” moments, I read that Jacob Rees-Mogg has said that EU sanctions for UK breach of an agreement with the EU—an entirely reasonable proposition—would be,

“against the EU’s own Charter of Fundamental Rights”.

So we have Jacob Rees-Mogg, the chairman of the so-called European Research Group, joining David Davis in finding it useful.

Time does not allow me to mention other cases. Earlier I mentioned the European arrest warrant, which would not work without the charter. Data transfers are the same. There was another speech this evening by a junior Trade Minister assuring the tech industry that there would be frictionless, seamless data flows after Brexit. That will not happen without the Charter of Fundamental Rights in domestic law. As the noble and learned Lord, Lord Goldsmith, said at Second Reading, wanting to make the Bill fit for purpose is not putting a spanner in the works: it is making the Bill actually work.

* Baroness Lister of Burtersett    Share this contribution I will make one brief point that no noble Lord has yet made about Northern Ireland, which I know is of concern to many Members of this House. At Second Reading, citing the Bingham centre and Lady Hermon, I asked the Minister to explain how the requirement in the Good Friday agreement for an equivalent level of human rights protection in Northern Ireland and the Republic would be maintained if the citizens of the former could no longer look to the charter. In his helpful letter to ​Peers, the Minister pointed out that the agreement preceded the charter and, as the charter is therefore not referenced in the agreement, the Bill should not affect our obligations to it. But the point is about equivalence. If the charter now applies in the Republic and not in Northern Ireland, with the loss of various rights in the latter, I ask again how that equivalence is to be maintained.

1. Baroness Deech    Share this contribution I will make a point that has not been made before. The charter has never been scrutinised by this House. If it had been, we would not have this lack of clarity. I have more confidence in the ability of our Supreme Court to protect us than I have in the ECJ. Bearing in mind what the noble Lord, Lord Cashman, said, what a failure the charter has been across Europe. The Roma are being persecuted, migrants are not getting proper treatment, the leaders of Catalonia are being locked up and extremist, right-wing parties are on the march. Freedom House is marking down European countries; they are sliding away from human rights. I am not proud of the charter; it has not worked in Europe. We are much better off with something home-grown and administered by our Supreme Court.
2. The Advocate-General for Scotland (Lord Keen of Elie) (Con)    Share this contribution My Lords, if I appear faint in my defence of the Bill it is due to a lack of food rather than a lack of enthusiasm. I am grateful for the opportunity to respond to this important debate and set out the Government’s position. I will start by making it clear that we are listening carefully to the debates on this issue, and will continue to do so. The Government agree that protecting our rights and liberties as we leave the EU is of critical importance and it is only right that every detail of our approach is scrutinised. This has been a wide-ranging debate about human rights after exit, but it is worth remembering that the amendments before us relate specifically to the charter and the question of what role, if any, it should have in domestic law when we are no longer a member of the EU. I maintain that the approach in the Bill to the charter as a document is absolutely right, and that the Bill in this respect is in no need of improvement. However, as many noble Lords have pointed out, that approach cannot be separated from the Bill’s approach to the general principles of EU law, including fundamental rights. In response to the strength of feeling conveyed not just in this House but in the other place, the Government are looking again at these issues. These are highly technical issues in some respects but they are undoubtedly important, so we will look further at whether this part of the Bill can be improved in keeping with some of the concerns that have been expressed. Indeed, my noble friend Lord Lamont referred to an observation made by the Secretary of State himself that, if there were specific examples of rights which were not otherwise covered, we would examine them to ensure that the rights were not lost. However, that is not the case. On the specific question of whether the charter should be kept, our view remains that not incorporating the charter into UK law should not in itself affect the substantive rights from which ​individuals already benefit in the United Kingdom. This is because the charter was never the source of those rights. The noble and learned Lord, Lord Goldsmith, anticipated that he might be reminded of his previous remarks on the matter, and I see no reason to disappoint him. In 2008, when this House debated the then European Union (Amendment) Bill, he was absolutely clear that, “the charter was never intended to be applied directly to member states in dealing with those matters that member states have the competence to deal with. It was always intended to constrain the European Union institutions … the United Kingdom’s position, like my position, has always been that the charter affirms existing rights, it does not create any new justiciable rights in any member state and does not extend the power of the courts. Moreover, in many cases the charter rights are based on national laws and practices and so they must mirror the extent and content of those national”,—[Official Report, 9/6/08; cols. 426-27.] laws. The noble and learned Lord observed that he had nevertheless then encountered the incorporation of the charter into the Lisbon treaty in 2009. Perhaps that was a game changer. I remind him of his evidence to the European Scrutiny Committee in 2014. At that time he referred back to his previous statements and publications with regard to the charter and went on to say that, as he had there explained, the fundamental point was to provide a clear and accessible statement of existing rights and therefore constraints on the power of the EU to legislate. As the noble and learned Lord’s previous remarks help to make clear, the charter is only one of the elements of the UK’s existing human rights architecture. It reaffirms rights and principles that exist elsewhere in the EU acquis, irrespective of the charter, and the Bill sets out how those rights and principles will continue to be protected in UK law after exit. The noble and learned Lord referred to a number of issues, such as the case of Benkharbouche in 2017 in the Supreme Court. In that case the court found that there was a breach of Article 6 of the convention but it also referred to Article 47 of the charter in the context not of rights but of remedies. One has to bear in mind the distinction between rights and remedies. The noble and learned Lord posed three questions in the context of previous observations about the charter. First, he talked about there being no loss of substantial protection. It is inevitable that leaving the EU will result in changes to the current arrangements, but certainly we do not accept that this in itself will result in a loss of substantive rights. Secondly, he referred to the procedural protections that will be excluded. When we leave the EU, a person can still rely on sources that are reaffirmed in the charter. I emphasise “reaffirmed in the charter”, as he himself observed in 2008 and 2014. Procedurally there may be differences but we do not consider that that can be a basis for incorporating the charter into domestic law. Indeed, we absolutely stand by what has been said by the Prime Minister: it is not necessary to retain the charter to ensure that rights are protected. The noble and learned Lord also referred to the body of the charter, beginning with Article 1, and suggested that these rights were contained only in the charter. I simply observe that on 5 December last year ​the Government published a very detailed paper setting out, as it were, a comparison of the rights in the charter and where they can be found elsewhere—in the convention, in the principles of EU law and in our own common law. The noble and learned Lord referred to Article 1, which concerns the right to human dignity. I remind him that there is a long series of case law both from the ECJ, as it then was, and from the European Court of Human Rights going back to 1995 in which, for example, the convention court emphasised that the very essence of the convention is respect for human dignity and human freedom. That has been repeated in a whole series of cases since then. These are well-established rights and they were well established when they were brought together into the charter. I want to reassure noble Lords that substantive rights protected in the charter are, and will continue to be, protected elsewhere in UK law after we leave the EU, most notably in convention rights, in retained EU law, in the common law and via specific statutory protections such as those in our own equalities legislation. I have already mentioned that the Government published a detailed analysis providing guidance about how substantive rights found in the charter would be reflected in domestic law after exit. Reference has been made to various legal opinions and that of Jason Coppel QC, who has had a number of name checks this evening. I can only implore noble Lords to look at the very detailed analysis the Government have produced. I also note that some of the references to Mr Coppel’s opinion involve references to his concern that Ministers might change rights, for example, or that the procedures will be affected. However, that is not to say that the fundamental rights underlying the charter are not found elsewhere.
3. Baroness Hamwee (LD)    Share this contribution My Lords, the noble and learned Lord quite rightly draws our attention to the distinction between rights and remedies, but he will agree that rights are not helpful unless there are remedies. If we were scrutinising the charter and the source of its rights to establish whether we were satisfied that the rights and remedies could still apply, we might, for instance, have noted that the sources of Article 1 mentioned in the analysis would not confer an enforceable right on individuals after exit day. That is the JCHR’s analysis of the analysis. I hope that the Minister can answer the question asked, in particular, by the noble Lords, Lord Pannick and Lord Kerslake, about why we have combined the two debates—one about the charter, its rights and wrongs and whether it is good or bad, and the other about the mechanisms. We have heard so often from the Government Front Bench that this Bill is about mechanisms. Why are the Government not using the mechanism they have themselves designed to give them the opportunity, and to give the Committee the opportunity, to consider the substance calmly after the chimes of midnight?

12.00 pm

* Lord Keen of Elie    Share this contribution Quite simply because, as I indicated earlier to the Committee, the rights underpinning the charter exist elsewhere than in the charter and it is not ​necessary to incorporate the charter into domestic law in order to find those fundamental rights in our domestic law after we leave the EU.

1. Baroness Lister of Burtersett    Share this contribution I am sorry to interrupt, but the analysis by the Joint Committee on Human Rights to which the noble Baroness referred, which is an analysis of the Government’s analysis, identified a number of rights that are not there other than in the charter. Does the noble and learned Lord reject the JCHR’s analysis?
2. Lord Keen of Elie    Share this contribution We have considered that analysis, and that is why I indicated that we were still looking at this. As I said, if rights are identified which are not in fact going to be incorporated into our domestic law in the absence of the charter, we will look very carefully at ensuring that those are not lost. Clause 5(5) makes it clear that, notwithstanding the non-incorporation of the charter, retained EU law will continue to be interpreted by UK courts in a way that is consistent with the underlying rights. I hope that addresses to some extent the issue raised by the noble and learned Lord, Lord Wallace, in that context. Interpretive provisions will retain a means by which we can look at these rights in the proper context. With regard to those who have expressed concerns about this Bill resulting in a loss of substantive rights, I repeat—as the noble and learned Lord, Lord Goldsmith, has done, at least prior to his recent Pauline conversion—that it is not necessary to retain the charter to retain those fundamental rights. If we see that there is a potential loss of such fundamental rights, we will address that, and that is what we have indicated.
3. Lord Pannick    Share this contribution I put it to the noble and learned Lord that there is no other area of retained EU law where the Government have carried out this exercise or said that we do not need to read across a particular provision because it is already in domestic law. Why are they making an exception of the charter?
4. Lord Keen of Elie    Share this contribution Because this is the only case in which we have identified that situation. There is no other reason for proceeding in this way except for that.
5. Lord Wallace of Tankerness    Share this contribution If, as the noble and learned Lord said on numerous occasions in his reply, the rights established in the charter are already there in our domestic law, what is lost by keeping the charter? If those rights are already there, the Government cannot be worried about anything if they retain the charter.
6. Lord Keen of Elie    Share this contribution I must compliment the noble and learned Lord on his second sight. As I was about to say, the next argument put to us is that if we say that the charter is not adding anything, what is the problem with keeping it? I hope that is a fair summary of the noble and learned Lord’s intervention. With respect, this argument simply fails to take account of how the charter applies at present. The charter and the rights that it reaffirmed have a limited application. They apply to the EU institutions all of the time, but apply only to member states acting within the scope of EU law. We will no longer be a member state and so we ​will be no longer acting within the scope of EU law. Simply retaining the charter would not reflect the realities of leaving the EU. It cannot be right that a document called the Charter of Fundamental Rights of the European Union could continue to be used as the justification to bring cases that would lead ultimately to the striking down of UK primary legislation after we leave the EU. Outside our membership of the EU, it is simply not appropriate to retain the charter. There are also practical questions to consider. It would be no simple matter to say that we are keeping the charter. The amendments in this group all attempt, in various ways, to solve the riddle of how an instrument inherently linked to and constrained by our membership of the EU could apply purely domestically. They each highlight the complexity involved in such an exercise. In Amendment 13A, the noble and learned Lord, Lord Goldsmith, requires the Government to lay a report on how the charter will continue to apply to retained EU law after we leave the EU. However, his other amendments are far from clear on precisely how he intends the charter to have effect domestically after exit. They would remove the exclusion of the charter provided for in Clause 5, presumably with the intention that it would now form part of retained EU law. I note that one of his amendments would excise the definition of what the charter is from the Bill, despite going on to say that this undefined, unclear thing will continue to have effect in relation to retained EU law under Clauses 2, 3 and 4. What would our courts make of that? Many articles of the charter set out principles, not rights, which can be relied on directly by individuals. How would these have effect after exit? Eight articles of the charter constitute rights intrinsically linked to EU citizenship—for example, the right to vote in an EU parliamentary election. Of course, they claw at the air—we appreciate that—but they do nothing. Let us pause again on the fact that the charter applies to member states only when acting within the scope of EU law. Presumably, if retained under the Bill, the charter would then apply only when we were acting within the scope of retained EU law, which I believe is the elaboration that the noble and learned Lord made in response to the noble and learned Lord, Lord Brown of Eaton-under-Heywood. Over time, our domestic law will evolve and new laws will be made by this sovereign Parliament and the devolved legislatures that will start to replace and supersede this category of retained EU law. We would be retaining the charter, in whatever capacity the noble and learned Lord intends, only for an ever-diminishing proportion of our law. This further risks incorporating complexity and confusion into our domestic statute book. We should not overstate the accessibility of the current rights regime, which relies on citizens knowing—
7. Lord Beith (LD)    Share this contribution The noble and learned Lord is right in that assertion, but it does not follow that retained European law should not be read across in the form of the charter as well as its other features on exit day. Lots of things will change over time. Parliament will no doubt amend retained European law so that it ceases to be retained European law, but the Bill is ​about legal continuity and what the situation is on exit day. For this purpose, surely the Minister should accept what is being proposed.
8. Lord Keen of Elie    Share this contribution I entirely agree with the noble Lord as to what this Bill is about. With regard to the charter, the point is that it does not bring anything over on its own. We already have these rights and obligations, as established by the principles of EU law, convention law and the common law. As to a concern that something is omitted at the end of the day, as I indicated, we would address that to ensure that all rights are brought across. However, with great respect to the noble Lord, Lord Cashman, I do not believe that you can never have too many belts and braces. If you have too many belts and braces, eventually you cannot stand up. It is therefore important that we approach this issue with a degree of proportionality, if I may use a European term. Following on from the point I made earlier, retaining the charter for what will become a fluid and changing category of law risks legislatively binding us to a document that would bring the illusion of clarity in the short term but serve only to undermine it in the longer term. Indeed, the other amendments in this group raise similar issues to those put forward by the noble and learned Lord, Lord Goldsmith. My noble friend Lord Hailsham has tabled amendments that seek to build on the amendments put forward by the noble and learned Lord, Lord Goldsmith. They seek to assign the status of primary legislation to the European Charter of Fundamental Rights. For reasons that we will go into in a later group, the Government believe that the question of assigning status to retained EU law is complex and should be approached with caution. I hope that we can come back to this question when we have concluded our debate on the approach to rights protection and to status more generally. I will not seek to take up time on that issue at this stage. I suspect that the amendment tabled by the noble Lord, Lord Wigley, would also add to the confusion. Seeking to afford charter rights the same level of protection as convention rights under the Human Rights Act 1998 is fraught with difficulty. Charter rights do not correspond exactly to ECHR rights and apply in different ways. The charter also contains non-justiciable principles as well as rights, and it is unclear what status these would have in domestic law under his amendment. Moreover, it does not deal with how explanations to the charter articles should be treated or how certain sections of the Human Rights Act would apply to charter rights. I appreciate that we are in Committee and that the noble Lord is entitled to say that he will look more carefully at the form of the amendment and perhaps elaborate upon it in due course, but there are fundamental difficulties with the approach he is attempting to take in simply trying to incorporate the charter when, as indeed the noble and learned Lord, Lord Goldsmith, himself observed, the expression of rights in the charter does not coincide precisely with the expression of rights in the convention. I would like to emphasise again that we remain committed to listening to this House and indeed to working constructively to ensure that we have a ​functioning statute book which maximises legal certainty. I understand the concerns expressed by some about whether some rights would somehow be left behind, but if we can and do identify a risk of such rights being left behind, we are entirely open to the proposition that we have to address that by way of amendment to the Bill, and we will seek to do that. I wish to reassure noble Lords on that point.
9. Lord Adonis    Share this contribution My Lords, can the noble and learned Lord give us any indication of when he thinks that that exercise will be completed?
10. Lord Keen of Elie    Share this contribution The potential answer is no, and the note says that my time is up. Nevertheless, and be that as it may, we will endeavour to address these issues as soon as we can. Clearly it will require us to consider not only the position we have adopted already in the document published in December last year, but to take into consideration the concerns expressed by other lawyers and in this Committee in the course of the debate. We will look at those and we will want to address them at the next stage of the Bill; of that, I am confident. At this stage I appreciate that there are some questions which I have not directly answered in the course of my response and it may be difficult to do so in the time remaining. Perhaps I may say that I endorse entirely the observations of the noble Baroness, Lady Deech, and of the noble and learned Lords, Lord Hope and Lord Brown of Eaton-Under-Heywood, with regard to the potential difficulties of simply drawing the charter over into domestic law. I am not going to elaborate on the consequences of doing that, but they can be summarised as confusion, uncertainty and difficulty, and ultimately could prove to be counterproductive. In these circumstances, I invite the noble and learned Lord to consider withdrawing his amendment.
11. Lord Goldsmith    Share this contribution My Lords, I am very grateful to all noble Lords and noble Baronesses who have taken part in the debate. It has been wide-ranging, as we anticipated it would be. I am grateful to the noble and learned Lord for his remarks. I shall obviously not spend long on what I say now, given the hour. As we ​approached midnight, I was looking around the corner to see whether a pumpkin would arrive with horses. I was not sure whether it would be for me or for the noble and learned Lord ***opposite***.

12.15 pm

I have three points in conclusion. I am grateful that the noble and learned Lord said that the Government are still looking and will continue to look at these issues. He has heard strong expressions of opinion from a number of noble Lords that there is a problem with what the Government are doing and they should think again about it. I urge that to be done. Secondly, he suggested that the way to do that would be for others to identify omissions from the protection that the Bill provides and present them to him or the Government. With respect, that is the wrong way to deal with it. The Government themselves have set about this by saying that they will incorporate the entirety of EU law on exit day and then change it through the processes provided in the Bill or through the possibilities in this House. That is the approach we strongly recommend that the Government should follow. It is what the Prime Minister said would happen and it is what ought to happen. That will allow the sort of debate and scrutiny that will take place. But, thirdly, if it helps in getting to that position for us to sit down with the noble and learned Lord and his officials to go through some of these technical issues, which there are, I am very happy that we should do that. Having said that, I beg leave to withdraw the amendment.

Amendment 13A withdrawn.

Debate on whether Clause 1 should stand part of the Bill.

* Lord Adonis    Share this contribution My Lords, we have been debating Clause 1 for 18 hours and three-quarters. That is probably enough, so I shall not prolong the debate any longer.

Clause 1 agreed.

House resumed.

**Load-Date:** February 28, 2018

**End of Document**

1. 1As a result of the combination between the 2, 4, 6 levels of relatedness (primary NAICS matches) and 1, 2, 3 levels (secondary NAICS matches), value 5 is, by construction, excluded from the scale. [↑](#footnote-ref-2)
2. 2The change in acquirer-to-target relatedness has been measured as a change from 0 to 1 in our six-level relatedness scale. Given our choice of ordered logistic regression as estimation method, the marginal effects associated with changes in other levels of product relatedness are very similar to those commented here. As example, when measured as a change between the two upper levels of acquirer-to-target relatedness in our scale, cross-border acquisitions for foreign country entry are associated with a 23.6 percent increase of the probability of higher product relatedness, if compared to domestic acquisitions. [↑](#footnote-ref-3)