January 16, 2018

Submitted via: www.regulations.gov

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 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 [CMS-4182-P]

Dear Administrator Verma:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the 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 (hereafter referenced as the proposed rule or NPRM) as published in the Federal Register on November 28, 2017.

PCMA is the national association representing America's pharmacy benefit managers (PBMs) which administer prescription drug plans for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid and the Federal Employees Health Benefits Program, as well as the Exchanges established by the Affordable Care Act (ACA).

The Medicare Part D program is a tremendously successful program that relies upon private plans operating in a competitive market to promote affordability and beneficiary satisfaction. Evidence of the success of this strategy includes low beneficiary premiums, high beneficiary satisfaction, taxpayer savings, and better health outcomes. We share your interest in exploring ways to improve the program while avoiding changes that would raise costs or disrupt the benefits seniors currently enjoy.

Our comments are divided into two parts. The first part addresses the provisions in the proposed rule, many of which we strongly support while others – most notably Any Willing Pharmacy (AWP) – raise significant concerns. The second part responds to the Request for Information (RFI) regarding the application of manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale (POS). After thoroughly reviewing the ideas in the RFI, we agree with CMS's assessment (found in Tables 10 and 11 on Pages 56425 and 56428, respectively) that they would raise premiums for beneficiaries, expose taxpayers to higher costs, and offer a significant windfall to brand manufacturers. The fundamental problem is that these ideas focus on

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micromanaging how plans use existing price concessions for Medicare beneficiaries, but do nothing to reduce the high prices set by drugmakers. It also imperils efforts to improve pharmacy performance. We see no way to implement the ideas in the RFI without significantly increasing costs to the program and most of those it serves.

In summary, PCMA's comments on the NPRM consist of this letter, and the attached comments on the proposed rule (Part One) and on the RFI (Part Two). All of this material should be reviewed by CMS in its entirety as our complete comments.

NPRM Provisions We Support

To begin, PCMA appreciates several of the changes CMS proposes in the NPRM. In particular, we would like to highlight the following:

1. **Medical Loss Ratio (MLR)**. Given the central and increasing role of fraud, waste, and abuse (FWA) reduction and medication therapy management (MTM) efforts in the Medicare program, we strongly support the proposal to include all expenditures in connection with fraud prevention and MTM-related activities as quality improvement-related expenditures.

2. **Treatment of Follow-On Biologics**. PCMA appreciates CMS's proposal to revise the definition of generic drugs to include follow-on biological products for purposes of cost-sharing. Lower cost-sharing for lower-cost alternatives will improve beneficiary incentives to choose follow-on biological products over more expensive reference biological products and will reduce costs to both Part D beneficiaries and the Part D program.

3. **Midyear Formulary Change**. Permitting expedited midyear formulary changes will allow Part D plan sponsors to act more quickly on newly available clinical information and to respond more timely and effectively to changing market dynamics.

4. **Days' Supply under the Part D Transition Process**. We appreciate the proposed modification of the transition rules, which will eliminate additional drug waste and costs by no longer requiring a longer transition days' supply in the long-term care setting and by making the transition days' supply be the same as in the outpatient setting.

5. **Part D Special Election Period (SEP)**. PCMA supports the proposal to discontinue the continuous SEP available to dual eligible beneficiaries. As CMS notes, this proposal would create greater stability among plans and limit the opportunity for aggressive marketing to dual-eligible individuals.

6. **E-Prescribing Standards**. PCMA supports the CMS proposal to implement the NCPDP SCRIPT version 2017071 for certain specified new transactions, as identified by CMS in

the proposed regulation. We also recommend at a minimum a 24-month implementation of the NCPDP transaction standard from the date the final rule is published.

7. **Other Issues**. We strongly support and thank CMS for proposals to provide significant new flexibility for Part D plan sponsors, including new flexibility in the marketing requirements, elimination of the meaningful difference requirement, the change in the required delivery date of the plan documents and the ability to allow Part D plan sponsors to provide these documents in electronic format, which will create plan efficiencies while also reducing beneficiary confusion. We also support the improvements in the tiering exceptions policy, although some issues continue to need to be addressed, such as the definition of alternative therapies. Finally, while we appreciate CMS's intent to alleviate the burden on first-tier downstream and related entities (FDRs) by eliminating the federal training requirement, we are concerned that this change may inadvertently increase the burden on FDRs that contract with multiple Part D plan sponsors.

Concerns with the NPRM

We have major concerns with the following proposals:

1. **Any Willing Pharmacy Standards Terms and Conditions**. We are very concerned by CMS's AWP discussion and proposals. Aside from its departure from the statutory authority for preferred networks, this proposal fundamentally undermines the current competitive and well-functioning Part D landscape and will make it more difficult for Part D plans to have important quality and other appropriate standards in their pharmacy networks. The discussion and proposed regulatory changes also undermine Part D plan sponsors' ability to negotiate lower prescription costs for beneficiaries and will result in federal government cost increases. Additionally, the AWP content interferes with plan/pharmacy contracting relationships, contrary to statute and the competitive principles that have kept this program affordable for beneficiaries. CMS should reconsider the discussion it sets out in the preamble regarding the current regulatory landscape and its proposed changes to the AWP rules.

2. **Implementation of the Comprehensive Addiction and Recovery Act of 2016**. PCMA supported the passage of the lock-in provisions in CARA and appreciates CMS for undertaking the process to get the lock-in implemented under Part D. We also support the flexibility to lock the beneficiary into a specific prescriber(s) or specific pharmacy or both, based on the utilization behavior of the beneficiary. However, we are very concerned that the proposal to require a Part D plan sponsor to wait at least six months from the date the beneficiary is first identified as a potential at-risk beneficiary before limiting that beneficiary to a given pharmacy or prescriber for frequently abused drugs works against the goal of CARA and indeed defeats the whole purpose of the lock-in program, which is to take steps quickly to reduce medication abuse in the Part D program. Without timely intervention, patients will continue to utilize opioids inappropriately. Furthermore, it is essential that CMS both preserve the flexibility of the

current Drug Utilization Review (DUR) and Overutilization Monitoring System (OMS) programs while also providing flexibility for Part D plan sponsors and their PBMs to develop and implement their lock-in programs.

3. **Prescriber Enrollment/Preclusion List**. CMS proposes an alternative approach to create a risk-based "preclusion list" that targets "demonstrably problematic prescribers," rather than "require the enrollment of Part D prescribers regardless of the possible level of risk posed." While PCMA supports the concept of a "preclusion list" as a way to ensure beneficiary safety and safeguard the program, we are concerned that if this proposal is implemented as is, it could unnecessarily increase complexity in the Part D program, expose Medicare beneficiaries to problematic prescribers, and perpetuate a cycle where there is insufficient time to implement complex new requirements that have substantial operational challenges. To mitigate some of these issues, we recommend that CMS create and manage a single prescriber preclusion list that is modeled after the OIG excluded provider list so the two files can be handled in a similar manner, including the elimination of the provisional supply requirement. We also recommend that CMS provide sufficient time to test and implement the new approach.

4. **Star Ratings**. PCMA generally supports the CMS effort to codify the existing Star Rating System with the changes proposed by CMS, subject to some suggestions. Specifically, PCMA recommends that a number of current measures be removed or downgraded. We also continue to be concerned with the use of civil money penalties and audit data in Star Measures. CMS should not include measures that rely on audit findings as the primary data source. While PCMA supports the changes related to contract consolidation, we suggest that CMS clarify that the changes not take effect for the 2019 plan year. Regarding measure-level Star Ratings, PCMA recommends that CMS use this opportunity to identify a methodology to determine cut points that more accurately reflect industry performance and that are not as susceptible to influence by outliers.

<u>Concerns with the RFI</u>

We have significant concerns with the RFI, which, if implemented, would require all Part D plan 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 POS. As set forth in Part Two of our comments, we urge CMS not to pursue any policy based on the content of the RFI for several reasons, including:

1. If formally adopted, the content of the RFI would violate at least four separate provisions of the Part D statute as well as the Trade Secrets Act. Moreover (and regardless of its legality under Medicare Part D), if CMS were to proceed to summarily adopt the policies in the RFI, it would raise significant concerns under the Administrative Procedure Act (APA).

2. Requiring POS rebates in Part D would significantly increase costs to the program, most beneficiaries and taxpayers. According to CMS estimates in the RFI (in Table 10 on Page 56425), requiring 100 percent of rebates to be passed through at POS would, over the next 10 years, increase government costs by $82.1 billion; increase beneficiary premiums by $28.3 billion (an 11 percent increase); and provide a windfall to drug manufacturers of $29.4 billion.

3. Requiring all Part D pharmacy DIR to be passed through at POS would also increase costs to the program, most beneficiaries and taxpayers. CMS estimates (in Table 11 on Page 56428) that requiring 100 percent of pharmacy DIR to be reflected at POS would, over the next 10 years, increase government costs by $16.6 billion; increase beneficiary premiums by $5.7 billion (an additional 2 percent increase for a total increase of 13 percent), and provide a drug manufacturer windfall of $5 billion.

4. The RFI construct creates a "false pricing transparency" because manufacturers with higher rebates will be subsidizing agreements with lower rebates. This cross-subsidization is more likely to lead to lower rebates and higher costs than it would meaningfully increase transparency to beneficiaries, and would also create major market distortions in manufacturer rebates.

5. Under the RFI scenario, plans would now be competing based on individual drug cost-sharing, under which incentives are very exposed to adverse selection and distortion of the risk pool.

PCMA appreciates the opportunity to share this feedback and we look forward to working with CMS to address any aspects of our comments. Please feel free to contact Wendy Krasner at 202-756-5731 or by email at wkrasner@pcmanet.org.

Sincerely,

Mark Merritt
President and CEO

Attachment

cc: Kristin Bass, PCMA
Wendy Krasner, PCMA
Mona Mahmoud, PCMA

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

[CMS–4182–P] RIN 0938–AT08

[1] The section numbers below correspond to the numbers as they appear in the proposed rule and RFI. Because we are commenting generally on the Part D aspects of the proposed rule, some section numbers (relevant to only Medicare Advantage) may be omitted.

PROVISIONS OF THE PROPOSED REGULATIONS

PART ONE

A. IMPROVING QUALITY, ACCESSIBILITY, AND AFFORDABILITY

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016

The United States is in the midst of an opioid public health emergency. According to the Centers for Disease Control and Prevention (CDC), overdose deaths involving prescription opioids have quadrupled since 1999.[2] From 1999 to 2014, more than 165,000 people have died in the U.S. from overdoses related to prescription opioids.[3]

In addition, HHS Office of Inspector General (OIG) reported that 14.4 million people (about one-third) who participate in Medicare Part D received at least one prescription for opioids in 2016, and that Part D spending for opioids in 2016 was almost $4.1 billion.[4]

In response to this epidemic, the President signed a memorandum on October 26, calling on the Acting HHS Secretary to declare an emergency under the Public Health Service Act, and directed the agencies to "use all appropriate authorities" to respond to the crisis.

PCMA is deeply concerned about the public health emergency that exists today as a result of inappropriate use of opioids. Our members supported the enactment of the Comprehensive Addiction and Recovery Act of 2016 (CARA) and the adoption in Part D of a lock-in mechanism as a means to curtail inappropriate abuse of certain medications by certain Part D enrollees. These programs increase care coordination by assigning at-risk patients to obtain these drugs from a designated prescriber and/or pharmacy.

However, to effectively impact the opioid crisis, drug management programs, including the lock-in function, must provide timely engagement to care coordination and treatment. For example, and as noted in greater detail below, the proposed six-month waiting period from the date the beneficiary is first identified as a potential at-risk beneficiary to the time the beneficiary can be locked in to a prescriber or pharmacy, significantly undermines the lock-in function and the ability of prescribers or pharmacies to intervene in a timely way that is needed to prevent beneficiaries from obtaining excessive quantities of frequently abused drugs.

In addition, because individuals struggling with addiction often have other chronic medical and behavioral health conditions, we strongly believe that these services must be customized to ensure the best possible opportunity for recovery. The drug abuse epidemic cannot be solved by

[2] Centers for Disease Control and Prevention, "Prescription Opioid Overdose Data." Available at: http://www.cdc.gov/drugoverdose/data/overdose.html.
[3] Ibid.
[4] Department of Health and Human Services Office of Inspector General, Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing, OE-02-17-00250 (July 2017).

implementing one-size fits all policies, but rather, solutions tailored to the Part D plan sponsors patient-mix. As referenced throughout our comments, we recommend that CMS both preserve the flexibility of the current Drug Utilization Review (DUR) and Overutilization Monitoring System (OMS) programs while also providing flexibility for Part D plan sponsors and their PBMs to develop and implement their lock-in programs. The evolving nature of the threat that opioid abuse poses to our country demands an approach in which Part D plan sponsors must continuously modify their programs as new information becomes available.

Over the years, our members have gained a wealth of experience with both OMS (in Medicare) and lock-in (in other programs), and we offer the following recommendations to help ensure these programs work as intended to reduce patient harm while providing access to effective pain management.

A. Integration of CARA and Current Part D Opioid DUR Policy and OMS

CMS Proposal: CMS proposes to implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid DUR policy and OMS.

CMS states that by integrating CARA lock-in with the current policy, a sponsor could limit 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 after case management and notice to the beneficiary.

Sponsors would report to CMS the status and results of case management to OMS and any beneficiary coverage limitations they have implemented to the Medicare Advantage Prescription Drug System (MARx).

Discussion: PCMA supports the integration of lock-in with the current drug management policies. We believe a common set of procedures will help to ensure a streamlined and efficient process for several aspects of the drug management program, including data reporting. However, as CMS contemplates merging the lock-in provisions with the current DUR and OMS policies, it is important that CMS integrate the programs in a way that not only retains the flexibility of the current policies, but also affords Part D plan sponsors with the needed flexibility to make necessary changes to their lock-in programs based on their experience and patient-mix.

At this point, Part D plan sponsors have gained extensive knowledge and significant experience implementing OMS, which CMS indicates has been successful in reducing high-risk opioid overutilization in the Part D program by 61 percent from 2011 through 2016. CMS should be

careful not to integrate the programs in a way that results in Part D plan sponsors having to retrofit their successful OMS programs, including their targeting criteria, to a more onerous or rigid framework that will inhibit plan sponsors from effectively implementing their current drug management programs and backtrack on program successes.

Throughout the preamble, CMS notes that its proposals support innovative approaches to improving quality, accessibility, and the affordability of healthcare. One of the key features of the Part D program is that it is provided by private plans and is able to leverage the creativity and innovations that are available in the private market. Through current lock-in constructs in the Medicaid and commercial markets, PBMs have obtained significant experience on best practices. We believe CMS should consider this experience as it works to implement the lock-in function under Part D and should not be so prescriptive as to limit innovative approaches of this important tool to combat our country's opioid epidemic.

As CMS contemplates systems and implementation protocols, PCMA suggests that CMS consider allowing Part D plan sponsors to pilot different approaches for the lock-in function. This type of approach was very successful in launching OMS and would create an opportunity for CMS to compare a variety of programs to determine which works best for reducing drug abuse. It will also help to assure a meaningful 2019 launch of the Part D lock-in as mandated by CARA.

While most Part D plan sponsors have the system capacity to exercise the lock-in function, integrating it with the current policy at the POS requires system modifications and enhancements. Depending on when implementation guidance is issued, Part D plan sponsors may not have the necessary changes in place to fully launch by the January 1, 2019 CARA lock-in effective date. Given the fact that these systems will need to be integrated and tested, we believe that a phased-in approach undertaken in 2018 will allow for a smoother implementation.

***PCMA Recommendation*: PCMA recommends that CMS provide as much flexibility as possible to Part D plan sponsors on pharmacy and prescriber lock-in implementation. To achieve that goal, CMS should consider launching short-term pilots in 2018 to help get lock-in underway, similar to what it did to launch OMS.**

B. (§423.100) Definition of Frequently Abused Drug

CMS Proposal: CMS proposes to define frequently abused drug as 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.

CMS plans to publish and update a list of frequently abused drugs for purposes of the Part D drug management programs, which will primarily be included in the annual Parts C&D Call Letter or in similar guidance.

For plan year 2019, consistent with the OMS policy, CMS proposes that opioids are frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables.

CMS notes that it is not compelled to include benzodiazepines, muscle relaxants, or other non-opioid controlled substances at this time.

CMS proposes that, if finalized, this rule would supersede its current policy, and Part D plan sponsors would no longer be allowed to implement the current policy for non-opioid medications.

Discussion: While we agree that the focus for the CARA lock-in function should first be on opioids, Part D plan sponsors should not be prohibited from expanding their programs to include other frequently abused drugs, particularly as it relates to their current POS claim edits. Our PCMA members have extensive experience operating their drug management programs, with some implementing the current policy for non-opioid medications and/or concurrent use of opioid pain medications with benzodiazepines or skeletal muscle relaxants.

Although CMS notes that limiting the drug management program to opioids will provide the added benefit of allowing CMS and stakeholders to gain experience with the use of lock-in, we reiterate that Part D plan sponsors and their PBMs have been operating this function in both the commercial market and the Medicaid programs for many years. Again, rather than imposing rigid requirements on all Part D plan sponsors, we recommend that CMS rely on existing industry practice which has worked well in the past, and also consider short-term pilots to help gather insights on the lock-in program or other aspects of the integrated drug management program.

If CMS proceeds to limit POS claim edits to opioids only, then at the very least, CMS should establish a process for grandfathering beneficiaries enrolled in plans implementing the current policy for non-opioid medicines prior to the January 1, 2019 CARA effective date.

***PCMA Recommendation*: CMS should permit Part D plan sponsors to continue implementing the current policy for non-opioid medications; and if CMS proceeds to limit POS claim edits to opioids only, then CMS should grandfather beneficiaries enrolled in plans implementing the current policy for non-opioid medicines prior to the January 1, 2019 CARA effective date.**

C. (§423.153(f)(16)) Definition of Clinical Guidelines and Program Size

CMS Proposal: CMS proposes 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 under such programs, and that are developed in accordance with the proposed standards in §423.153(f)(16) and published in guidance annually.

For 2019, CMS proposes the clinical guidelines in the preamble to be the OMS criteria established for plan year 2018:

1. Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent six months and either: four or more opioid prescribers and four or more opioid dispensing pharmacies OR six or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

2. Prescribers associated with the same single Tax Identification Number (TIN) be counted as a single prescriber.

3. 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.

Part D plan sponsors would no longer be able to vary the criteria to include more or fewer beneficiaries in their drug management programs.

Discussion: While PCMA supports the clinical guidelines established by the CDC, it is important to note that these guidelines are for prescribing opioids and managing risk factors associated with opioid-related harms, and are not intended and do not address the specific issue of how to best identify a Part D beneficiary who is at-risk for abuse or overutilization of frequently abused drugs.

As we have previously noted, we emphasize the need for flexibility for Part D plan sponsors to establish reasonable targeting parameters that recognize differences in their patient populations.

Criteria that are too rigid criteria could leave patients at-risk out of the program, while criteria that are too broad could needlessly burden the system with managing patients who are not overusing frequently abused drugs.

In the preamble, CMS notes that it currently expects Part D plan sponsors' Pharmacy and Therapeutics (P&T) committees to establish criteria consistent with CMS guidance to retrospectively identify potential frequently abused drug overutilizers. Consistent with this approach, we believe that Part D plan sponsors should continue to rely on their P&T committees for developing clinical criteria for their drug management programs.

While it is important for Part D plan sponsors to use objective established criteria, it is equally important for them to implement these programs based on clinical feedback from prescribers and/or pharmacies.

We offer an example to illustrate the limitations of using only established criteria. Our PCMA members often see in cases of “doctor shopping,” where a beneficiary has multiple opioid prescriptions (from multiple prescribers) that individually do not exceed the morphine equivalent dose (MED) and as a result, would not be identified as an at-risk beneficiary under the proposed clinical guidelines. However, given the other risk factors, including the lack of coordinated care from multiple prescribers, the beneficiary displays at-risk patient attributes.

Furthermore, Part D plan sponsors and their PBMs need to be flexible in the face of constant change in clinical evidence to adapt their programs based on lessons learned, involving data and new evidence. For example, clinical guidelines may change midyear without notice. Under the proposed approach, it appears that plans sponsors would need to follow the outdated clinical guidelines until the new clinical guidelines are proposed and then finalized (e.g. in the draft and final Call Letter). In order for drug management programs to be effective, Part D plan sponsors and their PBMs need the nimbleness to use the most up-to-date clinical and scientific data to determine potential at-risk and at-risk beneficiaries.

CMS asks whether it should adjust the clinical guidelines so that more or fewer potential at-risk beneficiaries are identified**.** We are very concerned that CMS is considering modifying the clinical guidelines in order to derive an “arbitrary” number of at-risk beneficiaries. The capacity to manage at-risk beneficiaries is plan-specific, meaning that the number of at-risk beneficiaries a small Part D plan sponsor can manage may be different from that of a large plan sponsor. CMS should not alter the clinical guidelines in order to achieve a “manageable” program size. Given the variation in plan capacity, we continue to suggest that Part D plan sponsors be permitted to

tailor their targeting criteria and program features –to be more or less aggressive –based on their capabilities and needs of their beneficiaries.

Finally, where a pharmacy has multiple locations that share real-time electronic data, CMS proposes that all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines. PCMA has concerns about identifying whether pharmacies, specifically regional chain pharmacies (e.g. those with the same chain number) that have multiple locations are able to share real-time electronic data. PBMs do not have the systems capabilities to discern if their systems are integrated and interchangeable. Further, because TINs are not included on pharmacy claims, Part D plan sponsors are also unable to determine if multiple prescribers are associated with the same single TIN and should therefore be counted as a single prescriber. We instead recommend that prescribers sharing the same National Provider Identifier (NPI) be counted as a single prescriber.

***PCMA Recommendation*: CMS should allow Part D plan sponsors to establish their own targeting parameters to include more or fewer beneficiaries in their drug management programs; CMS should take into consideration that PBMs do not have the system capabilities to determine if pharmacies with multiple locations are able to share real-time electronic data or if multiple prescribers are associated with the same single TIN. As such, we recommend that prescribers sharing the same NPI be counted as a single prescriber.**

D. Seven-Day Opioid Prescription Limits for Acute Pain

CMS Proposal: Under current Medicare rules, patients may request a shorter fill than that prescribed, but Part D plans may not unilaterally under fill a prescription. In other words, PBMs cannot fill seven days of a 30-day script for safety or potential abuse concerns, without a beneficiary request.

Discussion: CMS should change its rules and guidance, including subregulatory guidance so that prescriptions for acute pain can be limited to a seven days' supply without a beneficiary requesting such a limit. The limit would not apply to treatment of cancer or chronic pain, or the use of opioids in treating addiction or for patients in hospice care.

We believe CMS guidance is needed to achieve implementation under Part D of CDC Guideline for seven days' supply limit for acute pain management. Below are some of the questions that need to be addressed:

1. Does CMS consider this CDC guideline on a days' supply limit to be an utilization management (UM) edit that requires submission and approval by CMS under 30.2.2.1 OR a safety edit that does not require submission and approval from CMS under 30.2.2.2? Is the CDC guideline a safety edit or an UM edit that requires a coverage determination to determine appropriate use consistent with the CDC guideline? Is the seven days' supply limit a quantity limit over time or an opioid specific safety edit (both edits require submission and approval to CMS according to 30.2.2.1)?

2. Some plans have included all opioids on the non-extended day supply supplemental formulary file for 2018. Does the inclusion of a drug on the non-extended days' supply supplemental formulary file allow a plan to limit the day supply to seven days for opioids in acute pain management?

3. What process should a Part D plan sponsor use to make timely changes to the non-extended day supply formulary file if the plan wanted to limit opioids used for acute pain to a seven days' supply?

4. If CMS considers the seven days limit on opioids for acute pain UM under 30.2.2.1, what is the proper mechanism to submit the formulary change? Is it a maintenance change or a non-maintenance change as defined in 30.3.3? Will CMS consider issuing guidance that it will deem approved all our changes that are undertaken to reflect consistency with the CDC guidelines?

PCMA is also concerned with the number of RAC audit findings regarding refills on controlled substances, which threaten appropriate beneficiary access to controlled substances. RAC audits have systematically misidentified multiple "partial fills" as multiple refills, and flagged these transactions for review. This is a direct result of CMS's failure to approve the 'Quantity Prescribed' (460-ET) field in the National Council for Prescription Drug Programs (NCPDP) format. Immediate availability of this field would permit appropriate claims editing, ensuring beneficiary access while reducing the administrative burden on the part of Part D plan sponsors and PBMs – as well as RACs – in conducting retrospective reviews of these claims.

***PCMA Recommendation*: PCMA recommends that CMS remove any barriers to the ability of Part D plan sponsors and their PBMs to limit prescriptions for acute pain to a seven days' supply. PCMA also again recommends that CMS immediately adopt the NCPDP proposed 'Quantity Prescribed' field.**

E. (§423.100) Definition of Potential At-Risk Beneficiary

CMS Proposal: CMS proposes to define "potential at-risk beneficiary" as a Part D eligible individual who is identified using clinical guidelines (in §423.100) or for whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment that the beneficiary was identified as a potential at-risk beneficiary under the 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.

CMS proposes to define an "at-risk beneficiary" to be a Part D eligible individual (1) who is identified using clinical guidelines; is not an exempted beneficiary; and is determined to be at-risk for misuse or abuse of frequently abused drugs under a Part D plan sponsor's drug management program; or (2) for whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment.

Discussion: Similar to the current DUR and OMS policies, we believe there should be a single definition with regard to determining which patients are "at-risk". We do not believe there should be a separate distinction for "potential at-risk" beneficiaries. The added required verification, such as the two notice requirements, will cause unnecessary delays in access to care coordination that may result from Part D plan sponsors notifying the patients twice and awaiting additional information from prescribers or pharmacies before taking action.

If CMS retains the distinct definitions for potential at-risk and at-risk beneficiaries, then we suggest that CMS streamline the process, such as removing the need to obtain prior approval from the prescriber, for Part D plan sponsors and their PBMs to determine when a beneficiary transitions from being a potential at-risk to an actual at-risk beneficiary.

PCMA Recommendation: Similar to the current DUR and OMS policies, PCMA recommends that CMS adopt a single definition with regard to determining which patients are "at-risk." We do not believe there should be a separate distinction for "potential at-risk" beneficiaries.

F. Exempted Beneficiary

CMS Proposal: CMS proposes to exempt enrollees who: (1) elected to receive hospice care; (2) are residents of a long-term care (LTC) 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)have a cancer diagnosis.

CMS also seeks comments on whether they should also exempt: beneficiaries who are receiving palliative and end-of-life care, but not enrolled in hospice or reside in an LTC facility; beneficiaries in assisted living and other health care facilities, such as group homes and adult day care centers, where medication is supervised; beneficiaries with debilitating disorders or receiving MAT for substance abuse disorders.

CMS notes that the additional categories of beneficiaries (e.g. beneficiaries in assisted living and other health care facilities, such as group homes and adult day care centers) are not exempted under OMS and unlike cancer, it is not able to determine administratively through CMS data who these beneficiaries are.

Discussion: PCMA and its members are committed to protecting cancer patients' access to appropriate medical opioid therapy, and we understand that patients with an active cancer diagnosis represent a special population that should be generally exempt from regulations intended to restrict access or limit doses of opioids. However, while opioid therapy can be safe and effective for use in cancer patients with pain, there are rightful concerns about inappropriate opioid use even in the cancer population. As a result, we do not agree that there should be a blanket exemption for all patients under active cancer treatment. PBMs need to be able to continue to monitor the dispensing of chronic pain medications for beneficiaries with an active cancer diagnosis to help assure appropriate utilization. Our members monitor these patients with the understanding that a patient's medical diagnoses can sometimes warrant the use of high dose pain therapy or visits to multiple prescribers or pharmacies and our clinical review process ensures that patients with legitimate needs have access to pain therapy. Clearly, any decision regarding prescribing amounts and frequency of patient assessment is related to clinical and patient-specific factors and, as in all areas of medicine, requires a careful risk-benefit analysis, which is why again we do not recommend a one-size-fits-all approach to drug management programs.

All individuals with an opioid-related disorder should have rapid access to appropriate assessment, care coordination and treatment, regardless of condition. Rather than exempting patients under active treatment for cancer, we recommend that CMS allow Part D plan sponsors to rely on the clinical judgment of the prescriber or pharmacy to ensure that the use of opioid drugs to manage pain in these patients is done in a manner that is consistent with best clinical practices. Furthermore, should CMS proceed with this exemption, then CMS should specify that only cancer patients under active treatment be exempt. The presence of a history of cancer or cancer treatment should not merit exclusion.

Similarly, we believe that CMS should not exempt any other patient groups. When patient outliers are identified, Part D plan sponsors already take the steps necessary through their case management to determine whether the pattern is consistent with the medical service. While PCMA understands that beneficiaries in LTC facilities should be exempt since they do not fill their prescriptions at retail pharmacies, PBMs still need to be able to continue to review the use of pain medications for beneficiaries in LTCs to help assure appropriate utilization. Dispensing of controlled medications, including opioids, should be periodically reviewed, and treatment plans should be subject to review and modification based on the Part D plan and LTC facility working together to apply appropriate clinical guidelines.

If CMS proceeds with this exemption, then we also ask it to address some operational questions around beneficiaries residing in LTC facilities. For example, currently plan sponsors rely on the Long Term Institution (LTI) report to determine whether beneficiaries reside in LTC facilities.

Because this report is released on a quarterly basis, we are concerned that the information in the report may not be timely. In order to effectively and efficiently operationalize the exemption for beneficiaries who live in LTC facilities, plans sponsors will need the LTI report to be released on a more frequent monthly basis rather than the current quarterly basis.

Finally, as CMS notes that it is not able to determine administratively through CMS data whether a beneficiary resides in an assisted living or other health care facility for possible exemption from OMS reporting, Part D plan sponsors are also limited in their ability to determine whether these beneficiaries should be exempted from their drug management programs. There is no automated means to determine if beneficiaries are receiving palliative care but are not in a LTC facility.

***PCMA Recommendation*: PCMA recommends that CMS not exempt any patient groups as Part D plan sponsors already take the steps necessary through their case management to determine whether the pattern is consistent with the medical service. If CMS proceeds with an exemption for cancer patients, then CMS should specify that the exemption only pertain to cancer patients under active treatment. If CMS proceeds with an exemption for beneficiaries in LTC facilities, then we ask CMS to address the operational questions around the timely identification of these beneficiaries.**

G. (§423.153(f)(3)) Limitation on Access to Coverage for Frequently Abused Drugs

CMS Proposal: CMS proposes that a Part D plan sponsor may do all of the following: (i) Implement a POS claim edit for frequently abused drugs that is specific to an at-risk beneficiary;

or (ii) 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; dispensed to the beneficiary by one or more network pharmacies; or both.

Discussion: PCMA supports the flexibility to lock the beneficiary into a specific prescriber(s) or specific pharmacy or both based on the utilization behavior of the beneficiary. This proposal recognizes the difficulty in implementing both a pharmacy and prescriber lock-in requirement. Moreover, PBM experience in many Medicaid programs suggests that lock-in programs can be highly successful using only a pharmacy lock-in requirement.

PCMA Recommendation: PCMA supports the flexibility to lock the beneficiary into a specific prescriber(s) or specific pharmacy or both based on the utilization behavior of the beneficiary.

H. (§423.153(f)(4)) Requirements for Limiting Access to Coverage for Frequently Abused Drugs

CMS Proposal: CMS proposes that before a Part D plan sponsor can limit the access of an at-risk beneficiary to coverage for frequently abused drugs, the sponsor must first: conduct the case management; obtain the agreement of the prescribers of frequently abused drugs with the limitation, unless the prescribers were not responsive to the required case management; and provide notice to the beneficiary. CMS also proposes to require an additional step of prescriber agreement.

CMS invites stakeholders to comment on not requiring prescriber agreement to implement pharmacy lock-in and notes that if a plan sponsor complied with the case management requirements and the prescribers were not responsive after three attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirements of this section.

Discussion: PCMA supports the concept that if a prescriber fails to respond to a Part D plan sponsor's confirmation request and plans have supporting data showing the enrollee is engaged in overutilization behavior, Part D plan sponsors be permitted to take action in order to protect the health of the beneficiary and the integrity of the Part D benefit.

Part D plan sponsors should also have the ability to enroll a beneficiary in a drug management program even if the prescriber does not agree. To allow prescribers to override the designation of at-risk beneficiary would defeat the whole purpose of the program. Members are given ample

opportunities to appeal their designation and to select their prescriber and/or pharmacy. We believe that there are already ample protections for at-risk beneficiaries built into CARA.

As there is currently no requirement for a pharmacy to agree to a prescriber lock-in function, PCMA believes that similarly there should be no requirement for a prescriber to agree to the pharmacy lock-in. It is important for CMS to take into account that stand-alone Part D plans do not have contracts with most of the prescribers and, therefore, have limited opportunity to have clinical contact with these prescribers. Thus, while it is appropriate for Part D plan sponsors to use their best efforts to contact the prescribers, we recommend that the rules not mandate that such contact be made prior to allowing lock-in implementation.

Furthermore, most at-risk beneficiaries who qualify for a pharmacy lock-in receive prescriptions from multiple prescribers (e.g. doctor shopping). It is unclear which prescriber a Part D plan sponsor would therefore need to obtain an agreement from or if a plan sponsor would need to obtain agreements from each of the prescribers, which would significantly undermine the timeliness and effectiveness of the lock-in program.

***PCMA recommendation*: PCMA recommends that CMS not require prescriber agreement as a condition precedent for pharmacy lock-in.**

I. (§§423.153(f)) 423.153(f)(8)) Beneficiary Notices

CMS Proposal: CMS proposes that sponsors 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. The sponsor would be required to make reasonable efforts to provide the prescriber(s) of frequently abused drugs with a copy of the notice. CMS believes 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, so as to avoid unnecessarily alarming the beneficiary.

CMS proposes 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, thus, the second notice would be required to include the effective and end date of the limitation. Those notices would be required to be provided no less than 30 days after the initial notice and no more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice with one exception.

CMS notes its current thinking which is that, exemptions to the 30-day timeline between the initial and second notice may not be otherwise waived, even in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court.

Discussion: While PCMA supports beneficiary notification, we encourage CMS to consider alternatives to the mailing of more paper to beneficiaries. Given that these notices are associated with utilization, we believe existing documents such as the EOB could serve as useful notice vehicles, given that they are more likely to be read and retained by beneficiaries. We also have concerns about the time period for the notices. The time period a beneficiary is sent the first notice to the time that they are locked-in to a pharmacy and prescriber may be too long.

PCMA recommends that CMS eliminate the second notice. Instead, it could establish a pilot where the notice requirements are streamlined to a single notice, similar to the OMS notice requirement. Part D plan sponsors have been operating OMS with success for several years using just a single notice. In addition to the proposed notice information, this single notice would contain an explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary and that the beneficiary will be subject to the requirements of the sponsor's drug management program 30 days after the letter. This notice would include the limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs, and if applicable, any limitation on the availability of the SEP.

If CMS proceeds with both the initial and second notices, then we recommend that CMS shorten the time frame between the notices to allow Part D plan sponsors to send the second notice within 15 days of the initial notice. This notice would serve as reminder that the lock-in program will take place 30 days after the date of the initial notice. This time frame would preserve the opportunity for the beneficiary to submit his or her prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs. It would also provide time for the Part D plan sponsor to conduct beneficiary outreach if necessary to obtain this information. We see no added value in waiting 30 days after the initial notice to provide the second notice that merely restates essentially the same information that was provided in the initial notice.

We also have additional questions and concerns around the substance and timing of the model notices:

1. When will CMS release the model notices?

2. Will plan sponsors have an opportunity to comment on the model notices?

3. Will plan sponsors be permitted to modify the notices to reflect other needed information?

4. Will the onerous and confusing section 1557 notice and tagline requirements apply to these notices?

We are concerned that given these outstanding questions, there will be insufficient time to implement the notices by the January 1, 2019 effective date. We think this is another area that CMS could test through short-term pilots early in 2018 so PBMs can be ready to implement the lock-in for 2019.

Finally, these requirements should pertain to just the lock-in program. In other words, CMS should retain the current notice protocols for OMS.

***PCMA recommendation*: PCMA recommends that CMS eliminate the second notice or establish a pilot where the notice requirements are streamlined to a single notice, similar to the OMS notice requirement. If CMS proceeds with both the initial and second notices, then we recommend that CMS shorten the time frame between the notices to allow Part D plan sponsors to send the second notice within 15 days of the initial notice. In any event, CMS should retain the current notice protocols for OMS.**

J. (§423.153(f)(4)) Special Requirement to Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s)

CMS Proposal: CMS proposes 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 six months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary.
In the preamble, CMS states that it believes the lock-in should be a tool of last resort to manage at-risk beneficiaries' use of frequently abuse drugs.

CMS seeks comments on whether this six-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).

Discussion: PCMA does not support the six-month waiting period for several reasons:

1. *It is inconsistent with the spirit of a national public health emergency*. We strongly urge CMS to keep in mind that we are in the midst of an opioid public health emergency and that the President has directed the executive government to "use every appropriate emergency authority" to fight the crisis. The imposition of a six-month waiting period works against the end goal of CARA, which is to stop medication abuse in the Part D program. PCMA believes that at-risk beneficiaries should be locked in as quickly as possible to avoid further harm to themselves and also to prevent fraud if they are diverting drugs.

2. *It goes against the intent of the law*. Lock-in programs permit Part D plan sponsors to intervene with at-risk individuals before they develop long-term dependence and addiction to frequently abused drugs and success of such interventions depends upon how early they occur. The six-month waiting period creates ample opportunity for beneficiaries to receive large quantities of frequently abused drugs from multiple prescribers or pharmacies, creating substantial potential for diversion and other abuse. CARA sets out a process to safeguard the reasonable interests of beneficiaries in receiving care from certain providers, in appealing such decisions, and having reasonable access to drugs.

3. *It undermines efforts by the prescriber and or pharmacy*. In our members' experience, prescribers and pharmacies view the lock-in function as an effective way to facilitate appropriate care coordination for at-risk beneficiaries. While CMS views the lock-in function as a "burden on providers" and a tool of "last resort", lock-in programs are actually useful tools used by both prescribers and pharmacies to prevent dangerously uncoordinated care. Imposing a six-month waiting period prior to lock-in limits the ability of providers (prescribers and pharmacies) to prevent patients from improperly obtaining prescriptions (doctor shopping) and for getting them filled (pharmacy shopping). It is also limits the ability of providers to offer the patient the care and treatment needed to address their addiction. Through current lock-in constructs, our members work with prescribers and pharmacies to provide them with the tools and data to effectively manage the care of the patient. Finally, a six-month waiting period undermines the ability for a patient to self-identify as a candidate for lock-in. This opportunity represents an important safeguard for patients.

In addition, we have a number of legal concerns with the proposed six-month waiting period. We set forth below our most significant concerns.

a. CARA Establishes Only a Notice Requirement for Lock-In, and Prioritizes Patient Health and Safety and Stopping Drug Diversion over Other Objectives

First, we believe the six-month waiting period prior to lock-in is not a permissible construction of CARA. The law authorizes Part D plan sponsors to establish drug management programs for at-risk beneficiaries, under which a beneficiary's access to frequently abused drugs may be locked-in to "one or more prescribers" or "one or more pharmacies." CARA imposes only two requirements on Part D sponsors prior to initiating a lock-in:

> "(i) In general. A part D plan sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor--
>
> (I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and
>
> (II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse."

42 U.S.C. §1395w-104(c)(5)(B)(i)(I-II) (emphasis added). CARA then details the content of the required notices, which must include, *inter alia*, information about how a beneficiary can appeal his or her designation as an "at-risk beneficiary" and the meaning and consequences of such designation. CARA specifies that the time between the initial and second notice must be "not less than 30 days," subject to an important caveat:

> "In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the Part D plan sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the Part D plan sponsor may provide such second notice on such earlier date."

42 U.S.C. §1395w-104(c)(5)(B)(iv)(II). This provision identifies "the health or safety of the beneficiary" and "significant drug diversion activities" as the sole bases on which an adjustment affecting the timing of implementing a lock-in should be made.

b. The Proposed Rule Creates More Delay Prior to Lock-In than Congress Intended and Impermissibly Elevates Objectives Not Identified by CARA

Second, the proposed §423.153(f)(3)(ii)(A), if finalized, will allow an at-risk beneficiary's access to coverage for frequently abused drugs to be limited to those "[p]rescribed for the

beneficiary by one or more providers." CMS proposes a six-month waiting period on a Part D plan sponsor's ability to so limit a beneficiary's access with the following regulation to be promulgated as 42 CFR §423.153(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 §423.153(f)(3)(ii)(A) unless—
>
> (A) At least six 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."

CMS argues that "prescriber lock-in should be a tool of last resort to manage at-risk beneficiaries' use of frequently abused drugs," citing "impacts [to] the beneficiary's relationship with his or her health care provider" and potential "burden[s] upon prescribers in terms of prescribing frequently abused drugs." 82 Fed. Reg. at 56,354-55. CMS anticipates that "the 6-month waiting period will provide the sponsor additional time to assess whether case management or another tool […] has failed to resolve the beneficiary's overutilization of frequently abused drugs." *Id*. at 56,355.

c. <u>The Proposed Rule is Not a Permissible Construction of CARA</u>

Third, the proposed rule impermissibly relegates lock-in to a tool of "last resort," and creates a waiting period – based on objectives not identified by CARA – that contravenes CARA's purpose. Courts analyze a challenged regulation's permissibility by applying the principles of statutory interpretation established in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984). There, the Supreme Court established a two-step test:

> At *Chevron* step one, we ask "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. Where "the intent of Congress is clear, that is the end of the matter; for [we], as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. But if "the statute is silent or ambiguous with respect to the specific issue," we proceed to *Chevron* step two, where "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id*. at 843.

United States Telecom Ass'n v. FCC, 825 F.3d 674, 701 (D.C. Cir. 2016). An agency violates Congressional intent when Congress has "prescribe[ed] a precise course of conduct other than the one chosen by the agency," or when Congress "grant[ed] the agency a range of interpretive discretion that the agency has clearly exceeded." *Vill. of Barrington v. Surf. Transp. Bd.*, 636 F.3d 650, 659-60 (D.C. Cir. 2011). Where Congress has not expressed clear intent, though an agency is permitted to make "a reasonable accommodation of conflicting policies," it may not do so if "it appears from the statute or its legislative history that the accommodation is not one Congress would have sanctioned." *Eagle-Picher Industries, Inc. v. United States Environmental Protection Agency*, 759 F.2d 905, 920 (D.C. Cir. 1985).

The policy in the proposed rule fails *Chevron* step one. CARA specifies only two requirements that a Part D sponsor must fulfill prior to undertaking a lock-in, neither of which involves a six-month waiting period. It does not require a Part D plan sponsor to take "additional time to assess whether case management or another tool" will "resolve the beneficiary's overutilization of frequently abused drugs," nor to take a "'wait and see'" approach to a beneficiary potentially in the grip of addiction. 82 Fed. Reg. at 56,355. CARA speaks unambiguously on the issue of timing: the only delay required after an individual has been identified as an at-risk beneficiary is the "not less than 30 days" period between the initial and second notices. Further, CARA makes clear that even this much shorter time limit may bend downwards because of concern for "health or safety of the beneficiary" or "significant drug diversion activities." The ability to adjust the time limit downward is the *only* discretion granted to CMS. *See* 42 U.S.C. § 1395w-104(c)(5)(B)(iv)(II). Indeed, even the 30-day period is not intended to serve as an opportunity to employ other management tools as the proposed rule requires – as noted below, lock-ins are not a "last resort" under CARA – but rather to give the beneficiary the opportunity to appeal identification as an at-risk beneficiary, and to submit prescriber and pharmacy preferences to facilitate the lock-in. *See* 42 U.S.C. §1395w-104(c)(5)(B)(ii).

Similarly, the six-month waiting period contravenes Congress' clearly stated effective date for beginning to allow lock-ins. CARA specifies that the lock-in provision applies "for plan years beginning on or after January 1, 2019" and instructs CMS to undertake stakeholder engagement and promulgate regulations to facilitate such date. 42 U.S.C. §1395w-104(g)(1-2). Congress intended to allow Part D sponsors to begin to undertake lock-ins on January 1, 2019, consistent with the emergency nature of the crisis sought to be addressed. CMS may not delay that date by creating a process that would not allow any lock-in to occur far after the effective date (likely late 2019). *See, e.g., National Assoc. of Rehabilitation Facilities, Inc. v. Schweiker*, 550 F. Supp. 357, 365-66 (D.C. Cir. 1982) (where "Congress commanded a specific effective date," agency was not free to "substitute[e]" a different date). Should CMS proceed to finalize its proposal,

Part D plan sponsors would be incapable of proceeding with lock-in until well into the end of 2019, in direct contravention of Congress's express intent.

Even if the proposed rule did not fail *Chevron* step one, it will fail step two because it conflicts with clear Congressional intent. The proposed rule and CARA do superficially address different time periods. The time period under the proposed rule policy is an overall six-month period from the time that a beneficiary is identified as a potential at-risk beneficiary, while CARA addresses the time period between the required first and second notices to such beneficiary. Practically, however, these time periods are the same because Part D plan sponsors will attempt to move swiftly to initiate a lock-in once an at-risk beneficiary is identified.[5] The proposed rule thus has the effect of sextupling the wait time identified by Congress simply because CMS "believes prescriber lock-in should be a tool of last resort,"[6] on the basis of concern for "provider burden" – which is not addressed by the lock-in provisions of CARA – and potential disruption to a beneficiary's "relationship" with a provider. 82 Fed. Reg. at 56,354. The latter concern is addressed by CARA in a different fashion; 42 U.S.C. § 1395w-104(c)(5)(D) lays out a process whereby a beneficiary's choice and reasonable access to providers must be protected by the Part D sponsor. But CARA is clear that this process takes place *after* a beneficiary is served with an initial notice. Additional authority to create a waiting period cannot be presumed from the lack of an explicit prohibition, *see, e.g., Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995) (courts "will not presume a delegation of power based solely on the fact that there is not an express withholding of such power"), and such authority could not be exercised to subvert the 30-day period specified by Congress in any event.

Additionally, the proposed rule is not a "permissible construction" of the statute because CARA does not allow concern about the beneficiary-provider relationship, if any, to predominate over the stated goals of beneficiary safety and prevention of drug diversion. Thus, the proposed rule cannot be read as a permissible "accommodation" of conflicting policy goals, because it elevates goals Congress *did not* instruct CMS to consider over goals Congress explicitly *did* instruct CMS to consider.

In summary, lock-ins offer an opportunity for Part D plan sponsors and their PBMs to manage at-risk patients before they develop long-term dependence and addiction to opioids and to enhance the coordination and quality of care for the locked-in beneficiary. The success of lock-in

[5] The proposed rule argues that, even though CARA only requires two notices to be provided prior to a lock-in, a Part D plan sponsor seeking to implement a lock-in would actually have to provide both notices twice, once when the beneficiary is first identified as at-risk, and then "again" when approaching the end of the six-month period. 82 Fed. Reg. at 56,355. CMS has no authority under CARA to double Congress' specific notice requirement.

[6] CARA in no way suggests that lock-ins are a "last-resort." CARA allows Part D plan sponsors to implement drug management programs for at-risk beneficiaries in 42 U.S.C. § 1395w-104(c)(5) and employ utilization management tools to prevent drug abuse in § 1395w-104(c)(5); it does not suggest any priority as between the two, and imposes on each kind of measure its own pre-requisites. For drug management programs, such pre-requisites are limited to proper notice and verification that a beneficiary is in fact "at-risk."

depends upon how quickly patients are identified and connected to an intervention. Without timely intervention, patients will continue to inappropriately utilize opioids. A six-month waiting period would defeat the whole purpose of the lock-in program.

Furthermore, timely lock-in programs are needed to reduce diversion of controlled substances. If plan sponsors are not able to lock-in the beneficiary until after six months, that may lead to six months of individuals seeking large quantities of controlled substances from multiple prescribers or pharmacies for the purpose of channeling them to another party for nonmedical use.

***PCMA Recommendation*: For the enumerated policy and legal reasons, PCMA strongly urges CMS to withdraw the proposal that Part D sponsors wait at least six months from the date the beneficiary is first identified as a potential at-risk beneficiary before limiting an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) and/or pharmacy(ies).**

K. (§423.153(f)(10)) Selection of Pharmacies and Prescribers / Beneficiary Preference

CMS Proposal: CMS proposes that if a sponsor intends to impose a lock-in requirement and a beneficiary identifies his or her preferred pharmacy or prescriber, then the plan sponsor must implement the lock-in based on those preferences, assuming that the pharmacy or prescriber are in the plan's network. CMS proposes an exemption to the above in the case in which the plan sponsor believes that the beneficiary's preferred prescriber or pharmacy would contribute to the beneficiary's prescription drug abuse. The sponsor would be required to provide notice at least 30 days in advance and would need to include a rationale for not honoring the preference.

Discussion: PCMA supports that the lock-in pharmacy must be in-network. PBMs work with all network pharmacies to make sure they offer affordable and safe options for enrollees. The use of network pharmacies is an important tool for keeping premiums low. Allowing beneficiaries to select an out-of-network pharmacy would undermine the ability of PBMs to obtain these lower costs, which would result in higher prices for prescription drugs and higher premiums for enrollees. The use of out-of-network pharmacies also weakens efforts to combat pharmacy-based fraud and abuse.

PCMA also agrees that if the Part D plan sponsor determines that the pharmacy is contributing to the prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preference.

In response to CMS's request for feedback on whether a limit should be created for the number of times a beneficiary can submit their preferences, we recommend capping the number of times a beneficiary can submit their preferences to 3 times per year.

***PCMA Recommendation*: PCMA supports that the lock-in pharmacy must be in-network and supports the ability to override a beneficiary's pharmacy preference if the pharmacy is suspected of contributing to the drug abuse or diversion. We also recommend capping the number of times a beneficiary can submit their preferences to 3 times per year.**

L. (§423.153(f)) Drug Management Program Appeals

CMS Proposal: CMS expects 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. CMS proposes that at-risk determinations made under the processes at § 423.153(f) be adjudicated under the existing Part D benefit appeals process and time frames set forth in Subpart M.

CMS notes that 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.

CMS states that an adverse redetermination would not be automatically escalated to the Part D IRE, unless the plan sponsor fails to meet the redetermination adjudication time frame.

Discussion: PCMA supports using the existing Part D appeals process for drug management programs. We agree that Part D enrollees, plan sponsors, and other stakeholders are already familiar with the Part D benefit appeals process and that 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 the appeals process.

Though PCMA supports the beneficiary's ability to appeal, we ask CMS to confirm that the appeal be treated as a redetermination and not as a coverage determination (CD).

Furthermore, the appeal should solely be limited to the issue of whether the beneficiary is an appropriate candidate for lock-in, and not have any other scope. In other words, the appeal should not relate to whether the plan may impose prior-authorization or other utilization management restrictions on certain prescriptions. Rather, beneficiary appeals should be limited to compliance with internal program criteria and CMS guidance, rather than allowing

beneficiaries to challenge the underlying criteria and guidance. Moreover, the appeals process should not mean that the enrollee continues to receive inappropriate fills of opioids during the appeal process.

We support that an adverse redetermination would not be automatically escalated to the IRE.

We also seek additional guidance on a number of issues our members have encountered when there's overlap between the Part D opioid management program and the CD/appeals process:

1. Per the CFR, all "exceptions" approved through the CD/appeals process must be made effective through the end of the current plan year (at minimum). Plans effectuate these favorable exception decisions by entering an 'override' or 'authorization' into their pharmacy claims processing system. During opioid case management, it may be in the enrollee's best interest to terminate an exception override prior to the end of the plan year, but there's apparently nothing spelled out in CMS' guidance allowing plans to do so. In such cases, Part D plan sponsors must choose between implementing effective case management programs or following a path that appears safe from a CMS audit perspective. It would be extremely helpful for CMS to issue guidance clearly advising plans whether we can terminate opioid exceptions early due to opioid case management, and if so, about any prior notice requirements for the enrollee and/or prescriber. To illustrate this issue we have included two scenarios below:

    a. Consider a scenario where the enrollee requests a quantity limit exception for a hydrocodone-containing drug. The Part D plan sponsor denies the higher quantity initially and on appeal. The enrollee appeals to the IRE with support from a prescribing doctor, and the IRE approves coverage. The Part D plan must enter an override effective through the end of the plan year and inform the IRE that it did so. Later in the year, the enrollee enters opioid case management and a different doctor will now be writing all opioid prescriptions. This doctor asks the plan to remove access to all hydrocodone-containing products and instead wants approval for oxycodone in place. Under current rules, the plan doesn't have the authority to reopen and revise the IRE's approval, even though restricting access to the drug is in the enrollee's best interest. It is unclear in this situation what the Part D plan sponsor should do.

b. Consider a scenario where the enrollee has a member-specific opioid restriction placed due to case management. The enrollee successfully appeals for a lower cost share on the allowed drug. This is a tiering exception, which must be in effect through the end of the plan year. Suppose the enrollee later enters a narcotic treatment program, and his doctor asks the plan to terminate all approvals for opioid containing drugs except Suboxone. We seek clarification on the following: Can the Part D plan sponsor terminate the tiering exception early? If so, is this to be handled as a reopening of its prior tiering exception approval or can it be handled in a different way through the case management program? What notice requirements must the Part D plan sponsor send to the enrollee? Must the Part D plan sponsor wait some length of time after informing the enrollee before terminating the authorization?

2. Opioid restriction reviews aren't represented in required CD/appeals case reporting. For example, Part D plan sponsors and their PBMs file an annual report in HPMS where they must report their case volume by case types, disposition, and timeliness, per quarter. Another example relates to the CMS audit universes. In both types of reporting, Part D plan sponsors are required to classify their case types (i.e. prior authorization, tiering exceptions, etc.) and are only allowed to use CMS's pre-specified values in these reports. There are no allowable values that designate a case as an opioid restriction appeal. Part D plan sponsors can only classify cases as types of formulary UM reviews, types of formulary exceptions, tiering exceptions, or hospice reviews. Of note, for CMS audit universes, Part D plan sponsors are required to populate the expiration date for every approved 'exception.' If these approvals are terminated prior to the end of the plan year, CMS could easily detect such cases if they're included in the time period subject to the audit. If Part D plan sponsors are found to be non-compliant with exception processing requirements, they can be subject to significant fines and penalties.

3. CMS proposes to make pharmacy restrictions and prescriber restrictions appealable issues through the existing Part D appeals process. Although the draft rule specifies such cases would be handled as 'exceptions,' it does not propose any criteria which plans should use to evaluate the appeals. For exceptions, CMS publishes the criteria which, when met, would lead to an exception approval. All these criteria are related to formulary and tiering exceptions. There's no guidance surrounding opioid restriction reviews, let alone pharmacy or prescriber restrictions. Considering that exception approvals must be in place for the remainder of the plan year, this is very concerning. Untimely or unfavorable appeals can be appealed to the IRE. Since the

IRE doesn't administer a Part D plan, it is not experienced in administering an opioid case management program. Unless CMS provides guidance around review criteria, the IRE is likely to review these restrictions similarly to formulary and tiering exceptions, which may have an adverse impact on plans' D03 STARS Ratings. Even if the IRE upholds the decision, the case may still be appealed at higher levels. In any case, if approved by any adjudicator, an exception must be effectuated through the end of the plan year. This could essentially remove the enrollee from case management for the rest of the year even if the enrollee continues to meet criteria for case management.

***PCMA Recommendation*: PCMA supports using the existing Part D appeals process for drug management programs. PCMA asks CMS to confirm that the appeal be based solely on whether the beneficiary is an appropriate candidate for lock-in and be treated as a redetermination and not as a coverage determination. PCMA also supports that an adverse determination would not be automatically escalated to the IRE.**

M. (§423.153(f)(14)) Termination of Identification as an At-Risk Beneficiary

CMS Proposal: CMS proposes a maximum 12-month period for both lock-ins and POS claim edits for frequently abused drugs. CMS notes that this 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.

Discussion: PCMA does not support an automatic termination of the lock-in or POS claim edit for at-risk beneficiaries based solely on an arbitrary time period. Termination of such programs should be based on the needs of an enrollee following a clinical assessment. An arbitrary time limit assumes without any clinical justification that the patient is no longer at-risk for drug abuse after 12 months.

There is no one-size-fits-all optimal time period for terminating a beneficiary's at-risk status. Part D plan sponsors, with input from a prescriber or pharmacy, reevaluate the patient after certain time intervals to determine whether the beneficiary's behavior regarding use of frequently abused drugs has improved. Only after this clinical assessment is performed, can a Part D plan sponsor determine if a patient's frequently abused drug use still requires either a lock-in or POS claim edit to prevent inappropriate use or harm.

Arbitrarily removing patients from these programs without any clinical input, puts the patient at continued risk for drug abuse or diversion. Furthermore, Part D plan sponsors and their PBMs

would have to conduct prescriber and pharmacy outreach all over again; creating more challenges, particularly in situations where providers are reluctant to respond.

CMS notes that the 12-month period for such programs is common in Medicaid; however, it is important to note that most Medicaid lock-in programs require a clinical assessment after the 12-month period, meaning that patients are not automatically removed from the program after this time period.[7] If CMS wishes to align with the Medicaid program, then it should clarify that the "maximum 12-month time period" signals the time for when the Part D plan sponsor should reassess the patient's at-risk determination, not when the sponsor should automatically remove the patient from the program.

***PCMA Recommendation*: PCMA does not support automatically terminating the beneficiary's lock-in or POS claim edit based solely on an arbitrary time period. Termination of such programs should be based on the needs of an enrollee following a clinical assessment.**

N. (§423.38(c)(4)) Special Election Period

CMS Proposal: CMS proposes modifications to §423.38(c)(4) to limit the availability of the special election period (SEP) for low-income subsidy (LIS) eligible individuals who are designated to potentially be at-risk or at-risk.

Discussion: CMS states that based on an analysis of 2015 OMS data, more than 76 percent of all beneficiaries estimated to be potentially at-risk or at-risk are LIS-eligible beneficiaries. Given this grave statistic, PCMA supports that an LIS-eligible beneficiary's SEP would no longer be available once the individual is identified and notified as being at-risk or potentially at-risk if CMS retains this separate distinction. This protocol is needed to prevent individuals from changing plans in order to avoid a drug management program or to circumvent lock-in requirements.

While PCMA supports that the SEP would no longer be available to LIS-eligible beneficiaries identified as potentially at-risk or at-risk, it is unclear to us what data sources CMS will use to identify those LIS beneficiaries that are potentially at-risk.

***PCMA Recommendation*: PCMA supports that an SEP would no longer be available to LIS-eligible beneficiaries identified as potentially at-risk or at-risk, however we ask CMS to clarify**

[7] Pew Charitable Trusts. Curbing Prescription Drug Abuse With Patient Review and Restriction Programs. Available at: http://www.pewtrusts.org/~/media/assets/2016/03/curbing_prescription_drug_abuse_with_patient_review_and_restriction_programs_appendices.pdf

what data sources it intends to use to identify those LIS beneficiaries that are potentially at-risk.

O. (§423.153(f)(15)) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments

CMS Proposal: CMS proposes to expand the scope of the reporting to MARx under OMS 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.

Discussion: PCMA supports integrating the reporting process for both OMS and CARA; however, we ask CMS to clarify whether Part D plan sponsors and their PBMs will need to submit specific transaction codes related to lock-in.

PCMA Recommendation: PCMA supports integrating the CARA lock-in and OMS reporting processes, and asks CMS to clarify whether Part D plan sponsors and their PBMs will have to submit specific codes related to lock-in.

9. §§423.560, 423.578(a) and (c) – Part D Tiering Exceptions (pp. 56371 – 56373)

A. Background (p. 56371)

CMS Proposal: The prescription drug landscape has changed since initial tiering exception rules. Formularies have increasingly complex tiering and cost-sharing levels (e.g., 5-6 tiers). These changes have lead CMS to revise and clarify how tiering exceptions should be handled.

Discussion: We appreciate that CMS recognizes that the prescription drug landscape has changed, and that formularies have evolved. That said, we are confused about certain aspects of what CMS is proposing and thus note below some comments which we hope will help result in a clear, consistent tiering exceptions policy.

PCMA Recommendation: ***We appreciate CMS's effort to improve and update the tier exceptions policy, and ask that CMS take into account our comments below as it seeks to revise the tier exceptions rules.***

B. General Rules (p. 56371)

CMS Proposal: CMS would revise §423.578(a)(2) to base eligibility on the lowest applicable cost-sharing for the tier containing the preferred alternative drug, and not based on tier labels.

Discussion: PCMA agrees with the regulatory revisions which clearly cross-reference the allowable limitations on tiering exceptions. Our comments on those exceptions are discussed below.

PCMA Recommendation: ***PCMA agrees with the change CMS makes to the general rule on tiering exceptions to cross-reference the permissible limitations.***

C. (§423.578) Limitations on Tiering Exceptions (pp. 56371-56372)

CMS Proposal: CMS believes that the current rule, which allows Part D plan sponsors to exempt any dedicated generic tier from exceptions, is problematic. Its proposal would not require a plan to offer a tiering exception to a preferred cost-sharing level that applies only to generic alternatives, but plans would not be permitted to exclude from tiering exceptions a tier containing alternative drugs with more favorable cost-sharing just because the lower-cost tier is dedicated to generic drugs.

Discussion:

1. *Limits on tiering exceptions – where alternatives include only generic drug types*

After reading the preamble carefully and subject to the discussion below on the definition of alternatives, we believe that CMS's intent is that, in its most basic form, brand exceptions go to the lowest brand; generic exceptions to the lowest generic; and biologic exceptions to the lowest biologic. In other words, Tier 4 brand drugs will never go lower than Tier 3. We generally agree with the content as we read it, but ask that CMS use language that makes this crystal clear.

We also note that CMS will have to change all of its current conflicting guidance to ensure all Part D stakeholders have the same understanding. The timing of this is complicated because CMS has issued: guidance in 2017 in HPMS; guidance in the 2018 Call Letter being implemented in 2018; and now new guidance for 2019. We are concerned that these changes will cause confusion for Part D plan sponsor auditors and the IRE, as well as for beneficiaries as to what requirements are in place for what time period. PCMA suggests that a thorough review to Chapter 18 be undertaken to update the examples to make sure they are not in conflict with this proposal. One possibility would be for the revised Chapter 18 to include examples for 2018 and then other examples for what would be different in 2019. CMS has indicated that in the first quarter of 2018, there will be an update to Chapter 18, thus it would be an appropriate time to reconcile the differences.

PCMA Recommendation: ***PCMA generally agrees with the CMS approach that brand exceptions should go to the lowest brand with an alternative and generic exceptions should go to the lowest generic with an alternative (subject to our discussion below on the definition of alternatives).***

2. *Limits on tiering exceptions – treatment of biological products*

CMS is proposing that biological products on a specialty tier do not have to be eligible for a tiering exception. We believe this is straightforward and obvious and appreciate that CMS is making this clarification.

PCMA Recommendation: ***PCMA agrees with CMS that biological products on a specialty tier should not be eligible for a tiering exception.***

3. *Limits on tiering exceptions – definition of specialty tier*

CMS notes that it is not proposing to change the definition of specialty tier, which will still be based on cost and still ensures "that very high cost drugs remain accessible to enrollees at cost-sharing equivalent to the defined standard benefit."

However, if specialty tier cost-sharing is more preferable than another tier, then CMS proposes to clarify that a drug on that non-preferred tier is eligible for specialty tier cost-sharing if the alternative drug is on the specialty tier. While in theory we understand what CMS is seeking to accomplish here, we believe that executing this will be extremely problematic for Part D plan sponsors. For example, for non-preferred brand tiers, some plans apply a cost-share and some apply a copayment. A plan would need to determine whether the alternative drug in the specialty tier is a brand, generic, or biologic and then figure out the difference between the cost-share and copayment. Traditionally, the lower the tier, the lower the cost, regardless of whether it was established as a cost-share or copayment. But when specialty tier is added to the tiers being considered, determining the appropriate beneficiary payment becomes much more complicated as it is no longer a simple calculation. Here are two examples to illustrate this point.

a. *Tier 4 allows 30/60/90 day supplies while Tier 5 only a 30 day supply – This situation would seemingly result in a beneficiary being restricted to a 30 day supply of a Tier 4 drug due to no Tier 5 cost-share associated with a 60- or 90- day supply. This scenario is commonly seen in bids.*

b. *Tier 3 has a copayment of $42, Tier 4 has a copayment of $80 and Tier 5 has a coinsurance of 33 percent, each for a one-month supply with alternatives for a Tier 4 drug found in Tiers 3 and 5. A drug on Tier 4 with a negotiated price of $150 would be $80 at Tier 4 cost. If a tier exception were granted it would be $49.50 at Tier 5 cost and only $42 if granted into Tier 3. Therefore, the exception should be to Tier 3. In contrast, a Tier 4 drug with a negotiated price of $100 would have an $80 copayment at Tier 4, $42 copayment at Tier 3, and 33 percent coinsurance at Tier 5 cost, so in this case the exception should be to Tier 5. This creates a situation that is both inconsistent and very difficult to implement.*

These simple examples present a number of challenges: for beneficiaries to understand when a tier exception would or would not be in their best interest; for plan sponsors to operationalize and maintain; and for CMS auditors and the IRE to determine retrospectively if guidance was followed. Yet, these scenarios become significantly more complex when considering all potential

factors which impact coinsurance at once such as (e.g. negotiated price changes, new drugs in the market which result in changes to the tier in which alternatives reside, days' supply, quantity of drugs dispensed, pharmacy dispensing the prescription). Moreover, if a provision along the lines of the manufacturer rebate pass-through discussed in the RFI is duly implemented, it would be beyond daunting to even consider the number of challenging scenarios in terms of the calculation as to which tier would be more favorable.

We are also concerned about the effective date for the new CMS interpretation that a non-preferred tier is eligible for specialty tier cost-sharing if the alternative drug is on the specialty tier. We view this as a major change that will take significant systems and operational effort to implement, and thus request that CMS clarify that if it proceeds with this new interpretation, the effective date would need to be for the 2019 plan year.

PCMA Recommendation: ***We are concerned that the proposal to allow tiering requests for drugs on a non-preferred tier to qualify for exceptions to the specialty tier cost-sharing will be extremely difficult to implement. If CMS maintains this interpretation, it needs to provide guidance with clear examples on how this can be accomplished and it needs to specify that the new interpretation takes effect in 2019.***

4. *Limits on tiering exceptions – additional limits plans could place on tiering exception requests*

CMS notes that plans would be able to limit availability of tiering exceptions to a preferred tier for brand name drugs where there is a generic approved under an Abbreviated New Drug Application (ANDA), and biological products, including follow-on biologics. It further notes that plans would not have to offer tiering exceptions for brand name drugs or biologics at the cost-sharing level for alternative drugs where the alternatives include only the following drug types: generic drugs with approved ANDAs or authorized generics.

We understand that CMS is seeking to provide that non-preferred brands can be approved to a preferred brand tier, and that non-preferred generics can be approved to a preferred generic tier regardless of the label. We agree that there is now a definition for an authorized generic (using the FDA definition); and, assuming the other changes being proposed go into effect, this definition is a reasonable one. We commend CMS for including authorized generics as this provides clarity that a generic is a generic regardless of how it was approved by the FDA.

PCMA Recommendation: ***We agree with CMS that authorized generics should be included as generics and that the FDA definition for authorized generics is the appropriate one to use.***

5. *Limits on tiering exceptions – Select Care Tier*

While CMS does not discuss this limit, we note that there are some plans that use a Select Care Tier. These tiers provide no or very low-cost coverage for very specific drugs or vaccines. As previously noted by PCMA, failure to exempt these tiers from the tier exception process could have significant financial implications, cause member confusion, and lead to lower plan adoption of Select Care tiers. CMS should specifically provide that the Select Care Tier is exempt from tier exceptions.

***PCMA Recommendation*: PCMA urges CMS to specifically provide that the Select Care Tier is exempt from tier exceptions.**

D. Alternative Drugs (pp. 56372-56373)

CMS Proposal: In response to the request from plan sponsors and PBMs, CMS offers guidance on the definition of alternative drugs to mean treatment of the "condition as it affects the enrollee – that is, taking into consideration the individual's overall clinical condition, including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regiment, which can factor into which drugs are appropriate alternative therapies for that enrollee."

Discussion: PCMA appreciates that CMS is offering guidance on the definition of alternative drugs for the treatment of an enrollee's condition. However, we continue to believe that the definition suggested remains subjective and that it would be significantly improved if CMS would add the important clarification that the alternative drug needs to be approved by the FDA or have compendia support for the same indication, be an appropriate treatment based on place of therapy (current compendia and treatment guidelines), and share the same therapeutic classification and the same route of administration.

We are not clear on why CMS omitted the concept of "same route of administration" from the definition. Without clear direction in regulatory language indicating that tiering exceptions are limited to drugs with a similar indication, it is conceivable that a Part D plan sponsor would be required to allow a tiering exception for a prescription for an injectable diabetic medication to be covered for the copayment associated with an oral diabetes medication. There are two classes of injectable (non-insulin) diabetic medications: glucagon like peptide-1 (GLP-1) receptor agonists (incretin mimetics) and an amylin analogue. Other unsupportable scenarios that could occur where the same route of administration is omitted include: (a) a PCSK9 (for example, evolocumab/Repatha) being subject to a tiering exception and covered at the same cost-share as

an oral statin; (b) ivabradine/Corlanor being covered at the same tier as metoprolol tartrate; (c) Elidel going to the same tier as oral prednisone, or (d) Botox going to the same tier as sumatriptan.

We do not believe that CMS intends for these medications to be subject to a tiering exception as therapeutic alternatives for oral diabetes medications. Clinically, insulin and oral diabetic medications are not within the same place of therapy in treatment guidelines and therefore should not be considered therapeutic alternatives. It is essential that CMS include the concepts of indication, place of therapy, objective therapeutic classification, and same route of administration for clarity to Part D plan sponsors when determining therapeutic alternatives.

Additionally, as we have previously suggested, and once again request, that, for a plan to approve a requested tiering exception, the therapeutic alternative drug must:

1. Be FDA approved for the same indication (e.g. type II diabetes),
2. Be an appropriate treatment based on place of therapy (current compendia and treatment guidelines),
3. Share the same therapeutic classification (e.g., insulins, sulfonylureas, DPP-inhibitors), and
4. Be delivered via the same route of administration.

We remain concerned as to how the IRE would interpret the language provided by CMS if it is not clear that the preferred alternative needs to meet the criteria listed above. Our members have consistently found that the IRE often applies a subjective standard resulting in decisions overturning a PBM determination as to whether a drug is an appropriate alternative.

As noted above, this is another aspect where CMS guidance needs to be synchronized. We suggest that the next updates to Chapter 18 clearly reflect the new definition of alternative drug for purposes of tiering exceptions.

***PCMA Recommendation*: PCMA recommends that CMS adopt a definition of alternative drug which includes that such drug must be provided by the same route of administration, in addition to the same indication of use.**

E. Approval of Tiering Exception Requests (p. 56373)

CMS Proposal: CMS seeks to codify its 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.

Discussion: PCMA continues to believe that the assignment should be to a "lower" applicable tier in this scenario. That said, if CMS adopts the definition of alternative drug to include the mechanism of action as recommended above, it would address our most significant concern about loopholes presented by the use of lowest instead of lower.

PCMA Recommendation: ***PCMA continues to believe that CMS should codify its policy as currently noted in Chapter 18 that tiering exception requests should be made to a "lower" tier.***

10. §423.38 - Establishing Limitations for the Part D Special Election Period for Dually Eligible Beneficiaries (p. 56373-56375)

CMS Proposal: CMS proposes to make the current "open-ended" Special Election Period (SEP) for Full Benefit Dual Eligible (FBDE) and other subsidy-eligible individuals available only in the following circumstances (and only if the beneficiary has not been identified as potentially at-risk or at-risk): (1) within a certain period of time after a CMS or state-initiated enrollment; or (2) as a one-time annual opportunity that can be used at any time of the year.

Specifically, CMS proposes revisions to specify that the SEP is available only as follows: 1) Eligible beneficiaries (that is, those who are dual or other low-income subsidy (LIS)-eligible and do not meet the proposed definitions of at-risk beneficiary or potential at-risk beneficiary) would be able to use the SEP once per calendar year. 2) 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 or within two months of their enrollment in that plan. 3) 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 two months of the change, or of being notified of such change, whichever is later. 4) 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.

Discussion: PCMA agrees that this proposal would create greater stability among plans and limit the opportunity for aggressive marketing to dual-eligible and other LIS-eligible individuals. The change should not impact a significant number of beneficiaries, as indicated by the statistics shared by CMS in the preamble: Most LIS beneficiaries do not make an active choice to join a Part D prescription drug plan (PDP). For plan year 2015, over 71 percent of LIS individuals in PDPs were placed into that plan by CMS. Once in a plan, most LIS beneficiaries do not make changes during the year.

The statistics above support the CMS proposal to allow the SEP only once per calendar year. CMS indicates in the preamble that it considered multiple alternatives related to the SEP proposal. PCMA supports the change as identified by CMS in its proposal, rather than the alternatives considered by CMS.

For the purposes of appropriately reflecting our support for the CMS proposal, PCMA notes one discrepancy in the preamble, which indicates that:

> "Specifically, CMS proposes revisions to §423.38(c) to specify that the SEP is available only as follows:
>
> 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 §423.100) would be able to use the SEP once per calendar year."

We believe that the language should include "do not" prior to the word "meet" so it reads as follows:

> "Eligible beneficiaries (that is, those who are dual or other LIS-eligible and ***do not*** meet the definition of at-risk beneficiary or potential at-risk beneficiary under proposed §423.100) would be able to use the SEP once per calendar year."

This would make it consistent with the language as written in the proposed regulatory text on Page 56507:

> (4) The individual is a full-subsidy eligible individual or other subsidy- eligible individual as defined in §423.772, who has not been identified as a ''potential at-risk beneficiary'' or ''at-risk beneficiary'' as defined in §423.100 and—

Further, while PCMA supports excluding a beneficiary that has been identified as a "potential at-risk beneficiary," CMS has not provided information on how it will know that a beneficiary has been identified as being a "potential at-risk beneficiary." Once a beneficiary is identified as "at-risk," the beneficiary will be identified as such in the Medicare Advantage Prescription Drug System (MARx) system. Until then, our understanding is that CMS will not know about the beneficiary's change in status. PCMA asks CMS to provide clarification on how it will prevent potential at-risk beneficiaries from utilizing the SEP process.

PCMA Recommendations: ***PCMA supports the CMS proposed changes to the regulation to make the current "open-ended" SEP for dual-eligibles and other subsidy-eligible individuals available only in the following circumstances (and only if the beneficiary has not been identified as potentially at-risk or at-risk): (1) within a certain period of time after a CMS or state-initiated enrollment; or (2) as a onetime annual opportunity that can be used at any time of the year.***

PCMA asks CMS to provide clarification on how it will prevent potential at-risk beneficiaries from utilizing the SEP process.

11. §§422, 423 – MA and PDP Quality Rating System

A. Introduction (p. 56375-56376)

CMS Proposal: CMS proposes to codify the existing Star Ratings System for the Medicare Advantage (MA) and Part D programs with some changes. The proposed changes include clearly delineating the rules of adding, updating, and removing measures and modifying how CMS calculates Star Ratings for contracts that consolidate.

Discussion: CMS established the current Star Ratings System and has used the Star Rating measures for the past decade. Star Ratings are posted on the Medicare Plan Finder (MPF) tool to assist beneficiaries in making plan choices and are also used in calculating quality bonus payments (QBPs) and as the basis for terminating Part C and Part D plans. However, the current Part C and Part D Star Ratings System was implemented via the annual advance notice and rate announcement process ("Call Letter"). The draft and final Call Letters attached to the rate announcements have been used each year by CMS to propose for comment and finalize the Star Ratings System.

CMS indicates that it has received comments for the past several years for organizations asking that CMS use Federal Register rulemaking for the Star Ratings System. PCMA agrees with CMS that this is an appropriate time to codify the methodology because the rating system has been used for several years and is relatively mature so there is less need for extensive changes every year.

In the past, PCMA has indicated that it has concerns with constant changes to the Star Ratings measures, especially cut points and methodology. Part D plan sponsors need more stability to make long-term plans to improve measures and then to execute on those plans. While individual changes to the Star Ratings measures may be appropriate when evaluated in a vacuum, constant changes to the Star Ratings measures may be counter-productive to overall improvement in beneficiary care.

PCMA Recommendation: PCMA supports the CMS proposal to codify the existing Star Rating System with the changes proposed by CMS and additional changes recommended by PCMA addressed below.

B. Background (p. 56376-56377)

CMS Proposal: CMS identifies the principles that guided its proposals: alignment with the CMS Quality Strategy; use of consensus-based measures as much as possible; ratings that reflect

true plan quality; methodology that minimizes the risk of misclassification; ratings that are stable over time; fair and equal treatment of contracts; measures are selected to reflect prevalence of conditions and importance of health outcomes in the Medicare population; complete, accurate, and reliable data; improvement on measures is under plan control; ratings useful for public accountability, beneficiary enrollment choice, and driving quality improvement; minimizing unintended consequences; and a transparent process involving multi-stakeholder input.

In the background section of the preamble, CMS requests feedback on a number of topics, including:

- Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.
- Whether CMS's current process for establishing the cut points for Star Ratings 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. CMS is requesting input on additional improvement adjustments that could be implemented, and the effect that these adjustments could have on new entrants.
- Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance, and the operational difficulties that plans could experience if such adjustments were adopted.
- Adding measures that evaluate quality from the perspective of adopting new technology or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.
- Including survey measures of physicians' experiences.

Discussion: PCMA addresses a number of the general topics on which CMS requests feedback.

1. *Measures to be removed/downgraded in future revisions to star ratings*

As CMS considers feedback to improve measures so that the measure set reflect the quality of health outcomes under the rated plans, PCMA has identified current measures that it believes CMS should consider for removal or downgrading. These measures are:

- D01- Call Center – Foreign Language Interpreter and TTY Availability (Part C & D) – As PCMA has previously communicated in its comments on the 2018 Call Letter, CMS test calls do not align with the rate that each foreign language is spoken in the U.S. and in the Medicare population, which we believe should be aligned. In addition, PCMA has a

concern that the sampling methodology is based on the number of call centers a plan sponsor may use and does not consider contract enrollment size. CMS's approach to sampling based on number of physical locations does not adequately account for variability across the broader pool of customer service representatives needed to serve a larger enrolled population. CMS's current approach favors Part D contracts that distribute representatives across multiple physical locations. Until the testing sample mix is properly adjusted, the measure should be moved to the Display Page.

- D05 – Members Choosing to Leave the Plan – The percent of enrollees who choose to leave the contract comes from disenrollment reason codes in Medicare's enrollment system. The disenrollment reason codes do not provide insight as to why members choose to leave a plan. Therefore, the Voluntary Disenrollment measure does not accurately reflect the enrollee's experience or dissatisfaction with the plan's quality of service. This measure is primarily influenced by plan pricing strategies and competitive market dynamics that result in beneficiaries choosing to leave the plan during the Annual Enrollment period (AEP). If the intent is to measure pricing strategies and competitive market dynamics, then the measure is incomplete as it does not account for LIS beneficiaries that are re-assigned during AEP due to loss of benchmark. The Voluntary Disenrollment measure should be moved to the Display Page as CMS considers alternative approaches to measure enrollee experience in a more effective manner.
- Appeals measures – All four appeals measures use data reported by sponsors to Maximus, the independent review entity (IRE). Sponsors have raised concerns about CMS's use of audit findings to determine the completeness of the IRE data used for Star Ratings, since only a small subset of sponsors are audited each year. PCMA is concerned that using data from program audit findings or other reviews, which do not have a required minimum number of cases, can lead to erroneous conclusions about data accuracy.
- Medicare Health Outcomes Survey (HOS) measures - The longitudinal outcomes for the HOS analysis are based on risk-adjusted mortality rates, changes in physical health as measured by the physical component summary score, and changes in mental health as measured by the mental component summary score for the participating MAOs. Several CMS reports have indicated that plans may not be able to move this measure. As one of the principles that CMS has identified is that improvement on measures is under plan control, PCMA encourages CMS to consider removing or downgrading the measurement weight.
- Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey measures – The primary concern with the CAHPS measures has to do with the survey questions used to solicit information from beneficiaries about their experience with the plan. Members do not have knowledge as to what decisions are determined by plans and what decisions

are based on CMS policy, pricing, and coverage requirements. Therefore, plan sponsors may not be able to influence this measure. As one of the principles that CMS has identified is that improvement on measures is under plan control, PCMA encourages CMS to consider removing or downgrading the measurement weight.

PCMA continues to be concerned with the use of civil money penalties (CMPs) and audit data in Star Measures, which are understood to measure quality rather than operational processes. PCMA believes that CMS should eliminate the impact of CMPs and audit results from the Star Ratings program for a number of reasons articulated in previous communications with CMS specific to the Beneficiary Access and Patient Protection (BAPP) measure. The most significant of those are highlighted below:

- Adjustment of the Star Rating measures by audit results creates an un-level playing field. Since not all plans are audited during a given review period, it does not account for the audit/review lifecycle of plans. For every other current Star Ratings measure, performance data is collected for all plans annually using a consistent methodology and data source.
- CMS itself has acknowledged that there is no correlation between plan audit performance and Star Rating measure performance in its 2015 Part C and Part D Program Audit and Enforcement Report: "While Star Ratings remain a valuable measure of quality and beneficiary experience, they evaluate different aspects of sponsors' operations and delivery of the benefit. Therefore, both Star Ratings and audit scores are valuable measures."[8]
- The proposed mixture of Star Ratings measures and audit results is inconsistent with the CMS Quality Strategy, which states that CMS will lead quality measurement alignment.[9] This proposal is not an alignment of measurement systems as CMS does not generally adjust quality/performance metrics based on audits of CMS regulatory requirements in any part of the Medicare program. For example, the recently finalized rule for the Merit-based Incentive Payment System (MIPS) does not include an audit measure or audit adjustment.[10] Although audit results produce a CMS-derived "quantitative score," program audits of plan sponsors are really qualitatively categorical in nature, meaning CMS scrutinizes compliance with CMS requirements in a checkbox fashion based on documented policy, procedures, and process. In contrast, the Star Ratings program is an aggregate quantitative metric based on quantitative metrics that are more outcomes-

[8] CMS, "2015 Part C and Part D Program Audit and Enforcement Report," September 6, 2016. Accessed at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2015_C_and_D_Program_Audit_and_Enforcement-Report.pdf
[9] CMS Quality Strategy.
[10] 81 FR 77008 (CMS-5517-FC)

based, clinical in nature, and developed by independent measurement organizations, such as the Pharmacy Quality Alliance.

While PCMA concurs with CMS that information on audit scores and CMPs are important to beneficiaries as they evaluate plans, integrating these results into Star Ratings limits the transparency to beneficiaries. It is unrealistic to expect beneficiaries to translate an overall Star Ratings measure displayed on MPF into a differentiated understanding of the plan's performance on quality measures and the plan's performance on audits or enforcement action. CMS has the opportunity to share information on audit scores and CMPs on the MPF website, which is a more appropriate way to provide clear visibility for such information to beneficiaries. PCMA would value the opportunity to work with CMS and other stakeholders to determine the best method to communicate audit scores, CMPs, and sanctions to beneficiaries by making such information available more broadly and publicly.

2. New technology

PCMA supports the addition of measures that evaluate quality from the perspective of adopting new technology or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan. Specifically, PCMA supports measures that demonstrate an ability to leverage technology, specifically use of EHRs and measures that reflect the MACRA telehealth measures. PCMA encourages CMS not to use measures that become "check-the-box" measures or measures that serve only to identify plans sponsors that are incorporating basic technology. PCMA looks to work with CMS on developing measures related to the use of e-prescribing, e-prior authorization (ePA), and the use of the Cancel Rx feature. However, CMS must take into consideration that PDPs do not have a contractual relationship with prescribers and can encourage but not require the use of valuable technology.

***PCMA Recommendation*: PCMA recommends that CMS remove or downgrade the following measures as it proposes new measures for future years based on the discussion above:**

- ***D01 - Call Center - Foreign Language Interpreter and TTY Availability (Part C & D)***
- ***D05 – Members Choosing to Leave the Plan***
- ***Appeals measures***
- ***HOS measures***
- ***CAHPS survey measures***

CMS should not include measures in the Star Ratings program that rely on audit findings as the primary data source. PCMA acknowledges the need to provide beneficiaries with insight

into a plan's audit findings but firmly believes this insight needs to be accomplished outside of the Star Ratings program to achieve CMS's stated goal of transparency to beneficiaries.

PCMA supports the addition of measures that evaluate quality from the perspective of adopting new technology or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan. Specifically, PCMA supports measures that demonstrate an ability to leverage technology, specifically use of EHRs and measures the reflect the MACRA telehealth measures.

C. Basis, Purpose and Applicability of the Quality Star Ratings System (p. 56378)

CMS Proposal: CMS proposes that the existing purposes of the quality rating system – to provide comparative information to Medicare beneficiaries pursuant to sections 1851(d) and 1860D-1(c), to identify and apply the payment consequences for MA plans under sections 1853(o) and 1854(b)(1)(C), and to evaluate and oversee overall and specific performance by plans – would continue.

CMS propose to codify the current quality Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019. In addition, CMS proposes that the current quality Star Ratings System and the procedures for revising it will remain in place for the 2019 and 2020 quality Star Ratings. CMS intends to continue the current process at least until the 2019 measurement period that CMS is proposing as the first measurement period under these new regulations, but CMS may discontinue that process at a later date as the rulemaking process may provide sufficient opportunity for public input.

Discussion: In the preamble, CMS indicates that it is continuing the existing purposes of the Star Ratings System, including:

- provide comparative information on plan quality and performance to beneficiaries making enrollment and coverage decisions;
- provide quality ratings, which for MAOs plans are to be used in determining quality bonus payments status; and
- provide a means to evaluate and oversee overall and specific performance by plans.

PCMA supports the CMS proposals for retaining and codifying the current Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019.

CMS finalized a rule in 2011 to implement a provision to calculate additional bonus payments to MAOs and to use the existing Star Ratings System on which to base the additional bonus payments. However, Part D plan sponsors are not eligible for quality based payments or rebates. In addition to the proposed provisions, PCMA suggests that CMS add financial incentives, similar to the MA-PD Quality Bonus Payments for stand-alone PDPs. Unlike MA-PD plans that receive high Star Ratings and receive Quality Bonus Payments or a higher reimbursement rate, stand-alone PDPs do not receive similar payments for high Star Ratings. As in previous PCMA comments, PCMA continues to recommend that CMS add financial incentive, similar to MA-PD Quality Bonus Payments, for stand-alone PDPs. Due to disparities in the use of prescription drugs, PCMA recommends that Star Ratings be risk-adjusted for LIS beneficiaries if and when a Part D QBP is developed.

***PCMA Recommendation*: PCMA supports the CMS proposal to continue the existing purposes of the quality rating system. PCMA supports the CMS proposal to codify the current quality Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019, with the exceptions discussed in recommendations in this letter. However, PCMA recommends that CMS add financial incentive, similar to MA-PD Quality Bonus Payments, for stand-alone PDPs, but only if Star Ratings are risk-adjusted for LIS beneficiaries. PCMA also supports the CMS proposal that the current quality Star Ratings System and the procedures for revising it will remain in place for the 2019 and 2020 quality Star Ratings**.

D. Contract Ratings (p. 56379-56380)

CMS Proposal: Star Ratings and data reporting are currently at the contract level for most measures. CMS proposes 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.

Discussion: CMS indicates that it has considered whether data should be collected and measures scored at the plan level rather than at the contract level and indicates that, when enough data are available, plan level quality reporting would better reflect the quality of care provided to enrollees in that plan. PCMA has concerns with the suggestion that data could be collected and measures scored at the plan level. PCMA believes that data collection at the plan level would create increased administrative burden for both plans and for CMS, with the more expansive review necessary to validate measure scores. The additional administrative resources required would take away from the important focus on improved quality. PCMA is also concerned about the reliability of data scored at the plan level. In addition, plan level reporting would increase

administrative burden for CMS. If CMS moves to quality scores at the plan level, CMS should be required to provide monthly Acumen reports and plan preview data at the PBP level.

CMS also indicates that it is exploring whether some measure data could be reported at a higher level (parent organization versus contract) to ease and simplify reporting yet still remain useful (e.g., call center measures). PCMA believes that reporting different Star Ratings measures at different levels (contract, plan, parent organization) would cause confusion for Medicare Advantage and Part D plan sponsors, although the increased volume may help with more accurate measures.

***PCMA Recommendation*: PCMA supports the CMS proposal to continue the practice of calculating the Star Ratings at the contract level; all PBPs under the contract would have the same overall and/or summary ratings.**

E. Contract Consolidations (p. 56380- 56382)

CMS Proposal: CMS is proposing a change in how contract-level Star Ratings are assigned in the case of contract consolidations. Instead of assigning the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, CMS proposes to assign and display on MPF 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.

CMS is proposing both a specific rule to address the QBP rating following the first year after the consolidation and a rule for subsequent years. The process for assigning Star Ratings for posting on MPF for the first 2 years following the consolidation would be as follows:

- For the first contract year following a consolidation, the enrollment-weighted means would be used to set Star Ratings 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 mean enrollment during the study period.
- For the second year following the consolidation, 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.

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, CMS proposes to calculate the QBP rating for that first year following the consolidation using the enrollment-weighted mean 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.

Discussion: PCMA supports a Star Ratings System that accurately reflects plan performance, and, therefore, supports the CMS proposal to assign and display 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 involved in the consolidation. These proposed new rules should more accurately reflect performance of the surviving and consumed contracts to change how contract-level Star Ratings are assigned in the case of contract consolidation.

While PCMA supports the proposed change to the calculation of Star Ratings in cases of contract consolidation, we have concerns as to the timing of the change. CMS indicates in the preamble on page 56378 that it intends for the proposed changes to the Star Rating System to take effect beginning with the 2019 measurement year and the 2021 Star Ratings, which implies that the contract consolidation is part of the overall update to the Star Rating System. However, the information provided in the regulatory impact analysis section, specifically Table 28 on page 36486, suggests that CMS intends for this change to take effect beginning with the 2019 plan year, based on a recalculation of 2018 Star Ratings.

Should CMS finalize the proposed change to the treatment of Star Ratings in cases of contract consolidation, this change should not take effect for the 2019 plan year, but should be implemented on the same schedule as other changes to the Stars Rating System. To do otherwise would be to violate the principles of transparency and consistency that CMS lays out at the start of the Quality Ratings System section of the proposed rule. Part D plan sponsors that make decisions around contract consolidation in anticipation of the 2019 plan year should be able to rely on a set of rules that will not change after the fact. Part D plans will need to notify CMS of any planned contract consolidations for the 2019 plan year by early April 2018. Changing the rules for how contract consolidations are to be treated with regard to Star Ratings after Part D plan sponsors have made business decisions and filed required notifications to CMS would be

inappropriate and be in direct conflict with CMS's stated goals of increasing transparency and stability in the Quality Rating System program.

***PCMA Recommendation*: PCMA supports the CMS proposal to change how contract-level Star Ratings are assigned in the case of contract consolidation. If CMS finalizes the proposed change to the treatment of Star Ratings in cases of contract consolidation, PCMA urges that the changes not take effect for the 2019 plan year.**

F. Data Sources (p. 56382)

CMS Proposal: CMS proposes that the type of data used for Star Ratings will be data consistent with the section 1852(e) limits. The data would 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. In addition, CMS proposes a regulatory provision that requires MAOs and Part D plan sponsors to submit unbiased, accurate, and complete quality data. CMS indicates that its authority to collect quality data is clear under the statute and existing regulations.

Discussion: PCMA recognizes that it is important that the data underlying the ratings are unbiased, accurate, and complete so that the ratings themselves are reliable. This proposed text would clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance.

However, PCMA is concerned about the use of audit data in Star Ratings, which are understood to measures quality rather than operational processes. As indicated in the background section above, PCMA believes that CMS should eliminate audit results from the Star Ratings program for a number of reasons, including:

- Adjustment of the Star Rating measures by audit results creates an un-level playing field.
- CMS itself has acknowledged that there is no correlation between plan audit performance and Star Rating measure performance in its 2015 Part C and Part D Program Audit and Enforcement Report.
- The proposed mixture of Star Ratings measures and audit results is inconsistent with the CMS Quality Strategy, which states that CMS will lead quality measurement alignment.

***PCMA Recommendation*: CMS should not include measures in the Star Ratings program that rely on audit findings as the primary data source.**

G. Adding, Updating, and Removing Measures (p. 56382-56385)

CMS Proposal: CMS proposes specific rules to govern the addition, update, and removal of measures and which rules would be applied to the proposed measure sets, 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.

CMS proposes 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, CMS would to continue the current practice of removing the measure from the Star Ratings.
- New measures and substantive updates to existing measures would be added to the Star Ratings System based on future rulemaking. Prior to rulemaking, CMS would announce new measures and substantive updates to existing measures and solicit feedback using the Call Letter.
- Existing measures used for Star Ratings would get regular updates from the measure stewards when the changes are not substantive.
- Existing measures used for Star Ratings would be removed using the Call Letter when there has been a change in clinical guidelines associated with the measure or reliability issues identified in advance of the measurement period. Removal might be permanent or temporary, depending on the basis for the removal.

CMS is proposing specific rules for updating and removal that would be implemented through subregulatory action, and not through rulemaking; CMS would announce application of the regulation standards in the Call Letter.

- CMS would codify the general rule that CMS would add, update, and remove measures used to calculate Star Ratings. The rules would identify when these types of changes would not involve rulemaking. CMS would solicit feedback of its application of the rules using the draft and final Call Letter each year.
- CMS would review the quality of the data on which performance, scoring, and rating of measures is done each year and would continue its 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. If a systemic data quality issue is identified during the calculation of the Star Ratings, CMS would remove the measure from that year's rating.

- CMS will be guided by the principles of the proposed rule in identifying whether to add a new measure. Measures should be aligned with best practices among payers and the needs of the end users. CMS strategy is to adopt measures when they are available, nationally endorsed, and in alignment with the private sector, 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). CMS does not intend this standard to require that a measure be adopted by an independent measure steward or endorsed by NQF in order for CMS to propose its use for the Star Ratings.

For the 2021 Star Ratings, CMS expects measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures.

CMS indicates that over time new measures will be added and measures will be removed from the Star Ratings program to meet its policy goals. Guidelines for deciding whether to propose new measures through future rulemaking will use the following criteria: 1) importance, 2) performance gap, 3) reliability and validity, 4) feasibility, and 5) alignment. CMS will solicit feedback on any potential new measures initially through the Call Letter. As new performance measures are developed and adopted, CMS proposes that they would be incorporated into the display page for at least two years but that CMS 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.

CMS proposes 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), CMS proposes 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. CMS 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. CMS proposes 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, the measure would be moved to the display page for at least two years and proposed through rulemaking for inclusion in Star Ratings. 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.

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. CMS proposes to use such updated measures to calculate and assign Star Ratings without the updated measure being placed on the display page, consistent with current practice.

CMS proposes to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period. Measures with non-substantive updates would not be moved to the display page. The following circumstances would allow the updated measure to be used in the Star Ratings program without interruption:

- The change narrows the denominator or population covered by the measure with no other changes
- The change does not meaningfully impact the numerator or denominator of the measure
- The updates address revisions to the clinical codes without change in the intent of the measure and the target population
- The measure specification change is providing additional clarifications
- The measure specification change is adding additional data sources

CMS proposes the two circumstances under which a measure would be removed entirely from the calculation of the Star Ratings: 1) For changes in clinical guidelines that mean that the measure specifications are no longer believed to align with or promote positive health outcomes, CMS needs the flexibility to remove measures that are not consistent with current guidelines. CMS is proposing to announce such subregulatory removals through the Call Letter. 2) CMS 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.

Discussion: PCMA supports the CMS proposal to formalize the rules that govern the addition, update and removal of measures. In previous communications with CMS, PCMA shared our concerns with constant changes to the Star Ratings measures, especially cut points and methodology. Part D plan sponsors need more stability to make long-term plans to improve measures and then to execute on those plans. While individual changes to the Star Ratings measures may be appropriate when evaluated in a vacuum, constant changes to the measure set may be counter-productive to overall improvement in beneficiary care. In addition, the adoption of a formal rulemaking process for future changes to the Star Ratings measures will provide the opportunity for comments from a wider range of stakeholders versus the existing Call Letter process. PCMA supports the CMS proposal to formularize the rules to govern the addition, update and removal of measures, and to reduce the constant changes to the Star Ratings measures.

PCMA supports the CMS proposal to keep measures on the display page for at least two years and supports the acknowledgement that CMS would keep a new measure on the display page for a longer period of time if CMS finds there are reliability or validity issues with the measure. The longer display measure period will provide the opportunity to further observe a potential star measure, with the results available to the public, before including a measure in the Star Rating calculation which may have significant impact on plans.

PCMA believes that all measures should be prospective. CMS should not adopt a measure for a given year with a measurement period that has passed, presenting a plan with no opportunity to influence that measure. PCMA is pleased that the timeline, as proposed by CMS, will not allow a measure to be added when the measurement period has passed.

CMS indicates that it will continue to analyze measures to determine if measure scores are "topped out" or if measures have low reliability. On the issue of topped out measures, PCMA notes as follows:

- CMS should determine how it handles topped out measures based on the merit and benefit of the individual measure and not specifically on whether the measure is topped out.
- Many topped out measures evaluate fundamental components of quality, and, as such, should not be removed from the Star Ratings measure set.
- CMS should develop an agency-wide policy related to topped out measures as this is an issue in all CMS programs and has been discussed in the recently issued proposed rule providing updates for the second and future years of the Quality Payment Program (QPP).
- Topped out measures, like other measures, should be re-evaluated to determine if the measure still provides merit. CMS may consider decreasing the weighting of a topped out measure rather than discontinuing the measure if it no longer provides a benefit.
- Some reasons to maintain topped out measures, as noted in comments received by CMS on the 2017 QPP proposed rule, include:
    - Topped out measures may serve to motivate continued high-quality care.
    - Declines in measure will not be captured if a measure is eliminated.
    - Providing beneficiaries with information about high performance is important.

PCMA supports CMS in its proposal to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period and agrees with the description that CMS spells out to determine whether a measure change is non-substantive. PCMA encourages CMS to be as specific as possible and asks that CMS provide more insight

than is contained in the proposed rule. PCMA has raised concerns in the past about changes that CMS staff determined to be non-substantive when the industry recognized that the changes were substantive (for example, last year's changes to the MPF Price Accuracy measure). PCMA recognizes that disputes as to substantive/non-substantive will arise, even with regulations to codify a list for identifying non-substantive changes. PCMA strongly recommends that CMS allow for input from the industry to determine whether a measure change is substantive or non-substantive and that CMS establish a process for any challenges raised as to whether a change is substantive or non-substantive. When CMS does make a change that it considers to be non-substantive, the industry needs to be provided with the full methodology and the results of the measure changes as calculated with simulated data.

PCMA Recommendation: ***PCMA supports the CMS proposal to formularize the rules to govern the addition, update and removal of measures, and to reduce the constant changes to the Star Ratings measures. PCMA recommends that all measures be prospective; PCMA supports the CMS proposal to keep measures on the display page for at least two years; PCMA supports CMS in its proposal to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period, encourages CMS to be as specific as possible, and asks that CMS provide more insight than is contained in the proposed rule. PCMA recommends that CMS allow for input from the industry to determine whether a measure change is substantive or non-substantive and that CMS establish a process for any challenges raised as to whether a change is substantive or non-substantive.***

H. Measure Set for Performance Periods Beginning or after January 1, 2019 (p. 56385-56393)

CMS Proposal: CMS is proposing the measures included in Table 2 (pages 56386-56393) to be collected for performance periods beginning on or after January 1, 2019 for the 2021 Part C and D Star Ratings.

Discussion: In general, PCMA supports the measure set included in Table 2 to be collected for the performance periods beginning on or after January 1, 2019 for the 2021 Star Ratings. However, as previously noted, PCMA strongly urges that CMS to not include measures in the Star Ratings program that rely on audit findings as the primary data source.

For measurement years going forward, PCMA recommends changes discussed fully in the section of this comment letter related to the Background section of the proposed rule. PCMA also recommends that CMS should eliminate the impact of CMPs and audit results from the Star Ratings program in future years for a number of reasons articulated earlier in this letter.

<u>PCMA Recommendation</u>: In general, PCMA supports the measure set included in Table 2 to be collected for the performance periods beginning on or after January 1, 2019, with additional recommendations found in the section of our comments responding to the Background section of the proposed rule. PCMA strongly urges that CMS to not include measures in the Star Ratings program that rely on audit findings as the primary data source.

I. Improvement Measures (p. 56394)

<u>CMS Proposal</u>: CMS proposes to continue the current methodology for calculating the improvement measures. The subset of measures to be included in the improvement measures following these criteria would be announced through the Call Letter. CMS proposes 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 two 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 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 two 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.

CMS proposes a special rule to hold harmless sponsoring organizations that have 5-star ratings for both years on a measure used for the improvement measure.

Discussion: PCMA is supportive of the focus on improvement; however, the current methodology assumes the possibility of unlimited improvement. Complex methods, used after the fact to determine the significance of improvement, can deter continuous improvement efforts. Depending on the level of measure performance, there is a natural concept of diminishing returns. If the current methodology is retained, CMS should make an adjustment to acknowledge that an improvement in scores from 95 to 96 is more difficult than an improvement in scores from 70 to 71.

PCMA recommends a predictable gold standard be established for determining meaningful improvement as a set percentage reduction of sub-optimal measure rate. As an example, if a contract in year 0 performed at a rate of 80 percent for a measure, where higher rates are better, meaningful improvement could be categorized for year 1 performance at 81 percent (a 5 percent reduction in sub-optimal rate). For the same measure for another contract performing at 60 percent, a meaningful improvement would then be achieved with a year 1 performance at 62 percent. With this proposal, contracts performing above the 5-star threshold should have a measure-level "hold harmless" criteria with the measure counted as compliant for inclusion in the improvement measure calculation.

In addition, CAHPS measures should be removed from the improvement measures calculation because survey data are based on respondents' perceptions of their health status and are not a true reflection of Part D plan performance or enrollees' health outcomes. Part D plan sponsors should not be judged on perceptions but on objective and clinically relevant outcomes. CMS has had challenges with its CAHPS vendor in recent years, particularly around sample selection. If performed inconsistently, the improvement comparison will not be valid—further emphasizing the importance of excluding CAHPS measures from the improvement measures.

PCMA also requests that CMS make the process more transparent and provide a clearer explanation of the process. Plan sponsors have not been able to accurately predict what results they will see on the improvement measures as calculated by CMS.

PCMA supports the provision to hold harmless sponsoring organizations that have 5-star ratings for both years on a measure used for the improvement process.

PCMA Recommendation*: PCMA recommends that CMS should adjust the improvement measures methodology to acknowledge that an improvement in scores from 95 to 96 is more difficult than an improvement in scores from 70 to 71. A predictable gold standard should be established for determining meaningful improvement as a set percentage reduction of sub-optimal measure rate. PCMA also recommends that CAHPS measures should be removed from the improvement measures calculation. PCMA requests that CMS make the process more transparent, providing a clearer explanation of the CMS process. Finally, PCMA supports the provision to hold harmless sponsoring organizations that have 5-star ratings for both years on a measure used for the improvement process.

J. Data Integrity (p. 56394-56397)

CMS Proposal: CMS proposes to codify 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).

CMS proposes rules for circumstances where CMS believe a specific response is appropriate.

- To reduce HEDIS measures to 1 star when audited data are submitted to NCQA with an audit designation of "biased rate" based on an auditor's review of the data if a plan chooses to report (as is current policy); this proposal would also apply when a plan chooses not to submit and has an audit designation of "non-report."
- To continue to reduce Part C and 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 data validation standards/sub-standards for data directly used to calculate the associated measure.
- To authorize scaled reductions in Star Ratings for appeal measures in both Part C and Part D. For instances where the integrity of the data is compromised because of the action or inaction of the sponsoring organization, CMS indicates that its only recourse is to reduce the rating to 1 star for affected measures. CMS proposes 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 CMS to use scaled reductions for the appeals measures to account for the degree to which the data are missing. CMS proposes to use multiple data sources whenever possible, such as the Timeliness Monitoring Project data or information from audits to determine whether the data at the IRE are complete.

- To reduce a contract's 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. CMS is proposing a methodology for reductions that reflects the degree of the data accuracy issue for a contract. 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.
- To use a three-stage process using 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 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.
- To use 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 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.

CMS proposes to authorize reductions in a measure's Star Rating when there are other data accuracy concerns.

Discussion: PCMA supports the concept of scaled reduction. However, PCMA has concerns with the rule proposed by CMS to authorize scaled reductions in Star Ratings for appeal measures. Specifically, PCMA's concerns are with the range of data sources that CMS proposes to use to determine whether the data at the IRE are complete. As indicated previously in this letter, PCMA opposes the use of audit data for use in the CMS Quality Measurement System. Among other PCMA concerns most relevant for this provision, the adjustment of the Star Rating measures by audit results creates an un-level playing field. Since not all plans are audited during a given review period, it does not account for the audit/review lifecycle of plans.

In addition, PCMA is concerned that the process as proposed raises questions about the administrative processes necessary, both for CMS and for Part D plan sponsors. PCMA would

recommend that CMS consider developing a data-driven, less complicated and more streamlined approach. PCMA asks that CMS provide additional information on the timeline/calendar for plans to be provided with information on scaled reductions.

***PCMA Recommendation*: While PCMA supports the concept of scaled reduction, it is concerned with the range of data sources that CMS proposes to use to determine whether the data at the IRE are complete. PCMA opposes the use of audit data for use in the CMS Quality Measurement System. Instead, PCMA recommends that CMS consider developing a less complicated and more streamlined approach. PCMA asks that CMS provide additional information on the timeline/calendar for plans to be provided with information on scaled reductions.**

K. Measure-Level Star Ratings (p. 56397-56399)

CMS Proposal: CMS proposes to continue to determine cut points by applying either clustering or a relative distribution and significance testing methodology and proposes to codify this policy. For non-CAHPS measures, CMS would use a clustering methodology detailed in the proposed rule and for CAHPS measures, CMS 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.

Discussion: As part of CMS's clustering methodology, for each individual measure, CMS 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. According to CMS, the current 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. Under the proposal to use clustering to set cut points, CMS would not require the same number of observations (contracts) within each rating and instead would use a data-driven approach. PCMA appreciates the information being provided on the proposed methodology to determine cut points as this information has been requested by Part D plan sponsors for several years.

PCMA recommends that, rather than codifying the current methodology to determine cut points by applying either clustering or a relative distribution and significance testing methodology, CMS use this opportunity to identify a methodology to determine cut points that more accurately reflect industry performance and that are not as susceptible to influence by outliers. If CMS continues the current methodology, CMS should make adjustments to put a lower weighting on low enrollment plans or to exclude such plans from the clustering methodology calculations.

PCMA encourages CMS to address the need to make adjustments to its methodology for determining cut points prior to the 2019 measurement year.

CMS indicates that it is 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. Part D plan sponsors have struggled with the expansiveness of cut point changes from year-to-year; therefore, PCMA welcomes CMS's effort to provide stability for cut points from year to year. However, the efforts to minimize year-to-year changes in cut points are building on a base of non-representative cut points. To achieve cut point thresholds that reflect industry performance, CMS should consider the need for cut points to change to reach an appropriate reflection of performance.

PCMA Recommendation: ***PCMA recommends that CMS use this opportunity to identify a methodology to determine cut points that more accurately reflect industry performance and that are not as susceptible to influence by outliers. If CMS continues the current methodology, CMS should make adjustments to put a lower weighting on low enrollment plans or to exclude such plans from the clustering methodology calculations. PCMA also recommends that CMS consider the need for cut points to change to reach an appropriate reflection of performance.***

L. Hierarchical Structure of the Ratings (p. 56399)

CMS Proposal: CMS proposes to continue existing policy to use a hierarchical structure for the Star Ratings. Because the 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. 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.

Discussion: PCMA is supportive of the current methodology of a hierarchical structure for the Star Ratings. 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.

PCMA Recommendation: ***PCMA supports the CMS proposal to continue existing policy to use a hierarchical structure for the Star Ratings.***

M. Domain Star Ratings (p. 56399-56400)

CMS Proposal: Currently the domains are used purely for purposes of displaying data on MPF to organize the measures and help consumers interpret the data. CMS proposes to continue this policy.

There are nine current domains - five for Part C measures for MA-only and MA-PDs plans and four for Part D measures for MA-PDs. CMS proposes to continue to group measures for purposes of display on MPF and to continue use of the same domains as in current practice. The current domains:

- Part C: 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; Health Plan Customer Service
- Part D: 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

Star Ratings for domains are calculated using the unweighted mean of the Star Ratings of the included measures and displayed to the nearest whole star, using a 1 - 5 star scale. CMS proposes to continue this policy and proposes to provide that a minimum number of measures must be reported for a domain rating to be calculated.

Discussion: 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. PCMA believes that the current domains are useful for the purpose of displaying data on the MPF and to help consumers interpret the data.

PCMA Recommendation: ***PCMA supports the continued use of the nine current domains for the purposes of display on MPF as in current practice.***

N. Part C and Part D Summary Ratings (p. 56400)

CMS Proposal: 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. CMS is proposing to codify in regulation the adoption of Part C summary ratings and Part D summary ratings.

CMS proposes the overall formula for calculating the summary ratings. Under current policy, 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 and the CAI. CMS proposes that the 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.

Consistent with current policy, CMS proposes that a 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 improvement measures are based on identified measures that are each counted towards meeting the proposed requirement for the calculation of a summary rating. CMS proposes 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.

CMS proposes that the summary ratings are on a 1- to 5-star scale in half-star increments and will be displayed in HPMS and MPF to the nearest half-star. If a contract has not met the measure requirement for calculating a summary rating, the display in HPMS and MPF 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."

Discussion: PCMA supports CMS plans to codify the system for summary rating scores and the display in HPMS and MPF to the nearest half-star, with one modification.

The current rule dates from the period during which all measures had a weight of 1. In the current system, measures have weights of 1, 1.5, or 3. As CMS now uses measure weighting, it would be appropriate to allow a summary rating to be calculated if the available measures for the summary rating are at least half of the weighted value of the full measure set.

PCMA Recommendation: ***PCMA supports the CMS proposal to codify in regulation the adoption of Part D summary ratings. PCMA recommends that CMS allow a summary rating***

to be calculated if the available measures for the summary rating are at least half of the weighted value of the full measure set.

O. Overall Ratings (p. 56400-56401)

CMS Proposal: CMS proposes to codify the standards for calculating and assigning overall Star Ratings for MA-PD contracts. 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. The overall rating 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 and the application of the CAI.

Consistent with current policy, CMS proposes 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 percent of the measures are reported. The 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. CMS proposes 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.

The overall rating would be posted on HPMS and MPF, with specific messages for lack of ratings for certain reasons. Low enrollment contracts and new plans do not receive an overall or summary rating because of the lack of necessary data.

Discussion: PCMA supports the overall Star Rating as a global rating that summarizes the plan's quality and performance for the types of services offered by the plans under the rated contract.

PCMA Recommendation: PCMA supports the CMS proposal to codify the standards for calculating and assigning overall Star Ratings for MA-PD contracts.

P. Measure Weights (p. 56401-56402)

CMS Proposal: CMS proposes 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). CMS indicates that it is considering increasing the weight of the patient experience and complaints and access measures.

CMS proposes 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.

Discussion: PCMA appreciates the importance of the patient experience as a view of the quality of plan operations. However, PCMA is concerned with some of the current patient experience measures as they fluctuate with patient experiences that cannot be impacted by the plan. For example, patients complain about not getting 90-day supply of medications when CMS regulations do not allow 90-day supply on all drugs. Cost and coverage issues are outside Part D plan control and make up some of the most significant beneficiary concerns. In addition, PCMA has concerns that CAHPS calculations may not be a clear and transparent as they should be. Therefore, PCMA recommends that the patient experience, complaints and access measures continue to be weighted at 1.0.

CMS proposes to assign new measures to the Star Ratings program a weight of 1 for their first year in the Star Ratings. PCMA supports the CMS proposal to assign new measures a weight of 1 for the first year to avoid dramatic shifts in Star Ratings (positive or negative) as CMS and plan sponsors gain experience with any challenges associated with a new measure.

PCMA Recommendation: ***PCMA recommends that the patient experience, complaints and access measures continue to be weighted at 1.0; PCMA supports the CMS proposal to assign new measures to the Star Ratings program a weight of 1 for their first year in the Star Ratings.***

Q. Application of the Improvement Measure Scores (p. 56402)

CMS Proposal: Consistent with current policy, CMS proposes a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings. CMS is proposing a series of rules that specify when the improvement measure is included in calculating overall and summary ratings.

PDPs would have the hold harmless provisions for highly-rated contracts applied for the Part D summary ratings. For a 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 and CAI, is done. The higher summary rating would be used

for the summary rating for the contract's highest rating. For 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.

Discussion: PCMA supports the CMS proposal for a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings. PCMA also supports the proposed rules that specify when the improvement measure is included in calculating overall and summary ratings.

PCMA Recommendation: PCMA supports the CMS proposal for a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings and supports the proposed rules used to determine the application of the provision.

R. Reward Factor (p. 56402-56403)

CMS Proposal: CMS proposes: 1) to codify the calculation and use of the reward factor and to update annually the performance and variance thresholds for the reward factor based upon the data for the Star Ratings year, consistent with current policy; 2) to continue the use of a reward factor to reward contracts with consistently high and stable performance over time; and 3) to continue to employ the methodology described in this subsection to categorize and determine the reward factor for contracts. These reward factor adjustments would be applied at the summary and overall rating level.

Discussion: In 2011, the integration factor (later renamed the reward factor) was added to the Star Ratings methodology to reward contracts that have consistently high performance. It is currently added to the summary and overall rating of contracts that have both high and stable relative performance for the associated summary or overall rating. The CMS proposal includes a multistep process to determine the values that correspond to the thresholds for the reward factors for the summary and/or overall Star Ratings for a contract. PCMA is supportive of the CMS methodology for calculating the reward factor.

PCMA Recommendation: PCMA supports the CMS proposal to codify the use and calculation of the reward factor.

S. Categorical Adjustment Index (p. 56404-56406)

CMS Proposal: CMS proposes to codify the calculation use for the Categorical Adjustment Index (CAI) and use of the reward factor and the CAI, while CMS considers other alternatives for the future. The adjusted measure scores of a subset of the Star Ratings measures currently serve as the foundation for the determination of the CAI values. Measures are excluded as candidates for adjustment if the measures are already case-mix adjusted for SES, if the focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue, 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). CMS proposes to codify the process for determining the measures for CAI values as detailed in the proposed rule. The set of measures for adjustment for the determination of the CAI would be announced in the draft Call Letter.

CMS proposes to continue the use of the CAI while the measure stewards continue their examination of the measure specifications and the Assistant Secretary for Planning and Evaluation (ASPE) completes studies as mandated by legislation and formalizes final recommendations. Contracts would be categorized based on their percentages of LIS/DE and disability using the data. 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. CMS would include the CAI values in the draft and final Call Letter each year while the interim solution is applied.

Discussion: PCMA continues to believe that SES adjustment is necessary to balance challenges encountered by PDPs with a large percentage of LIS enrollees. CMS should provide support to accelerate the development and adoption of measure-level risk adjustment methods proposed by national measure stewards.

In addition, PCMA recommends that CMS consider the following modifications to the current and future methodologies to increase the appropriateness of the adjustment: 1) Expand the number of measures included in the adjustment model; and 2) incorporate additional factors, including gender and age, that are predictors of medication adherence and other quality measures.

PCMA Recommendation: ***PCMA supports the CMS proposal to codify the calculation used for the CAI and use of the reward factor and the CAI, while CMS considers other alternatives for the future. However, PCMA recommends that CMS consider modifications to the current and future methodologies to increase the appropriateness of the adjustment.***

T. High and Low Performing Icons (p. 56406-56407)

CMS Proposal: CMS proposes 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 a contract for achieving a 5-star summary rating.

CMS proposes 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. 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.

CMS proposes to continue the policy of disabling the MPF online enrollment function for 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.

Discussion: PCMA is supportive of CMS's proposal for identifying a plan with a high or low performing icon as a result of its performance on the Part C or Part D summary ratings.

PCMA agrees with CMS that 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. PCMA agrees that 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 should be warned but allowed to enroll via contact with the plan directly.

PCMA Recommendation: ***PCMA supports the CMS proposal for identifying a plan with a high or low performing icon as a result of its performance on the Part C or Part D summary ratings.***

U. Plan Review of Star Ratings (p. 56407)

CMS Proposal: CMS proposes that CMS have plan preview periods before each Star Ratings release, consistent with current practice.

Discussion: Currently Part C and D sponsors can preview their Star Ratings data in HPMS prior to display on the MPF. During the first plan preview, plans sponsors can 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, preliminary Star Ratings for each measure, domain, summary score, and overall score would be displayed. Plan sponsors are again to closely review the methodology and their posted data for each measure on the second review, as well as their preliminary Star Rating assignments. CMS is proposing that CMS continue to offer plan preview periods, but is not codifying the details of each period. PCMA encourages CMS to continue the first and second plan preview process.

In addition, PCMA requests that CMS include full data sets that would allow plans to effectively analyze the measures and determine cuts points. Specifically, CMS should release the Improvement Measures details (i.e., the improvement measure calculation emulation spreadsheets) for all contracts, including unrounded rates, significance calculations, and other data.

***PCMA Recommendation*: PCMA supports the proposal that CMS have plan preview periods before each Star Ratings release. PCMA encourages CMS to continue this first and second plan preview process, consistent with current practice. In addition, PCMA requests that CMS include full data sets that would allow plans to effectively analyze the measures and determine cut points.**

12. §§423.100, 423.505 – Any Willing Pharmacy Standards Terms and Conditions and to Better Define Pharmacy Types (pp. 56407-56411)

A. Background (p.56407)

CMS Proposal: CMS sets forth its concerns that standard terms and conditions (T&C) have in some cases circumvented any willing pharmacy ("AWP") requirements and led to inappropriate exclusion of pharmacies from network participation. CMS asserts that it wants plans to continue preferred networks, while "fully complying" with AWP.

Discussion: We are extremely concerned by CMS's AWP discussion and proposals. CMS appears to be undertaking this approach based solely on a few anecdotal complaints from pharmacies and selective reference to the Part D statute. CMS's remarks, if carried to their logical conclusion, will make it extremely difficult for Part D plan sponsors to have important quality and other appropriate standards either in their regular networks, or possibly even in their preferred networks. CMS further appears to be laying the groundwork for any retail pharmacy entity to also be considered a mail-order pharmacy, or any specialty pharmacy to qualify as a retail pharmacy, or even any retail pharmacy to qualify as a specialty pharmacy (if, in fact, there are still going to be T&Cs applicable to specialty pharmacies). We are baffled as to why CMS is seeking to make these changes in light of the major disruption that its positions will have on an efficient Part D, where 73 percent of seniors are currently enrolled in preferred networks (2017),[11] 99 percent of seniors will have the option of preferred network plans in 2018,[12] 93 percent say their prescription drug plan is convenient to use, and nearly nine out of ten seniors are satisfied with their benefit.[13] We also believe the current AWP rules and guidance (dated August 13, 2015) provide the right balance between AWP and non-interference, whereas the proposed rule proposal veers dangerously and impermissibly into CMS interference in contracting between Part D plans and pharmacies.

PCMA Recommendation: CMS should withdraw the changes as set forth in the preamble to the current AWP guidance as well as the regulatory changes proposed to the current AWP rules, as such changes threaten to undermine a popular and efficient Part D benefit.

B. AWP Required for All Pharmacy Business Models (p. 56408)

CMS Proposal: CMS, in the preamble, notes that many pharmacies no longer fit into traditional models, and provides as examples compounding pharmacies and specialty pharmacies. CMS further notes that Part D enrollees increasingly need access to the services of these and other

[11] Fein, A. (2017). New 2017 Part D Enrollment Data: Walgreens and Walmart Trounce CVS in Preferred Networks. *Drug Channels.* http://www.drugchannels.net/2017/01/new-2017-part-d-enrollment-data.html
[12] Fein, A. (2017). Preferred Pharmacy Networks Will Dominate 2018 Medicare Part D Plans (Plus: We Review the Top Plan Sponsors). *Drug Channels*. Retrieved from http://www.drugchannels.net/2017/10/Exclusive-Preferred-Pharmacy-Networks.html.
[13] Morning Consult for Medicare Today, National survey of 1,944 seniors who are Medicare Part D enrollees, June 18-July 6, 2017. http://medicaretoday.org/resources/senior-satisfaction-survey/

pharmacies and references "anecdotal evidence" that plans are not letting pharmacies participate if they do not meet the plan definition for a certain type of pharmacy. CMS provides that plans may not offer T&Cs specific to only one particular type of pharmacy and then not allow a willing pharmacy to participate on grounds that it does not squarely fit into the pharmacy type. CMS considers "similarly situated" to include any pharmacy with the capability of complying with a plan's standard T&Cs, even if the pharmacy is not exclusively that type.

Discussion: The CMS discussion is confusing, inconsistent and would fundamentally undermine the current competitive and well-functioning Part D landscape. We call out some of the key disruptions below.

1. *Compounding pharmacies*

We are surprised that CMS cites the need to increase participation by compounding pharmacies. Indeed, the FDA recently reported that one out of every four of its drug compounding inspections led to a recall in 2017.[14] The reference to compounding pharmacies is also puzzling to us in light of the fact that it is our understanding, based on discussions with CMS, that Part D plans have the authority under current regulations to designate any compound, including all topical compounds, non-formulary. In other words, compounds of any type can generally be excluded by Part D plans. By calling out the need to increase beneficiary access to compounding pharmacies, CMS seems to be opening the door to more bad actor compounders despite the fact that very few compounds should even be covered under the Part D benefit.

2. *Specialty pharmacies*

PCMA is concerned that CMS's proposed guidance on AWP will have the unintended consequence of discouraging the appropriate use of specialty pharmacies and thus encouraging less than optimal patient care. For a patient dealing with the challenges of a complex, chronic condition and a difficult-to-administer medication or a medication with special monitoring requirements, the assistance of a pharmacist and other clinicians with expertise in the patient's specific condition as well as in providing the necessary care is essential. While pharmacists working in retail pharmacy settings receive a strong pharmacy education and may have years of pharmacy experience, a pharmacist that dispenses hundreds of different drugs each day cannot have the same level of expertise in a specific disease or class of medications as a pharmacist who is trained and focused on that disease state. This specialized disease and drug knowledge combined with a specialty pharmacy's awareness of a patient's complete medication profile allows pharmacists and other clinicians at specialty pharmacies to identify issues beneficiaries may be facing and proactively intervene in the case of adverse events or omission of therapy.

[14] Ashley, D. (December 6, 2017). *Center for Drug Evaluation and Research - Compliance Central with FDA Center Compliance Directors: Part 1*[Presentation]. Washington, DC: Food and Drug Administration. Retrieved from https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM587828.pdf

Specialty pharmacies provide advanced care and benefit management capabilities for patients and caregivers by:

a. Providing disease and drug-specific patient care management services that meet the unique needs of each individual patient including support to prevent misuse and underutilization and achieve a desired therapeutic outcome;
b. Providing around-the-clock access to specially trained pharmacists and other health care professionals who offer patients and caregivers guidance and insight on disease states;
c. Providing comprehensive clinical consultations for patients with serious diseases (typically averaging 15 to 18 minutes as compared to the average of two minutes in traditional retail pharmacies);[15]
d. Consulting directly with prescribers to address patient side effects, adverse drug reactions, non-adherence and other patient concerns;
e. Coordinating services, as needed, with other healthcare providers, including those providing skilled nursing services, custodial care, infusion administration, and direct-to-physician distribution;
f. Managing patient medication adherence and persistency of drug regimens, improving adherence to treatment plans and supporting patient safety; and offering home delivery of medications. Specialty pharmacies provide beneficiaries and caregivers with a range of customizable clinical and operational services that enhance the safety, quality and affordability of care for patients being treated with specialty drugs. As a patient of a specialty pharmacy, the beneficiary has support of a team of health care professionals, led by pharmacists and other health care professionals with special training in the specific condition. The patient's pharmacist, nurse and other care team members will, as necessary, help manage side effects, remind patients when a prescription is due to be refilled, help patients remain on their therapy, set up injection training or arrange for home infusions, regularly confirm that the dosage and schedule is current, provide digital tools to help manage the disease, and answer any questions.[16] These services are well beyond those provided by most retail pharmacies, even ones saying they are specialty pharmacies.

3. *All pharmacies*

Likewise, we are puzzled by CMS's assertion that essentially all pharmacies are the same, and they cannot be classified in contracting or excluded on the basis that they do not fit into the correct pharmacy type classification. This totally flies in the face of the fact that distinctions based on pharmacy type are still used for virtually all plan-pharmacy contracting in all government and private sector offerings. Indeed, if plans/PBMs cannot delineate different types

[15] Express Scripts Lab. (Jul 8 2015), "What's Special About Specialty Pharmacy." Retrieved: http://lab.express-scripts.com/lab/insights/specialty-medications/what-is-special-about-specialty-pharmacy
[16] "Your Care Team," CVS Specialty. https://www.cvsspecialty.com/wps/portal/specialty/patients/learn-about-us/care-team/

of pharmacies, then this will result in several anomalies. For example, retail pharmacies will participate in any network, and there would be no such thing as specialty pharmacy T&Cs as all specialty pharmacies would have to be able to meet the definition of a retail pharmacy. Frankly, the result would be unmanageable. Below we list some of the numerous practical issues raised by what CMS presents, which include the following:

a. If a pharmacy is more than one type of pharmacy (e.g., retail and mail-order), how will a plan/PBM be able delineate which prescription claim goes under which contract and which T&Cs apply? For example, if a claim comes in for a 90-day maintenance supply, from a pharmacy that is both retail and mail-order, how will a plan know under which benefit it should be processed? This process will also be confusing to beneficiaries who will not be able to be sure if their prescription is being processed at the mail-order or the retail cost-sharing levels. Moreover, because CMS does not allow all types of pharmacies to be distinguished on Medicare Plan Finder, it is not even clear how a beneficiary will know what benefit they are entitled to at a particular pharmacy.
b. If pharmacies are counted in multiple categories, what is the impact on inclusion in access standards?
c. Mail-order, specialty and compounding (among other pharmacy types) each have T&Cs relevant to that particular type of pharmacy. T&Cs across different types of pharmacies are included primarily for patient safety. If these distinctions are not allowed to be used for standard networks, it will harm patient safety.

***PCMA Recommendation*: PCMA urges CMS to reconsider the need for any of this guidance as it could fundamentally uproot the Part D pharmacy network landscape. If CMS proceeds with its approach, it needs to document, based on data and not anecdote, why its current guidance is not sufficient to address its concerns (i.e. why new regulations are required) and it must consider the wide range of operational challenges that arise from its stated position.**

C. Revise Definition of Retail Pharmacy, and Add Definition of Mail-Order Pharmacy (p. 56408-56410)

CMS Proposal: According to CMS, pharmacies that are not mail-order but offer home delivery services complain that they are classified by plans as mail-order (often requiring multi-state licensure). Thus, CMS proposes to add a definition of a mail-order pharmacy as "a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost-sharing."

CMS also proposes a revised definition of retail pharmacy to incorporate the concepts of being open to the walk-in general public and dispensing prescriptions at retail cost-sharing. CMS declines to adopt a definition for specialty pharmacy, or to further define non-retail pharmacy. CMS solicits comments on the definitions; specifically, whether they "strike the right balance to

resolve confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations."

Discussion: As with the CMS position on all pharmacy business models, we are again perplexed at what CMS seeks to achieve by proposing these new and revised definitions. The proposed definitions are confusing, would mislead beneficiaries and hinder access, and would increase costs. On the one hand, CMS acknowledges that the market is dynamic and changing and that it cannot offer a definition of specialty pharmacy, but it then proceeds to adopt formal, limiting definitions of mail-order and retail pharmacies. While it is not clear to us what CMS is seeking to achieve here, CMS seems to be saying that any pharmacy can say it is retail if the public can walk through its door, and any pharmacy can be considered mail-order if it sends any prescription by courier.

1. *Definition of mail-order*

The definition offered by CMS is not only incomplete and puzzling, but will also cause significant plan and beneficiary confusion. It implies that all a pharmacy needs to do to qualify as mail-order is send one prescription to one customer using UPS or the mail, regardless of whether that claim is processed under a mail-order benefit. As CMS itself recognizes in the preamble, "[t]he mention of additional types of pharmacies in our regulation could contribute to more confusion instead of less." (p. 56409) Providing such a definition will likely undermine innovation, pigeon-hole plans, and constitute interference, in violation of the statute's non-interference requirement (discussed in more detail below in our legal assessment). If CMS proceeds with its proposed approach, the Agency will create a situation where a retail pharmacy which uses courier services claims it is a mail-order pharmacy because it will accept mail-order cost-sharing, but there is no guarantee that it will accept such cost-sharing for a particular prescription. This will cause massive confusion for beneficiaries.

We further do not believe that it is appropriate to define a pharmacy type based on a cost-sharing benefit that is determined by a plan sponsor, and not within the scope of a pharmacy's control. In other words, the proposed definition is based on a benefit parameter, or feature of the health plan, and not on the characteristics of the pharmacy. An example illustrates the illogic nature of this approach. Specifically, if a Part D plan stops offering a mail-order benefit, under this definition, there would be no mail-order pharmacies. In other words, the proposed definition is based on a benefit parameter, or feature of the health plan, and not on the characteristics of the pharmacy. Moreover, as noted in the discussion below on legal deficiencies of the AWP proposal, defining a pharmacy type based on a cost-sharing benefit appears to violate the statutory prohibition on the government instituting a pricing structure.

If CMS proceeds to define mail-order pharmacy, it should consider other options that are not as broad in terms of allowing any pharmacy to qualify as mail-order and that do not base the application of the label on whether they provide mail-order cost-sharing, including:

a. If CMS wants a more objective and realistic definition, it should look to whether the pharmacy is self-identified as mail-order per NCPDP protocols.
b. CMS should consider modifying the definition to state that the pharmacy "is licensed in each state, territory or the District of Columbia into which it dispenses and delivers extended days' supplies of covered Part D drugs via common carrier." This approach would ensure that pharmacies are licensed in the states in which they are practicing by the applicable entities charged with oversight of the practice of pharmacy.

2. *Definition of retail pharmacy*

We are likewise concerned that the revised definition of retail pharmacy will make the issue of appropriate labels for pharmacies more confusing, and not clarify anything at all. If CMS believes its definition has contributed to what it views as the current state of uncertainty, then it should consider removing the current definition of retail pharmacy and not establishing a new definition. Some examples of the uncertainty introduced by the proposed definition include:

a. We are puzzled as to why physician and hospital-owned pharmacies are required to be out of the calculation for access considerations. These pharmacies simply represent a different pharmacy business model, and it is seemingly inconsistent for CMS to single these out and not show them for access purposes (e.g., Medicare Plan Finder).
b. Another issue relates to the phrase "walk-in general public." The language could literally be interpreted to mean any pharmacy which has a front door through which the public can enter. For example, CMS's revised definition could classify as retail a pharmacy whose offices are located in a large industrial park, with no ability to dispense drugs to the public, but with a front entrance through which the public could enter.
c. As noted above regarding the mail-order definition, we further believe it is inappropriate to define a retail pharmacy based on a cost-sharing benefit decision that is not in the control of the pharmacy (but presumably in the control of the plan or even possibly the beneficiary seeking to save money by going the more efficient way). If CMS insists on developing definitions for some types of pharmacies, it should go back to the drawing board and propose definitions for all types of pharmacies for purposes of consistency.

3. *Definition of specialty pharmacy*

CMS acknowledges that it cannot define specialty pharmacy at this time due to the fact that the "pharmacy landscape is changing so rapidly, we believe that any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace." We completely agree with that statement and suggest it also compels CMS not to define mail-order pharmacy or further define retail pharmacy for the same reason.

***PCMA Recommendation*: PCMA strongly recommends that CMS not add a definition of mail-order pharmacy or revise the retail pharmacy definition.**

D. Treatment of Accreditation and Other Similar AWP Requirements in Standard Terms and Conditions (p. 56410-56411)

CMS Proposal: CMS notes its position that access to specialty pharmacies can be restricted only where necessary to meet FDA requirements (e.g., REMS) or to ensure appropriate dispensing where the drugs require extraordinary special handling that cannot be handled by a network pharmacy. CMS is concerned that plans might use standard contracts to limit dispensing

of specialty drugs to certain pharmacies. CMS once again cites anecdotal complaints that it has received from pharmacies about plans requiring accreditation by multiple organizations and plans adding additional credentialing requirements.[17] While CMS supports accreditation in some circumstances (e.g., to be included in a preferred network), it does not support the "use of PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations" (except for REMS and extraordinary special handling). CMS is again disturbed by anecdotes that such standard T&Cs are waived for pharmacies needed for network access. CMS claims that if a T&C can be waived, it is not a necessary standard. Specifically, CMS notes that waivers or inconsistent application of such standard T&Cs is explicit acknowledgement that "such terms and conditions are not necessary…. and thus neither reasonable nor relevant" for any willing pharmacy standard terms and conditions." CMS does not expect plans to limit dispensing of drugs for certain diseases to a subset of network pharmacies (except as noted). CMS solicits comments but does not propose new or revised regulatory language.

Discussion: We are very troubled by the CMS discussion on T&Cs and waivers, particularly by its very negative impact on the ability (and flexibility) of Part D plan sponsors to provide quality pharmacies in its standard networks. A pharmacy's practice of unique or innovative business or care delivery models does not authorize a pharmacy to be free of T&Cs that require meeting industry quality standards associated with those models. Moreover, CMS currently appropriately recognizes this as stated aptly in its 2015 guidance on complying with AWP requirements where CMS notes that a sponsor's standard T&Cs are:

> "a 'floor' of minimum requirements that all similarly situated pharmacies must abide by" *while sponsors may "modify some of their standard terms and conditions to encourage participation by particular pharmacies*." CMS believes that in general, the "floor" consists of conditions of participation established by the sponsor related to health and safety or financial integrity (such as licensure requirements, minimum levels of liability insurance, or *accreditation*), and that *sponsors may negotiate varying payment rates to attract the network participation of certain pharmacies*." [emphasis added][18]

[17] Indeed, it appears that CMS is conflating requiring both a credentialing and an accreditation requirement with requiring two accreditations.
[18] Larrick, A. (August 13, 2015). *Compliance with Any Willing Pharmacy (AWP) Requirements* [Memorandum]. Baltimore, MD: Centers for Medicare and Medicaid Services.

As noted in the legal discussion below, the approach articulated by CMS will interfere with negotiations between Part D plan sponsors and their PBMs and pharmacies, because it will prevent them from effectively negotiating contract agreements requiring the achievement of quality standards developed by national accreditation bodies for practicing a discrete type of pharmacy profession. The proposal interferes with the ability of a plan sponsor to selectively contract with only those pharmacies with the requisite services and infrastructure to deliver quality and cost-effective health care. Specifically, the proposal would require sponsors to contract for the standard offering with any pharmacy that agrees to meet the T&C, whether or not it can be shown that the provider meets both the quality standards and the geographic access needs of the health plan. This eviscerates a plan's ability to require quality pharmacy services to beneficiaries, setting up a race to the bottom for reimbursement in exchange for network participation. Such a limitation on negotiations is at odds not only with the purpose of the non-interference clause, but with the fundamental private sector construct of Medicare Part D, which is not a FFS program whereby any licensed provider can participate. We are not aware of any precedent in any program, healthcare or otherwise, where the waiver of a term means that the term is not reasonable or necessary. Frankly, we find that position to be indefensible. Our other concerns are below.

1. *Waivers of terms*

As noted above, in the preamble to its proposed rule, CMS takes the questionable position that, by virtue of a Part D plan waiving a particular T&C, a T&C is no longer "standard" and thus fails to qualify as a "reasonable and relevant" T&C. The agency goes as far as to state, without evidence or backing, that "a term or condition which can be dropped in such situations is by definition not 'standard' according to the plain meaning of the word."[19] CMS fails to actually reference where "standard" is defined, nor does it cite any legal or any other authority for this premise. In truth, there is no basis for such a position. Part D plans regularly waive standard T&Cs in order to meet access requirements – and this practice does not make these terms any less standard. Importantly, the term "standard" does not mean "compulsory" or "mandatory." Indeed, adoption of a set of T&Cs that could never be waived, regardless of circumstance, would likely be viewed by a court as unconscionable. In examining instances where courts have interpreted the meaning of the term "standard" in contract negotiations, it becomes quite clear that the proposition that "standard" terms or conditions **can** be waived is so well entrenched jurisprudentially as to hardly occasion comment at all.[20] For example, in rural areas with little competition, rates reflect a pharmacy's relative monopoly position in its market. If a PBM cannot waive or alter a term for those less usual instances without losing the term altogether or

[19] 82 Fed. Reg. 56,336, 56,411 (November 28, 2017).

[20] See, for example, *Orsi v. Aetna Ins. Co.*, 703 P.2d 1053, 1059-60 (Wash. App. 1985) (The meaning of 'reasonable concurrency' is clarified by RCW 48.18.130, which reads, in pertinent part: 'The commissioner may waive the required use of a particular standard provision in a particular insurance contract form if (a) he finds such provision unnecessary for the protection of the insured, and inconsistent with the purposes of the contract, and (b) the contract is otherwise approved by him.'") (emphasis added.) See also *Trent v. Cook*, 1996 W. Va. LEXIS 103, at *12 (W. Va. 1996) ("The provisions of West Virginia Code § 33-6-31, however, are not mandatory for every insurance policy issued in this state as indicated by the following language of West Virginia Code § 33-6-10(a) (1996): 'Insurance contracts shall contain such standard provisions as are required by the applicable provisions of this chapter pertaining to contracts of particular kinds of insurance. The commissioner may waive the required use of a particular standard provision in a particular insurance policy form, if he finds such provision unnecessary for the protection of the insured and inconsistent with the purposes of the policy, and the policy is otherwise approved by him.'") (emphasis added).

an altered term now becoming the standard for all pharmacies, then costs will increase dramatically and quality will suffer. If, for example, a plan must pay all pharmacies the rate of its most geographically isolated but necessary pharmacy, taxpayers and beneficiaries will bear the brunt of significantly increased costs.

2. *Applicability to rates*

A major concern is whether the CMS position on waivers applies to rates. In other words, if a Part D plan sponsor needs to waive its standard rates in order to get a pharmacy that is needed to meet the CMS access requirements, does that mean that every pharmacy has to get that rate? We would find that situation untenable as it would mean that every pharmacy would be compensated at the rate that applies to the highest paid pharmacy, as noted in our example immediately above regarding the scenario in a rural area with little pharmacy competition. We assume that is not what CMS intends but ask that CMS specifically clarify this point when it issues the final rule.

3. *Accreditation and credentialing*

Current CMS guidance (quoted above) allows accreditation as a "floor" for T&Cs for standard contracts. We are surprised that it appears that CMS is backtracking from this best practice. PBMs have selected accreditation agencies based on their additional T&Cs, and PBMs of course require credentialing in addition to accreditation. The two are separate exercises.

Credentialing involves requiring the pharmacy to provide basic information so that the PBM can then verify the pharmacy's credentials: that the pharmacy has a state license, that it is a legitimate pharmacy (typically PBMs require GPS-based photos documenting a retail pharmacy space, including the pharmacy counter, the cash register, and so forth), copies of a wholesaler invoice that includes the DEA and state licensure number within the past thirty days, evidence of insurance coverage, ownership information, and similar information. This information is necessary to ensure that the pharmacy is a legitimate business; given the pop-up pharmacies fraudsters perpetrate, CMS should appreciate these efforts. Other credentialing information includes languages spoken, hours, software vendors used, services and programs provided, the type of pharmacy it is, the pharmacists and pharmacy that will serve customers, and similar information. This information is necessary so that the PBM and Part D plan sponsor can accurately assess the services available to enrollees. Every health plan credentials physicians, hospitals, and other providers for the same purposes. It is absurd to think that Part D plan sponsors (and PBMs on their behalf) would not credential their pharmacies. Accreditation is entirely different.

Accreditation organizations go beyond the basics covered by credentialing and assess a pharmacy's quality of services and care. Just as NCQA accredits health plans, URAC and other organizations accredit pharmacies. Accreditation from a national body such as URAC or VIPPS demonstrates high standards of best practices, including for patient and proper drug handling and distribution. Accreditation assesses best practices for:

- Use of evidence-based practices and clinical decision support programs.
- Patient counseling and benefits coordination.
- Patient outcomes and quality of care.
- Many other clinical and patient care factors.

Accreditation is essential for demonstrating high expertise in caring for patients and being desirable network partners for insurers and PBMs. Moreover, there is a wide range of variability of accreditation entities in the marketplace, and at least some accreditation entities are not necessarily bona fide players. Once again, rather than focusing on the substantive merits of a policy, CMS refers only to anecdotal complaints by pharmacies about the costs of accreditation. We do not believe cost alone is a valid reason to disallow accreditation flexibility under standard T&Cs. We are not aware of any precedent in Medicare or elsewhere to cite the cost of accreditation as a reason that it cannot be a standard T&C. Should CMS proceed with this proposal, we remain very concerned that the Part D program is heading in a direction which will make it virtually impossible for Part D plan sponsors to negotiate anything, possibly even including rates, with pharmacies.

4. *Specialty pharmacy*

It is currently a best practice and common for PBMs to require credentialing for specialty pharmacies, where there is a greater need for robust infrastructure (nursing staff capacity, 24-hour service, compliance, adherence, etc.).

Specialty pharmacies are required to maintain appropriate inventories of drugs for their patients. Most community-based pharmacies are not able to adequate stock specialty medications (often due to high costs of these drugs) and therefore are not able to meet patients' need for immediate access to medications. In contrast, specialty pharmacies must be able to deliver urgent and same-day delivery of their specialty medications. Specialty pharmacies maintain drug inventories that are focused on complex diseases and conditions and do not maintain inventories of the most commonly dispensed medications. Under CMS's proposed rule, beneficiaries may find themselves waiting longer to start their therapies, which may impact their health outcomes, simply due to a community pharmacy not being adequately prepared to dispense the medication.

There is also evidence of community pharmacies refusing to dispense medications due to their cost and reimbursement from a payer. Community pharmacies that do not purchase high volumes of specialty medications may not have the ability to purchase a drug at a cost-effective rate and therefore CMS's proposal would drive up costs for the enrollee and plan, and thus also for taxpayers.

The proposed CMS ban on differences in pharmacy types and standard T&Cs will result in patients becoming frustrated and confused as to what pharmacies can dispense which medications. Patients will assume that all pharmacies carry every medication due to the lack of definitions and plans' inability to direct patients to appropriate pharmacies.

Indeed, the specialty pharmacy delivery channel is specifically designed to provide efficient access to complex medications. The unique requirements often necessary to handle and manage these medications obligate pharmacists to acquire special expertise. This expertise is not widely available in community pharmacies, forcing both Part D and MA-PD plan sponsors to embrace specialty pharmacies to meet the unique challenges of dispensing and monitoring the use of these medications. Traditional community pharmacies are acutely aware of this lack of appropriate expertise needed to dispense specialty medications and are using a range of approaches to develop the requisite services and technology infrastructure:

- *Build internal specialty pharmacy services.* Kinney Drugs, the second-largest regional drugstore chain, recently launched Noble Health Associates, LLC to dispense specialty medications by mail. In addition, regional chain Kerr Drug launched a subsidiary focused on specialty pharmacy and clinical services. Grocery chain Schnucks has opened five specialty-focused pharmacies within Schnucks stores and as stand-alone facilities within medical clinics and hospitals.

- *Create specialty-focused retail locations.* The larger drugstore chains have designated certain stores for specialty products. Walgreens has 700 HIV-specialized pharmacies that offer a broad range of patient services and dispense such HIV medications as Atripla, Truvada, and Norvir. HIV drugs currently constitute 10.5% of total specialty medication spending.

- *Acquire a specialty pharmacy.* As an alternative to building new specialty pharmacy capabilities, a retail chain can acquire a specialty pharmacy. Supermarket chain Kroger announced a merger with Axium Pharmacy, the third-largest private specialty pharmacy. Walgreens has become the third-largest specialty pharmacy by acquiring other specialty pharmacies.

- *Partner with an established specialty pharmacy.* A related strategy is partnering with a larger specialty pharmacy that can provide back-end clinical services and care management. For example, Fred's, the nation's largest regional drugstore chain, launched a partnership with Diplomat Specialty Pharmacy. Under the arrangement, Fred's maintains its consumer relationships, while Diplomat handles such specialty pharmacy services as prior authorization, adherence calls, copay assistance, injection training coordination, and pharmacist consultations. Diplomat provides similar services for Target and Safeway.

- *Join a specialty network services alliance.* Independent retail community pharmacies are also organizing into collaborative networks to penetrate the specialty market. Examples include the Armada Specialty Pharmacy Network, the Community Specialty Pharmacy Network, and Specialty First. These networks support retail community pharmacies that dispense specialty drugs by providing clinical support, contracting, data, and other services.

These strategies by community pharmacies to address their acknowledged specialty drug infrastructure deficits clearly demonstrate that not every retail pharmacy has the capacity, acting on its own, to dispense specialty drugs. Thus, CMS must fundamentally change its proposed policy on prohibiting Part D sponsors from restricting access to specialty drugs to a subset of their network pharmacies. As evidenced by the retail pharmacy market response outlined above, appropriate dispensing of specialty drugs *does* require extraordinary special handling, provider coordination, or patient education on administration; none of which are services typically offered within the traditional infrastructure of community pharmacy. For Part D plan sponsors to successfully manage the explosion of specialty drug spending for beneficiaries and the government, sponsors must be permitted to restrict the dispensing of specialty drugs to those network pharmacies with accreditation that demonstrates the requisite services and technology infrastructure to dispense specialty drugs.

5. *Relationship to preferred network T&C*

We appreciate recognition by CMS that nothing in the AWP proposal limits preferred network T&C. Moreover, nothing in the proposal places a floor or ceiling on the content of special T&C for purposes of a plan's preferred network. That said, we are concerned that CMS's discussion could be viewed as laying the groundwork for opening preferred pharmacy networks to AWP. We strongly urge CMS to make clear that this is not the case and to reiterate that it will not change its position and require that preferred pharmacy plans be subject to AWP.

6. *Impact of CMS statements*

As noted in detail below in our legal assessment, we are stunned that CMS has proposed such a far-reaching policy without even addressing the constraints placed on the Agency by the non-interference clause. Interference is exactly what this proposal does - de facto interference on a fundamental concept of contract negotiations. By placing significant limits on the content of contractual negotiations, CMS has reduced the contracting process to a bare bones one. Such a proposal will result in an expensive program with no meaningful quality protections.

***PCMA Recommendation*: PCMA strongly urges CMS to retract its whole discussion on the treatment of accreditation and other AWP requirements in standard T&Cs. The position is indefensible, would harm beneficiaries in that it undermines best practice standards for determining quality pharmacies and could significantly drive up program costs. Current CMS policy already addresses this arena appropriately and there is no justification for any change.**

E. Timing of Contracting Requirements (p. 56411)

CMS Proposal: CMS references complaints from pharmacies on timing of receiving T&Cs, and proposes to establish deadlines in regulations. Plans must have standard T&Cs by September 15th for the next plan year, and plans must provide T&Cs to pharmacies within two business days of a request. If confidentiality agreements are required, then T&Cs must be provided within two

business days of receipt of signed agreement. CMS seeks comments on whether the proposed time frames are operationally reasonable and examples of where a longer time frame might be needed.

Discussion: There are a significant number of downstream operational issues that need to be considered if CMS proceeds with the proposed rules on timing of the T&Cs. Plans need to be able to do some due diligence on what kind of contract the pharmacy seeks prior to sending over any contract terms. For example, T&Cs differ for retail and specialty pharmacies. A large number of pharmacies already seek to claim they are specialty pharmacies when, in fact, they are not. As another example, as CMS knows, there have been many longstanding problems associated with identifying home infusion pharmacies. Plans need time to assess what terms are appropriate for each applicant pharmacy based on what applies to similarly situated pharmacies already in their network. This assessment is not an automated process and needs to occur before T&Cs are sent.

Moreover, pharmacies often do not provide enough information for plans to perform even preliminary due diligence, making the two-day standard difficult to achieve. The standard itself also creates the risk of potential delays for pharmacies wishing to participate as an AWP, because it increases the odds of the wrong contract T&Cs being sent in the rush to meet an artificially short deadline and pharmacies could waste their time considering the wrong terms.

1. *Time frame*

PCMA does not in theory object to the two-business day time frame since that is already the standard articulated in current CMS AWP guidance which the industry already strives to follow despite the difficulties noted above.[21] That said, the time frames, coupled with the general CMS directions on how it views AWP as noted above, create significant operational issues and difficulties, which we urge CMS to consider before it finalizes any AWP requirements. The problems, including those related to volume, due diligence and program integrity, are set forth below.

a. The two-day scenario assumes that it is clear to the Part D plan sponsor which is the correct T&C to send to the pharmacy. The issue is with the pharmacy identification, assuming it is still permissible even to have T&C for different types of pharmacies anymore based on CMS's proposal.

   Given the apparent current direction of CMS regarding AWP, whereby any pharmacy could purport to be any type of pharmacy, it may be very difficult to ascertain what type of pharmacy the pharmacy actually is and thus which set of T&Cs to send. If the changes are as sweeping as CMS seems to imply

[21] Larrick, A. (August 13, 2015). *Compliance with Any Willing Pharmacy (AWP) Requirements* [Memorandum]. Washington, DC: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Retrieved from http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20065.

(where any pharmacy can basically seek the T&C for any type of pharmacy), we would expect a high demand by pharmacies to participate under AWP, and the requests would all be coming in around September 15, thus making it burdensome to meet the two-day standard at that time. More time would then be needed at that point to assess the type of pharmacy and the appropriate T&Cs.

b. Of critical importance, some program integrity protocols used to deter fraud and abuse are contrary to the CMS proposal (e.g., onsite inspection prior to sending the T&Cs). As we have addressed previously with CMS, there is a compelling due diligence need for plans to perform a preliminary assessment of whether the pharmacy is high risk, on any excluded provider lists, or otherwise poses FWA risks. For example, for certain areas designated as "HEAT" areas by the US Department of Justice (e.g. South Florida), many plans mandate an on-site pharmacy inspection prior to sending T&Cs as that is considered a "best practice" in these regions. It is not clear to us if these commonly used "checks and balances" practices to weed out bad actors would be feasible under the two-day standard especially as now expanded. Part D plan sponsor should not be required to include them in the network and then be required to pay and chase. These pharmacies may disappear after processing two weeks of claims.
c. CMS does not address the time period after the plan receives the T&C from the pharmacy as to when the contract needs to be executed. We assume that the standard remains as articulated in the current guidance that plans should not cause "undue delay" as they exercise reasonable due diligence (e.g., program integrity review) with respect to "eligible and interested" pharmacies.
d. That said, we are concerned about the following scenario. If a plan cannot vary the T&C for standard pharmacy participation, and the pharmacy accepts the T&C, then there is no opportunity to modify the September 15th terms and they essentially automatically become part of the network as of the following January 1 regardless of whether they actually are the type of pharmacy they claim to be.
e. Finally, depending on how CMS expects this to be implemented, a plan may not be able to add a pharmacy into its claims processing system (e.g., for Medicare Plan Finder) in time for open enrollment. There are also issues about whether and when the pharmacies must be added to the directory, and as what type of pharmacy. The key concern is that timelines and operations need to have a reasonable and standard business flow, and the new unnecessary CMS content on AWP raises serious concerns about how that will work.

2. *Confidentiality*

We appreciate that CMS has recognized that the standard Part D pharmacy T&Cs are not public documents by including timelines for providing the confidentiality agreements. That said, even

assuming a confidentiality agreement, we remain concerned because any pharmacy can apparently get access to confidential rate information for any type of pharmacy. The broad approach to the definition of pharmacy type may have adverse consequences for rate confidentiality and thus Part D plan sponsor competitiveness. Part D plan sponsors should not be required to widely distribute T&Cs, as these documents contain information that is both proprietary and would reveal contractual reimbursement rates. While it is reasonable to assert that any pharmacy that will be a contractual partner to a Part D plan sponsor has a need for such information, a pharmacy could be used by Part D plan sponsor competitors to "shop" for information on another Part D plan's T&Cs.

PCMA Recommendation*: *While PCMA does not object to the two-day requirement per se as it already is the applicable standard, the current CMS guidance on time frames is sufficient and there is no need for further regulation. However, there are a larger range of significant operational downstream issues that need to be addressed by CMS if it proceeds to finalize this proposed rule. We urge CMS to clarify that the two-day standard applies only after the type of pharmacy and the program integrity clearance have been determined.

F. Regulatory Impact Analysis (pp. 56486-56487)

CMS Proposal: CMS states that in considering the cost implications of this proposal, it received various perspectives from stakeholders including PBMs. It then asserts that because this provision clarifies existing AWP requirements, consistent with OACT estimates, "we do not anticipate additional government beneficiary cost impacts from this provision."

Discussion: While we appreciate the acknowledgement that PBMs are stakeholders, if we had been consulted, we would have respectfully disagreed that the provision clarifies existing AWP requirements and further that there would not be additional cost impacts. Specifically, based on an economic analysis conducted by The Moran Company on the proposed new AWP policy, the report (a copy of which is attached hereto as Exhibit A) found that it is reasonable to assess that, were the volume of services rendered by pharmacies in preferred networks to decline by as little as 2.5 percent as a result of this new AWP policy in 2019, Part D plan sponsor pharmacy costs could rise by $175 million, an amount sufficient to deem this policy as "economically significant" under Executive Order 12866. Under this E.O., the Agency has an obligation to offset the additional cost impacts from this proposal. Further, the report finds that, "since CMS presents no quantifiable evidence of benefits to offset these costs, this regulatory policy would appear to fail standards for regulatory clearance under E.O. 12866."

Recommendation*: *CMS must reassess its assertion that the AWP changes will have no economic impact. If CMS still intends to proceed with a new AWP regulatory policy with significant economic impact, it must subject such proposal to scrutiny under E.O. 12866 including providing offsets to the increased costs. Otherwise, any such regulatory policy cannot be implemented.

G. Other issues

There are several additional issues related to AWP that we believe CMS should consider before it finalizes its proposals.

1. *Anecdotes from all stakeholders*

CMS seems to be regulating based on anecdotes (largely from retail pharmacies); thus, if CMS is going to be regulating based on anecdotes, it should seek anecdotes from a wide range of stakeholders and not just independent retail pharmacies. Indeed, what CMS has done in the past is collect anecdotes from beneficiaries (at that time, related to mail-order). In the current instance, we did not see one CMS reference to any beneficiary complaints about not having access to pharmacies in the standard benefit. As discussed in our legal assessment below, we also believe regulating by anecdote (particularly one-sided, narrow views) is inherently problematic and subjects the Agency to legal risk.

2. *Allow pharmacy claims suspension*

Currently, plans cannot suspend pharmacies, or even payment to pharmacies, for suspected fraudulent activity. If CMS truly were concerned about bona fide pharmacy networks, it would be proposing to allow Part D plan sponsors/PBMs to suspend payment of pharmacy claims where fraud is suspected. In other words, if plans are really going to be precluded from using basic quality parameters in standard T&Cs (because if they have them and waive them for one pharmacy, they have to waive them for all), then the plans should be allowed to suspend payment of suspect claims where there is a credible allegation of fraud. In other words, CMS must allow greater ability for plans to suspend payment as there likely will be an increase in questionable pharmacies coming in through these protocols with limited quality checks.

3. *Role of PSAOs*

The CMS discussion of AWP ignores a major presence in the marketplace, namely of Pharmacy Service Administration Organizations (PSAOs), which currently contract on behalf of 80 percent of independent pharmacies.[22] We wonder whether CMS has looked into whether the pharmacy anecdotes about Part D plan sponsors and PBMs are in fact problems with PSAOs and their contracts with and on behalf of independent pharmacies. Indeed, PCMA has heard many anecdotes that PSAOs do not communicate contract terms to the pharmacies they represent. We are concerned that under the proposed CMS guidance, PSAOs are allowed to commit their networks to T&Cs even though there is no intention to monitor or communicate with the pharmacies; thus, there is no adequate informed consent. Likewise, we are concerned with the

[22] U.S. Government Accountability Office (GAO), *The Number, Role, and Ownership of Pharmacy Services Administrative Organizations.* (January 2013). http://www.gao.gov/assets/660/651631.pdf. The 4 largest PSAOs represent 18,000. Retrieved from: http://www.drugchannels.net/2017/10/how-independent-pharmacies-will.html.

scenario where a PSAO requests specialty T&Cs and commits its network to specialty capabilities even though some of the pharmacies it represents cannot possibly meet the T&Cs. As we have previously discussed with CMS, our PBM members have experienced numerous occasions where a pharmacy claims that it has not received the T&C when in fact a PSAO that represents the pharmacy was sent the T&C. We continue to be very troubled by the lack of accountability at either the PSAO or pharmacy level in this scenario.

4. *Relationship of AWP to RFI*

PCMA is very concerned that the AWP proposal, coupled with the end to pharmacy DIR as articulated in the RFI, would essentially serve to either significantly shrink or significantly expand pharmacy networks. We believe that CMS must consider the relationship of its AWP proposals in conjunction with the RFI, specifically as it relates to the potential approach of no longer allowing any pharmacy DIR. In other words, since under the RFI, by prescribing what pharmacies must get paid (and what must be passed on to the consumer), this inherently limits a plan's statutorily vested ability to offer lower cost-sharing or coinsurance for preferred networks. The definitions are so broad and sweeping that plans could readily find that all pharmacies always meet all T&Cs, which would hinder the ability of plans to pare the network and extract savings for taxpayers and beneficiaries. Or alternatively and depending on interpretations of definitions, plans may have to cut their network so narrowly to make the RFI work that it would then have no room to have preferred cost-sharing within the standard network. These concerns are discussed in more detail on our comments on the RFI. PCMA is perplexed why the Agency would seek to dismantle the very framework that has enabled Part D plan sponsors and PBMs to use robust competition among the abundant pharmacies in this country to create the most cost-effective Medicare pharmacy benefits possible, which deliver great value to beneficiaries at the lowest taxpayer cost, while providing convenient pharmacy access and clinically appropriate drugs for every condition.

H. Legal Assessment

1. *Introduction*

Section 1860D-4(b)(1)(A) of the Social Security Act provides that a Part D plan shall "permit the participation of any pharmacy that meets the terms and conditions under the plan." Known as the "any willing pharmacy" (or "AWP") provision of the Part D program, this requirement operates in tandem with the paragraph which follows it, 1860D-4(b)(1)(B), which permits Part D plan to "reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required" for drugs dispended through in-network pharmacies. In the preamble to the 2005 Part D rule, CMS noted the potential conflict between these two provisions – one requiring Part D plan to allow any willing pharmacy to participate in their pharmacy networks, while also allowing plans to reduce cost-sharing differentially for network pharmacies.[23] The

[23] See 70 Fed. Reg. 4,194, 4,254 (January 28, 2005) ("We believe that we have correctly interpreted the two related provisions in sections 1860D–4(b)(1)(A) and (B) of the Act, which require Part D plans to allow any willing pharmacy to participate in their pharmacy networks, while also allowing Part D plans to reduce cost-sharing differentially for network pharmacies. General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other

agency cautioned at that time, however, that general principles of statutory construction *prohibited* them from allowing one provision to essentially nullify the other.[24] Thus, CMS has long taken a position that operationalized both of these provisions, resulting in a system in which most Part D plans offer AWP pharmacies the ("standard" terms) to those pharmacies that qualify for participation as an in-network pharmacy, and then offer (the "special" terms) for those pharmacies that qualify for participation as an in-network preferred pharmacy.[25]

In its 2005 rulemaking, CMS also clarified the meaning of *standard* T&Cs for purposes of in-network participation. According to CMS's regulations, for purposes of complying with AWP, Part D plans must "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."[26] Notably, CMS declined to further define this requirement, noting a desire to "provide Part D plans with maximum flexibility to structure their standard terms and conditions."[27] Since the 2005 rule, CMS has consistently recognized that the content of these T&Cs, and the subsequent negotiations between a Part D plans and a pharmacy, are "fact-specific questions" that are "best left between the parties."[28]

Unfortunately in the proposed rule, CMS departs from this longstanding interpretation in favor of an interpretation that could undermine the ability of Part D plans to structure their standard T&Cs (and as a result, their pharmacy networks), noting that the development of preferred pharmacy networks 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."[29] As a result, CMS has proposed to "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."[30]

This misguided policy could raise consumer costs, introduce fraud and waste into the system, and force Part D plans to ignore important goals such as quality of care and value. Notably, CMS has not actually proposed to change the regulatory text at § 423.505(b)(18) so as to dictate the very T&Cs by which Part D plans and pharmacies currently negotiate in the open market. Nor

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provision. Consequently, when a statutory provision may reasonably be interpreted in two ways, we have an obligation to adopt the interpretation that gives full effect to competing provisions of the statute. We believe that our policy of permitting cost-sharing discounts for preferred pharmacies, as codified in § 423.120(a)(9), strikes an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs.")

[24] Id.

[25] See Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, 50.8.1 – Any Willing Pharmacy Requirement ("With standard terms and conditions as a "floor" of minimum requirements that all similarly situated pharmacies must abide by, Part D sponsors may modify some of their standard terms and conditions to encourage participation by particular pharmacies.")

[26] See 42 C.F.R. § 423.505(b)(18).

[27] 70 Fed. Reg. 4,194, 4,254 (January 28, 2005).

[28] Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, 50.8.1 – Any Willing Pharmacy Requirement ("These standard contracting terms and conditions must be reasonable and relevant. However, whether a Part D sponsor has permitted a pharmacy an opportunity to participate in its network, or whether a pharmacy can meet or has met contract terms in compliance with the law and CMS's regulations at 42 CFR 423.120(a)(8)(i) are fact-specific questions that are generally best left between the parties.") See also Memorandum from Amy K. Larrick, "Compliance with Any Willing Pharmacy (AWP) Requirements," (August 13, 2015) ("For those terms to be reasonable and relevant, they must identify for the pharmacy the plan(s) to which they apply, and the offer must include language that obligates the Part D sponsor to include the pharmacy in the identified plan(s) upon the pharmacy's acceptance of the terms and conditions.")

[29] 82 Fed. Reg, 56,336, 56,407 (November 28, 2017).

[30] Id.

should CMS move forward with such a policy. As discussed in detail below, a proposed reinterpretation of the AWP provision is a clear violation of the non-interference clause, and the prohibition on the establishment of a price structure in the Part D program, as well as a violation of the plain language of the underlying statute. Moreover, as worded and as discussed below, the proposal impermissibly relies on anecdotal evidence and implicates significant anti-competitive concerns – concerns that were first voiced to CMS by the Federal Trade Commission in 2015.

2. *The AWP Policy Contemplated in the Proposed Rule Violates the Non-Interference Clause*

Under the Part D statute, CMS may not "interfere with the negotiations between drug manufacturers and pharmacies and Part D plans."[31] In the 2005 Final Rule, CMS noted: "As provided in section 1860D–11(i) of the Act, we have no authority to interfere with the negotiations between Part D plans and pharmacies and therefore cannot mandate that Part D plans negotiate the same, or similar, reimbursement rates with all pharmacies."[32]

CMS has long read the requirements under AWP and the non-interference clause in tandem – requiring Part D plans to permit any willing pharmacy to participate in its network *so long as* the pharmacy meets the T&C required for participation under the plan. This reading is not only appropriate, but mandated by relevant canons of statutory construction, including the principle that "all clauses and words should be given meaning, if possible, so that a statute is not read in a way that renders some language superfluous."[33] In other words, CMS must take an interpretation of these two statutory requirements that ensures they both have meaning in the program.

CMS now proposes to disrupt this delicate balance by setting forth detailed requirements on how and when standard T&Cs are presented to pharmacies, as well as the very content of these terms. This type of regulation is the precise type of interference that Congress envisioned in drafting the non-interference clause. By instituting new restrictions on the T&Cs negotiated between Part D plans and pharmacies, and by adding new definitions which restrict a sponsor's ability to set rules for its own pharmacy networks, CMS will be preventing Part D plans from using their negotiating power to promote higher levels of service, access, and quality of pharmaceutical care than are required of participants out of the pharmacy network. In turn, beneficiary and government costs will increase while the quality of service deteriorates.

More specifically, and as discussed in detail above, in the proposed rule CMS contemplates intervening in discrete negotiating terms, such as a Part D plan's ability:

- to delineate between different types of pharmacies for purposes of preventing waste, fraud and abuse;[34]

[31] Section 1860D-11(i)(1) of the Social Security Act.
[32] 70 Fed. Reg. 4,194 4,255 (January 28, 2005).
[33] *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991).
[34] 82 Fed. Reg. at 56,408 ("…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.")

- to structure terms and conditions according to a particular pharmacy arrangement in order to control costs, set appropriate cost-sharing amounts;[35]
- to keep its own T&Cs privileged, confidential and out of the hands of competitors;
- to make a determination as to whether a particular pharmacy is more appropriately treated as retail, mail-order, or specialty;[36]
- to inspect or request addition information from a particular pharmacy before sending T&Cs;[37] and
- to select its own accreditation standards for purposes of promoting quality and beneficiary satisfaction.[38]

As noted above, CMS has in the past refused to further define what "reasonable and relevant" terms and conditions are for purposes of compliance with AWP so as to preserve the "flexibility" Part D plans have in structuring their benefit.[39] This "flexibility" is at the heart of the non-interference provision, long held up by the agency as the lynch pin in ensuring market competition, not government regulation, drives the operation of the Part D program. For example, in 2014 CMS proposed a dramatic reinterpretation of the AWP provision, so as to require Part D plans to have a single standard T&C for network participation that listed all combinations of cost-sharing and negotiated prices under the plan, effectively allowing any willing pharmacy to participate in preferred networks.[40] In the final rule, CMS retracted its proposal after commenters noted the clear violation of non-interference, had CMS proceeded with its proposal.

Indeed, this type of proposed regulation is the precise type of interference that Congress sought to prevent in drafting the non-interference clause.[41] By instituting new restrictions on the T&Cs negotiated between Part D plans and pharmacies, and by adding new definitions which restrict a sponsor's ability to set rules for its own pharmacy networks, CMS will be preventing Part D plans from using their negotiating power to promote higher levels of service, access, and quality of pharmaceutical care than are required of participants out of the pharmacy network. Under the plain language of the statute, CMS is prohibited from interfering in negotiations such as these.

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[35] Id.
[36] Id. at 56,408 ("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. ")
[37] Id. at 56,411 (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.")
[38] Id. at 56,410 ("…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…").
[39] 70 Fed. Reg. 4,194, 4,254 (January 28, 2005) ("We do not intend to define 'reasonable and relevant' in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.")
[40] 79 Fed. Reg. 29,844, 29,886 (May 23, 2014).
[41] See House Conference Report No. 108-391 at 461 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 1840 ("In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and Part D plans.") See also House Conference Report No. 108-391 at 748-9 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 2105 ("[t]hese negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.")

3. *If Adopted, the Proposed AWP Policy Would Institute a Price Structure in Violation of the Statute*

Under the Part D statute, CMS may also not "require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."[42] Like the non-interference clause, CMS has always carefully balanced the competing goals of pharmacy access and Part D plan flexibility, ensuring neither of these requirements is read out of the statute.

While neither Congress nor the Agency have ever formally adopted a definition of "price structure," the meaning of the clause is clear: CMS is prohibited from not only specifying a "standard" (i.e., what is paid or how payments are calculated), but also imposing any "structure" (i.e., any rules around the elements of that pricing). This meaning is evident both from the plain language of the statute (i.e., the term "structure" is commonly defined as an arrangement or organization of elements or parts,[43]) as well as other language in the Part D statute. For example, the significance of the clause is evident when one compares it to how Congress phrased the limitation on CMS activity involving formularies. Section 1860D- 11(i)(2) prohibits CMS from requiring a "particular" formulary. The statute does not use the same modifier "particular" in front of the price structure language.

The AWP proposal clearly violates the price structure prohibition by defining various pharmacy types (i.e. mail-order vs. retail) and, therefore, dictating cost-sharing terms. In other words, by removing the determination of what constitutes a mail-order (or retail, or specialty) pharmacy from the Part D plan,[44] and by requiring Part D plans to utilize the Agency's own standards for what constitutes a particular pharmacy type,[45] CMS is directly interfering in how Part D plans negotiate with pharmacies, impacting plan cost-sharing in violation of the prohibition on the institution of a price structure. Indeed, the agency goes as far as to define these pharmacy types by reference to the cost-sharing they accept (a very clear violation of the statute).

Moreover, CMS's proposal to define what are "reasonable and relevant" standard T&Cs inevitably impacts a Part D plan's ability to structure their special T&Cs, impacting preferred network participation, in direct violation of section 1860D-4(b)(1)(B), as well as the prohibition on institution of a price structure. As noted above, the ability of a Part D plan to structure its pharmacy networks, and in particular those "preferred" pharmacies with which it operates, is key to a plan's ability to negotiate lower pricing, improve the beneficiary experience, and improve access. By proposing to define what are reasonable and relevant T&Cs, CMS hampers Part D plan's ability to operate efficiently, and with success.

[42] Section 1860D-11(i)(2) of the Social Security Act.
[43] Merriam-Webster Dictionary (online); available at http://www.merriam-webster.com/dictionary/structure.
[44] 82 Fed. Reg. at 56,408.
[45] Id.

4. *CMS's Proposal Runs Contrary to the Plain Language of the Statute, in Violation of the APA*

As noted above, the plain language of the Part D statute requires Part D plans to permit any pharmacy meeting the standard T&Cs offered by the plan to participate in the plan's network.[46] CMS's proposal thus misrepresents the plain meaning of the AWP provision, essentially reading out of the statute the requirement that, in order to participate in a pharmacy network, a pharmacy must meet "the terms and conditions under the plan." This is not mere surplusage. As CMS has long-recognized "it is at [the] Part D plans' discretion how they will establish pharmacy networks…."[47]

Under the AWP proposal, Part D plans would no longer be granted the full authority to establish pharmacy networks, which promote quality, reduce fraud and abuse, and lower costs. Once an agency so clearly determines a statute's plain and states that determination repeatedly,[48] the agency cannot then re-interpret the law to suggest a different plain meaning while pretending that its prior interpretation never existed. Such conduct is arbitrary and capricious, and violates the agency's obligation to faithfully enforce the plain meaning of the statute. This is the case regardless of whether the initial agency interpretation was set forth in regulatory preamble language, or codified itself in a federal regulation. Thus, CMS has no authority to adopt a new interpretation that contradicts its prior findings about the plain meaning of the statute, regardless of the fact CMS is now proposing to do so through rulemaking.

As noted, plain meaning is determined based on a review of the statute as a whole, with each part interpreted within the broader statutory context to ensure its meaning is consistent with statutory purpose.[49] If language of a statute is clear using traditional tools of statutory construction, agencies are required to give effect to that plain meaning.[50] The language at 1860D-4(b)(1)(A) is clear – a Part D plan must permit the participation of any willing pharmacy *that meets the terms and conditions under the plan*. Under longstanding tools of statutory construction, CMS cannot read out this language in favor of a policy that dictates the T&Cs under which pharmacies may participate in a PDP network. Had Congress wanted to establish a regulatory regimen under which all Part D plans have the same T&Cs for in-network pharmacy participation, it would have done so.[51]

[46] Section 1860D-4(b)(1)(A) of the Social Security Act ("A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.")
[47] 70 Fed. Reg. 4,194, 4,249 (January 28, 2005).
[48] See id. at 4,244 ("To the extent that pharmacies believe that the discounts they are being asked to offer are too high, they can refuse to participate in Part D plan pharmacy networks.")
[49] *United Savings Ass'n v. Timbers of Inwood Forest Assoc.*, 484 U.S. 365, 371 (1988).
[50] *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).
[51] Central Bank of Denver v. First Interstate Bank, 511 U.S. 164, 176-77 (1994) (For example, the Court reasoned that, although "Congress knew how to impose aiding and abetting liability when it chose to do so," it did not use the words "aid" and "abet" in the statute, and hence did not impose aiding and abetting liability.)

5. *CMS's reliance on anecdotal evidence to support its proposed policy is arbitrary and capricious because it deprives stakeholders of an opportunity to provide meaningful public comment*

In its explanation for re-interpreting the "any willing pharmacy" provision, CMS offers as justification only "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."[52] Mere anecdotes, stated in entirely conclusory fashion, do not suffice as a reasoned basis for decision in this context, nor do they provide public commenters sufficient information to participate meaningfully in responding to CMS's proposal.

"Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[53] The arbitrary and capricious standard "require[s] the reviewing court to engage in a substantial inquiry."[54]

Importantly, as part of proposed rulemaking, an agency must "provide an accurate picture of the reasoning that has led the agency to the proposed rule."[55] The courts reject any claim that deference to the agency requires the abdication of judicial duty to ensure the agency exercised a reasoned decision.[56] Reasoned decision-making requires an agency to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between

the facts found and the choice made.'"[57] It requires an affirmative showing "that the agency genuinely consider[ed] the salient problems presented in the record.[58] As such, "*ipse dixit* conclusion[s]…epitomizes arbitrary and capricious decision making."[59] Furthermore, an agency's mere assertion that a factor was taken into consideration cannot serve as a substitute for actually considering it.[60]

Although anecdotal evidence can serve as a basis for agency decisions, it is frequently relegated to a supportive role.[61] Here, CMS merely asserts that it has un-specified anecdotal evidence that

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[52] 82 Fed. Reg. at 56,408.
[53] See *Motor Vehicle Mfrs Ass'n of the United States, Inc. v. State Farm Mutual Auto. Ins. Co*., 463 U.S. 29, 43 (1983).
[54] *Citizens to Preserve Overton Park*, 401 U.S. 402, 415 (1971).
[55] *Connecticut Light & Power Co. v. Nuclear Regulatory Com.*, 673 F.2d 525, 530 (D.C. Cir. 1982). See also *Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin*., 494 F.3d 188, 199 (D.C. Cir. 2007) (agency must allow its decision-making to be "exposed to refutation" as part of rulemaking) (citing *Association of Data Processing Service Organizations* 745 F.2d at 684); *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 ("[T]he notice required by the APA, or information subsequently supplied to the public, must disclose in detail the thinking that has animated the form of a proposed rule").
[56] See *American Mining Cong. v. EPA*, 907 F.2d 1179, 1187 (D.C. Cir. 1990).
[57] *State Farm*, 463 U.S. at 43 (1983); see also *Bowman Trans., Inc. v. Arkansas-Best Freight Syst., Inc.*, 419 U.S. 281, 288 n.4 (1974) ("[A] party is entitled…to be apprised of the factual material on which the agency relies for decision so that he may rebut it.").
[58] See *Cross-Sound Ferry Servs. v. Interstate Commerce Com.*, 738 F.2d 481, 487 (D.C. Cir. 1984).
[59] See *Illinois Pub. Telecomm. Ass'n v. FCC*, 117 F.3d 555, 564 (D.C. Cir. 1997).
[60] See *Treasury Employees Union, v. Horner*, 854 F.2d 490, 499 (D.C. Cir. 1986).
[61] See *Prometheus Radio Project v. FCC*, 373 F.3d 372, 399 (3d Cir. 2004) (upholding the agency's reliance on anecdotal evidence for its decision because the agency "used anecdotal evidence merely to illustrate its statistical findings—it did not rely on anecdote as the sole basis for its conclusions about localism."); see also *High Sierra Hikers Ass'n v. Weingardt*, 521 F.Supp. 2d 1065, 1077 (N.D. Cal. 2007) (holding Forest Service's reliance, under the Wilderness Act, on a flawed survey methodology to be arbitrary and capricious in part because the agency "made sweeping statements" based on "only limited anecdotal evidence and certain very general trends.").

supports its reinterpretation. CMS offers no hint as to the details of this evidence, and thus gives stakeholders no means of challenging CMS's conclusion, on the basis, for example, that other factors caused the outcomes in CMS's anecdotes. In so doing, CMS forecloses upon the reasoned consideration of, and response to, contrary evidence by commenters that must underlie agency decision-making under the APA.[62] Thus, not only is the proposed rule itself vulnerable to attack, but its non-specificity also endangers CMS's ability to respond meaningfully to comments, as it must.[63]

6. *CMS's AWP Proposal Raises Significant Anti-Competitive Concerns*

The genesis for the Part D program, and the principle upon which it has always operated with success, is Congress' desire to "promote competition in the private market for Part D drugs."[64] The ability of Part D plans to construct networks that include some, but not all, providers (so-called selective contracting) has long been seen as an important tool to enhance competition and lower costs for consumers. Yet, in dictating the very terms and conditions upon which Part D plans and pharmacies negotiate, CMS's policy runs counter to the intention of the Part D program, and counter to both the economic principles and empirical evidence that support the goals of competition.

When CMS first proposed a similar policy in 2014, the Federal Trade Commission ("FTC") wrote a strongly worded comment letter arguing against any policy that would threaten the effectiveness of selecting contracting with pharmacies, on the ground that selective contracting is one of a Part D plan's key tools in lowering costs.[65] As the FTC noted at that time, "Requiring prescription drug plans to contract with AWP would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies." While CMS is no longer proposing to entirely do away with preferred networks, by defining the very T&Cs upon which Part D plans and pharmacies negotiate, "the incentive for providers to bid aggressively for the plan's business – by offering better rates – is undermined."[66] CMS has long known that selective contacting is one of, if not *the*, key to the success of the Part D program. Study after study has shown that free market competition has resulted in lower drug prices overall, and lower prices for consumers.[67] Therefore, as CMS considers ways in which to improve upon the Part D

[62] See, e.g., *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 263-64 (D.D.C. 2015) (observing that "meaningful public comment" on proposed Medicare rule was precluded by failure to disclose evidence upon which rulemaking relied). See also *Connecticut Light & Power*, 673 F.2d at 530-31 (agency may not "play hunt the peanut" with information critical to rulemaking, but must rather disclose information sufficient to allow "genuine interchange" and "meaningful commentary").
[63] See, e.g., *Illinois Pub. Telecomm. Ass'n*, 117 F.3d at 564 (faulting FCC for "cavalierly" dismissing contrary evidence offered by commenters).
[64] 79 Fed. Reg. 1,918, 1969 (January 10, 2014).
[65] Comments of the Federal Trade Commission re: CY 2015 Policy and Technical Rule, Submitted to CMS on March 7, 2014 (available at https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf.)
[66] See id.
[67] Part D Claims Analysis: Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks (April 30, 2013), available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf. See also Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies, available athttps://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf.

program, it should keep in mind the very principles upon which the Part D program is founded – and upon which it has succeeded – and leave in place existing pharmacy network standards.

7. *The AWP Proposal is Contrary to the Direction for Executive Agencies set forth by President Trump*

Finally, the proposed AWP policy clearly runs in the face of the Trump Administration's explicit goal of reducing the regulatory burden on the private sector, and not regulating where existing rules and regulations are sufficient. For example, the Executive Order entitled, *Reducing Regulation and Controlling Regulatory Costs*, signed by President Donald Trump on January 30, 2017, directs agencies that, for any new regulation, two existing regulations must be repealed and any new regulation must be implemented in such a way that the total cost of regulations is net neutral. Stated differently, we interpret that the cost of implementation of the new requirements must be less than or equal to zero. However, as we have illustrated above, the operational challenges that are likely to result from changes to AWP will not only increase operational burdens for PBMs but increase costs. We also reiterate the economic analysis, as discussed in Section F above, which determined that the costs of the AWP proposal would trigger the economically signficant threshold under Executive Order 12866. In light of this, we believe this proposal runs counter to the current policies of this Administration and should be carefully scrutinized prior to implementation.[68]

[68] *See also* Exec. Order No. 13813, 82 Fed. Reg. 48385 (Oct. 17, 2017) (instructing regulatory agencies to incentivize "high-quality care at affordable prices for the American people" and minimize "burdens on affected plans, providers or payers").

13. § 423.120 - Changes to the Days' Supply Required by the Part D Transition Process (p. 56411-56412)

CMS Proposal: CMS proposes to make two changes to the regulations on its transition policy: 1) CMS proposes to shorten the required transition days' supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting; and 2) CMS proposes a technical change to the current regulatory language to provide that the required supply in the outpatient setting be a month's supply. (The current requirement is to provide a one-time, temporary supply for at least 30 days of medication, unless the prescription is written for less than 30 days and requires the Part D plan to allow multiple fills to provide up to a total of 30 days of medication).

Discussion: CMS currently requires that Part D plan sponsors provide for an appropriate transition process for Part D drugs that are not on the drug plan's formulary or require prior authorization (PA) or step therapy under a plan's utilization management rules. Plans are required to ensure beneficiary access to a temporary supply of drugs within the first 90 days following a change in Part D plan enrollment. In the outpatient setting, the transition supply must be for at least 30 days of medications. In the LTC setting, the supply must be for up to 91 days and may be up to 98 days, depending on the dispensing increment.

CMS indicated in the preamble that it originally required an extended transition for beneficiaries residing in an LTC facility because these residents 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 time frames in order for the physician to work with the facility and LTC pharmacies. CMS acknowledges that, after more than 10 years of experience with Part D in LTC facilities, CMS has not seen the concerns that it expressed most recently in the 2010 final rule materialize. CMS indicated that it does have continuing concerns about drug waste and the costs associated with such waste in the LTC setting. PCMA concurs with the CMS position that a different days' supply requirement is not necessary in the LTC setting. The extended days' supply may have served a purpose when LTC facilities, LTC pharmacies and the prescribers that work in LTC settings were first implementing the Part D prescription drug benefit. Today, systems are in place to address medication changes determined to be appropriate following a change in Part D plan enrollment. CMS has additional beneficiary protections in place to handle coverage of non-formulary medications when appropriate.

CMS is also proposing to change the regulation from "30 days" to "a month's supply." If finalized, this change would mean that a transition fill in the outpatient setting would be required for "one-time, temporary supply of a least a month 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." PCMA supports the change from "30 days" to "a month's supply." However, PCMA believes that the language as proposed by CMS is confusing and does not best address the current operations of the program. In addition, from a clinical point-of-view, Part D plan sponsors can best serve beneficiaries by reviewing medications for clinical appropriateness before the next refill. This clinical review is particularly important as Part D plan sponsors work with CMS to prevent inappropriate opioid use.

As CMS notes in discussing the days' supply issue for the LTC setting, extensive transition supplies no longer best serve the program. It no longer makes sense for a non-formulary or non-covered medication to be covered for multiple fills to provide a total of a month's supply of medication. If a prescriber has written a prescription for a seven- or 10-day supply, there are systems in place to request a formulary exception or PA at the time the original transition supply is provided to the beneficiary. If a prescriber has specified that the prescription should be filled for a seven- or 10-day supply, the patient has the supply determined to be appropriate by the prescriber. The Part D program has beneficiary protections in place to handle coverage of non-formulary medications when appropriate. With CMS requirements in place for expedited review of PAs if necessary, there is no justification to require multiple fills to provide for up to a total of a month's supply of medication. As indicated in the LTC discussion, after more than 10 years of experience with the PA process, CMS should use this opportunity to restate its proposed change to require that a transition fill in the outpatient setting be for a "one-time, temporary supply of a least a month of medication, unless the prescription is written by a prescriber for less than a month's supply." To do otherwise, leaves language that is confusing for the pharmacy, the beneficiary, the prescriber and the Part D plan sponsor.

***PCMA Recommendation*: PCMA supports the CMS proposal to shorten the required transition days' supply in the LTC setting to the same supply currently required in the outpatient setting. For the standard transition days' supply, PCMA supports the change from 30 days to a month's supply. PCMA encourages CMS to use this opportunity to revise its proposed change to require that a transition fill in the outpatient setting be for a "one-time, temporary supply of a least a month of medication, unless the prescription is written by a prescriber for less than a month's supply."**

14. §§ 423.100, 423.120, and 423.128 - Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (p. 56413-56416)

A. Implementing Generic Substitution

CMS Proposal: CMS proposes a number of changes to enable Part D plan sponsors to immediately substitute newly released equivalent generics for brand name drugs. Specifically, CMS proposes to permit Part D plan 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 plan sponsors replace the brand name drugs with therapeutically equivalent newly approved generics— rather than having to wait until the current direct notice and formulary change request requirements have been met. CMS also proposes to allow Part D plan sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect two months after the start of the plan year. The generic drug would need to be offered at the same or lower cost-sharing and with the same or less restrictive utilization management criteria originally applied to the brand name drug.

CMS proposes to permit Part D plan 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. CMS would require that Part D plan sponsors must provide direct notice to affected beneficiaries and other specified notice to CMS and other entities. Finally, CMS proposes that the transition process would not be applicable in cases in which a Part D plan substitutes a generic drug for a brand name drug.

Discussion: CMS currently provides that Part D plan sponsors generally cannot remove drugs or make cost-sharing changes between the beginning of the Annual Enrollment Period (AEP) and 60 days after the plan year begins. PCMA concurs with CMS that revising this provision would assist Part D plan sponsors to best manage the costs incurred by the program by permitting substitutions to take place during a longer time period than is currently permitted; therefore, PCMA supports CMS's proposal to permit Part D plan sponsors to immediately remove brand name drugs, or to make changes in their preferred or tiered cost-sharing status, when those Part D plan sponsors replace the brand name drugs with therapeutically equivalent newly approved generics— rather than having to wait until the direct notice and formulary change request requirements have been met.

In addition, PCMA supports the CMS proposal to conform the definition of ''affected enrollees'' to clarify that applicable changes must affect a beneficiary's access to drugs during the current plan year for the beneficiary to be an "affected enrollee." PCMA also agrees with CMS in its response to those stakeholders that 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. Since CMS would permit immediate substitution only when the generics are deemed therapeutically equivalent to the brand name drug being removed by the FDA and meet certain other requirements discussed below, the generic substitution would always be a medication considered by the FDA to be a therapeutically equivalent generic drug.

PCMA strongly concurs with CMS's position that a transition policy would not be appropriate for these situations. The purpose of the transition process is to make sure that the medical needs of beneficiaries are safely accommodated in that they do not go without their medications or face an abrupt change in treatment. Beneficiaries receiving coverage for generic medication when the brand-name product was previously covered would not have previous experience with the generic alternative prior to the drug substitution to see how it worked for them. Therefore, it is not possible for a beneficiary to accurately assert that a generic substitution would not work, since he or she would not have tried the generic drug. PCMA agrees with CMS that the appropriate beneficiary protections as identified below have been included with the proposed changes.

1. The proposed language addresses safety concerns by permitting Part D plan sponsors to add only therapeutically equivalent generic drugs. This means the FDA must have approved the generic drug in an abbreviated new drug application (NDA), 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, and whether they are considered to be therapeutically equivalent to the brand name drug. PCMA supports the proposed language that permits Part D plan sponsors to add only therapeutically equivalent generic drugs under this provision.

2. CMS would require that, before making any generic substitutions, a Part D plan 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 when a new equivalent generic is added. This would, for instance, include the Evidence of Coverage (EOC). The provision 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 such notice would advise them of the steps they could take to request coverage determinations and exceptions. When the Part D plan sponsor substitutes a generic for a brand name drug, CMS would require the Part D plan sponsor to provide affected enrollees with direct notice. PCMA supports this requirement.

3. CMS proposes to permit generic substitutions to take place throughout the entire year. CMS would encourage Part D plan sponsors to provide direct notice as early as possible to any beneficiaries who have reenrolled in the same plan and are taking a brand name drug that will be replaced with a generic drug at the start of the next plan year. Part D sponsors should be promptly updating the formularies posted online and provided to potential enrollees to reflect any permitted generic substitutions—and at a minimum meeting any current timing requirements provided in applicable guidance. At this time, CMS is not proposing to set a deadline by which Part D sponsors must update their formularies before the start of the new plan year. CMS currently requires that the current formulary posted online be updated at least monthly. CMS is encouraging Part D plan sponsors to provide the retrospective direct notices of these generic substitutions no later than by the end of the month after which the change becomes effective. PCMA is supportive of this provision.

4. Beneficiaries would be protected from higher cost-sharing under proposed paragraph (b)(5)(iv)(A). Through this provision, CMS proposes to require Part D plan 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.

CMS has included a provision intended to ensure that prospective enrollees would not be misled by Part D plan sponsors that could 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. Specifically, CMS proposes that a Part D plan sponsor cannot substitute a generic for a brand name drug unless it could not have previously requested formulary approval for use of that drug. A Part D plan sponsor could not remove a brand name drug or change its preferred or tiered cost-sharing if that Part D plan sponsor could have included its generic equivalent with its initial formulary submission or during a later update window. While PCMA agrees with the intent of this proposed beneficiary protection, we believe that CMS should allow immediate substitution of generics, in certain circumstances, for which Part D plan sponsors could have previously requested formulary approval. PCMA strongly believes that CMS should recognize that there are a number of circumstances in which Part D plan sponsors would not immediately add a generic drug to formulary when the first generic product enters the market: 1) the first generic product available may be an authorized generic (produced by brand companies and marketed as generics under private label); 2) the generic manufacturer may market the product while struggling with supply quantity issues; or 3) the first project may come to market with pricing similar to the brand name product. A recently published GAO report on the drug industry

noted that research it reviewed indicated that fewer competitors in the drug industry are associated with higher prices, particularly for generic drugs.[69]

For those reasons, Part D plan sponsors may delay the addition of the generic product to their formulary. Part D plans and beneficiaries should not be penalized for a delayed formulary addition based on challenges in the industry landscape. Therefore, PCMA recommends that CMS allow immediate substitution for specified generics for which Part D sponsors could have previously requested formulary approval in certain circumstances. PCMA believes it would be reasonable for CMS to require that the Part D plan sponsor provide notification to CMS as to the reason for the delayed addition when it notifies CMS of the formulary change.

CMS notes that these` provisions would not apply to follow-on biological products under current FDA guidance. While PCMA understands CMS's reasons for not applying this provision to follow-on biological products, PCMA recommends that CMS review this provision in the future when interchangeable follow-on biological products are available.

***PCMA Recommendation*: PCMA supports the CMS proposals (1) to permit Part D plan sponsors meeting all requirements to immediately remove brand name drugs, or to make changes in their preferred or tiered cost-sharing status, when those sponsors replace the brand name drugs with therapeutically equivalent newly approved generics, (2) allow Part D plan sponsors to make the specified changes during any time of the year, and (3) to conform the definition of ''affected enrollees'' to clarify that applicable changes must affect a beneficiary's access to drugs during the current plan year for the beneficiary to be an "affected enrollee."**

PCMA encourages CMS to recognize that market circumstances may justify exceptions to the proposal that Part D plan sponsors cannot remove a brand name drug or change its preferred or tiered cost-sharing if they could have included its generic equivalent with its initial (or updated) formulary. For example, Part D plan sponsors should be able to delay the addition of the generic product to formulary due to supply and pricing issues.

PCMA supports the CMS proposal to use a general notice which would advise beneficiaries 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.

B. Otherwise Facilitating the Use of Generics

CMS Proposal: CMS proposes that a Part D plan sponsor would need to provide at least 30 days' online notice to affected enrollees before removing drugs or making cost-sharing changes

[69] General Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals," November 2017. https://www.gao.gov/assets/690/688472.pdf.

except when adding a therapeutically equivalent generic as specified, and removing unsafe or withdrawn drugs. Part D plan sponsors could provide online notice after the effective date of changes only in those limited instances. CMS requires—and would continue to do so under the proposed revisions—that Part D plan 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. CMS currently requires Part D plan sponsors to furnish directly to enrollees an explanation of benefits (EOB) that includes any applicable formulary changes for which Part D plan sponsors are required to provide notice. In addition, CMS currently requires Part D plan sponsors to post at least 60 days' notice of removals and cost-sharing changes online for current and prospective Part D enrollees. CMS proposes to require Part D plan sponsors to provide ''timely'' notice. Posting information online related to removing a specific drug or changing its cost-sharing solely to meet the content requirements of § 423.128(d)(2)(iii) cannot replace general notice direct notice to affected enrollees; or notice to CMS.

CMS proposes to require Part D plan sponsors to provide the following entities with notice of the generic substitutions: CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists (''CMS and other specified entities''). Even though, as proposed, a Part D plan 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 plan sponsor must include the generic substitution in the next available formulary submission to CMS. Part D plan sponsors can determine the most effective means to communicate formulary change information to CMS and other specified entities and that, under this provision, CMS would consider online posting sufficient for those purposes.

CMS plans 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. Section 423.120(b)(5)(i) currently requires at least 60 days' notice to all specified 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. CMS proposes to reduce the notice requirement in both instances to at least 30 days and the refill requirement to a month. Enrollees 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 (PA) requirements as a result of new safety-related information or clinical guidelines.

Discussion: Currently, Part D plan 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 plan sponsors may choose to remove a brand name drug, or change its preferred or tiered cost-sharing, and substitute or add its therapeutic equivalent. For Part D plan sponsors to offer best utilization management, this change should take place in a

timely manner; however, these changes take some time under current CMS regulations under which Part D plan sponsors must submit formulary change requests to CMS and provide specified notice before removing drugs or changing their cost-sharing. Also, § 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 beneficiaries or a 60-day refill. The ability of Part D plan sponsors to make generic substitutions as approved by CMS is further limited by the fact that as detailed previously they generally cannot remove drugs or make cost-sharing changes from the start of the annual election period (AEP) until two months after the plan year begins.

Some stakeholders may be concerned that CMS is reducing the number of days advance notice is afforded to beneficiaries in these instances. PCMA concurs with CMS's belief that current CMS requirements provide the necessary beneficiary protections, and that 30 days' notice will afford beneficiaries sufficient time to either change to a covered alternative drug or to obtain needed PA 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 time frames for exigent circumstances, and a requirement that Part D plan sponsors automatically forward all untimely coverage determinations and redeterminations to the IRE for independent review. CMS also indicates that, while 60 days' notice is currently required, CMS has no evidence to suggest that beneficiaries are currently utilizing the full 60 days. The reduction to 30 days would align these requirements with the time frames for transition fills. CMS also indicates that, with over 11 years of program experience, it has no evidence to suggest that 30 days has been an insufficient temporary day supply for transition fills.

PCMA Recommendation: ***PCMA supports (1) the CMS proposal that a Part D plan 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 removing unsafe or withdrawn drugs), (2) CMS's plans 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, (3) the CMS proposal to require Part D plan sponsors to provide ''timely'' notice and supports CMS's proposal to reduce the notice requirement in both instances to at least 30 days, and (4) the CMS proposal to require Part D plan sponsors to provide CMS and other specified entities with notice of generic substitution, with online posting being sufficient for these purposes.***

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing (p. 56416-56417)

CMS Proposal: CMS proposes to revise the definition of generic drugs at §423.4 to include follow-on biological products (or biosimilars) 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). Specifically, CMS proposes to limit inclusion of follow-on biological products in the definition of generic drug for purposes of non-LIS catastrophic cost-sharing and LIS cost-sharing to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations. CMS continues to consider biosimilar biological products more like brand name drugs for purposes of transition or midyear formulary changes because they are not interchangeable. Therefore, the proposed change to treat follow-on biological products as generics is limited to purposes of non-LIS catastrophic and LIS cost-sharing only.

Discussion: PCMA applauds CMS for its proposal to revise the definition of generic drugs to include follow-on biological products for purposes of cost-sharing. Lower cost-sharing for lower cost alternatives will improve beneficiary incentives to choose follow-on biological products over more expensive reference biological products and will reduce costs to both Part D beneficiaries and the Part D program.

Increased use of follow-on biological products has the potential to cause gains in health for beneficiaries taking follow-on biological products; if lower prices of follow-on biological products relative to reference products result in lower copayments for beneficiaries, beneficiaries' adherence to medication regimens may increase, improving their health.[70] In addition, changes in Medicare Part D coverage policy will impact physician uptake of follow-on biological products. Lower copayments or cost-sharing will remove a barrier for prescribing follow-on biological products as there is no incentive to prescribe such a product when the cost-sharing is the same for the biosimilar and the reference product. Removing barriers for biosimilar prescribing will lead to lower costs for the Part D program.

As CMS notes, 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 has generated a great deal of confusion and concern for Part D plan sponsors, beneficiaries and advocates alike. CMS noted that advocates have expressed concerns that LIS enrollees are

[70] *Andrew W. Mulcahy, Zachary Predmore, and Soeren Mattke (*Rand Corporation), "The Cost Savings Potential of Biosimilar Drugs in the United States." https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

required to pay the higher brand copayment for biosimilar biological products. PCMA shares that concern. The designation of biosimilar biological products as brands for purposes of LIS cost-sharing creates a disincentive for LIS enrollees to choose lower cost alternatives. This designation is also a concern for non-LIS enrollees in the catastrophic portion of the benefit.

In the preamble, CMS notes that treating biosimilar biological products the same as generic drugs for purposes of transition or midyear formulary changes would incorrectly signal that CMS has deemed biosimilar biological products (as differentiated from interchangeable biological products) to be therapeutically equivalent. PCMA encourages CMS to revisit this issue when the first interchangeable biosimilar is designated as interchangeable by the FDA.

In this proposed regulation, CMS does not address the widely recognized problem related to the treatment of biosimilars in the coverage gap period. PCMA remains very concerned with the discrepancy in application of the 50 percent price discount for biosimilars in the Part D coverage gap. PCMA recommends that CMS change the rules so that the 50 percent manufacturer discount for brand products applies to biosimilar in the coverage gap. We realize this change arguably requires legislative authorization but also urge CMS to assess whether this could be implemented under its Center for Medicare & Medicaid Innovation authority.

In CMS's March 30, 2015, letter to Part D sponsors entitled, "Part D Requirements for Biosimilar Follow-On Biological Products," CMS reiterated that "biosimilars are non-applicable drugs for purposes of establishing coverage gap cost-sharing under the basic Part D benefit, and are not discounted or otherwise subject to Discount Program requirements."[71] Thus, because biosimilars are excluded from the definition of 'applicable drugs,' they are exempt from the 50 percent discount manufacturers are required to provide on branded drugs for Part D beneficiaries in the coverage gap, often resulting in higher costs to beneficiaries for biosimilar products relative to their reference drug. Not only does this policy come at the expense of additional federal dollars expended for biosimilar products, it results in a distorted market for biosimilars, creating incentives that drive beneficiaries toward more expensive medications. Indeed, a November 3, 2017 Medicare Payment Advisory Commission presentation demonstrates that seniors pay more for biosimilars in Medicare Part D because these products are not subject to the manufacturer discount applied to brand drugs and biologics in the coverage gap.[72]

PCMA believes that it is appropriate for CMS to use its waiver authority to test a correction to this market distortion. Waiving the definition of certain applicable drugs, including biosimilars,

[71] Amy Larrick, CMS memo: "Part D Requirements for Biosimilar Follow-On Biological Products," March 30, 2015. http://www.amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-_docs/2015/cms_guidance_biosimilars_part_d_3_30_2015.pdf

[72] Medicare Payment Advisory Commission (MedPAC), "Biosimilars in Medicare Part D," November 3, 2017. http://www.medpac.gov/docs/default-source/default-document-library/biosimilars-in-medicare-part-d_nov-2017_final_print-version.pdf?sfvrsn=0

will permit CMS to apply its payment model across drug categories and classes and ultimately determine the most cost-effective method of providing quality care to Medicare beneficiaries, regardless of a particular product's approval pathway. Thus, if CMS believes it does not have specific authority to revise the current rules, PCMA requests that CMS use its authority to waive the definition of 'applicable drug' under Medicare Part D for purposes of the Medicare Coverage Gap Discount Program (MCGDP), so as to include biosimilar biologic products. In particular, CMS should use the authority granted to CMMI to waive section 1860D-14A(g)(2)(A), which exempts from the definition of the term 'applicable drug' under the MCGDP products "licensed under subsection (k) of such section 351."

PCMA Recommendation*: *PCMA supports the CMS proposal to revise the definition of generic drug at § 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), therefore, treating follow-on biological products as generics for non-LIS catastrophic and LIS cost-sharing. PCMA encourages CMS to revisit the treatment of biosimilar biological products for purposes of transition or midyear formulary changes when the first interchangeable biosimilar is designated as interchangeable by the FDA. PCMA recommends that CMS use its authority to waive the definition of 'applicable drug' in Medicare Part D for purposes of the MCGDP to include biosimilars in the discount program, in order to permit the agency to test the most cost-effective way of providing quality care to Part D beneficiaries.

16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences

CMS Proposal: CMS proposes to revise the Part D regulations at §423.265(b)(2) to eliminate the PDP Enhanced Alternative (EA) to Enhanced Alternative (EA-to-EA) meaningful difference requirement. This change would be effective for contract year 2019. The requirement that EA plans be meaningfully different from the basic Part D plan offered by a plan sponsor in a service area would be maintained.

In its regulatory impact analysis, CMS estimates that the proposed change could result in as many as 125 additional enhanced plans (an increase of 15 percent) and a modest savings in burden and cost. To the extent that CMS finds the elimination of the EA-to-EA meaningful difference requirement results in potential beneficiary confusion or harm, CMS will consider reinstating it through future rulemaking or other action.

CMS discusses the possibility of eliminating the meaningful difference test between basic and EA plans but concludes that, for now, the meaningful difference test between basic and enhanced plans should be maintained to ensure that there is a meaningful value for beneficiaries given the supplemental Part D premium associated with the enhanced plans.

Discussion: PCMA supports eliminating the requirement to provide PDP EA-to-EA plan offerings with meaningful differences. We agree that this change will help to balance the Agency's goals of increasing competition and plan flexibility while still affording beneficiaries with meaningfully different choices in Part D benefit packages.

Similar to this proposal, the Center for Consumer Information and Insurance Oversight recently proposed removing the meaningful difference standard in the individual and small group markets to encourage plan design innovation and increase plan choice for beneficiaries.[73] For these same reasons, we believe that CMS should eliminate the meaningful difference requirement in Part D.

We appreciate that CMS is contemplating eliminating the meaningful difference between basic and EA plans. As CMS deliberates this option, here are a few things the Agency should consider:

- This test may stifle innovation, reduce consumer choice, and impose additional costs on plans.
- While in the 2018 Call Letter, CMS lowered the out-of-pocket cost (OOPC) differential between basic and enhanced PDP offerings, the OOPC difference between basic and EA

[73] 2019 Notice of Benefit and Payment Parameters Proposed Rule Available at https://www.gpo.gov/fdsys/pkg/FR-2017-11-02/pdf/2017-23599.pdf

PDP offerings is still too high, which may make enhanced plans very expensive and out of reach for many beneficiaries, further limiting consumer choice. Furthermore, it will eliminate unneeded disruption and provide more plan stability to beneficiaries currently enrolled in second EA plans, as Part D plan sponsor's will not be forced to adjust benefits to comply with changing OOPC requirements.

***PCMA Recommendation*: PCMA supports eliminating the requirement to provide PDP EA-to-EA plan offerings with meaningful differences. PCMA asks CMS to consider the negative consequences with retaining the current meaningful difference test between basic and EA plans.**

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point-of-Sale

SEE PART TWO (PAGES 138 - 181)

B. IMPROVING THE CMS CUSTOMER EXPERIENCE

2. (§423.504(b)) Reducing the Burden of the Compliance Program Training Requirements

CMS Proposal: CMS proposes to eliminate a federal training requirement for certain providers and entities that have relationships with MA and Part D plans. Under existing rules, in order for a Part D plan to have a contract with CMS, the Part D plan sponsor must have an effective compliance program that includes training and education between the compliance officer and the sponsoring organization's employees, senior administrators, governing body members and first-tier downstream and related entities (FDRs).

CMS notes that because CMS does not generally interfere in private contractual matters between sponsoring organizations and their FDRs, and because CMS continues to audit sponsors' compliance programs including their monitoring, auditing and oversight of FDRs, this requirement is no longer necessary.

Discussion: PCMA agrees with CMS's intent to alleviate the burden on plan sponsors and FDRs in complying with the compliance program training requirements. However, to the extent that compliance and FWA training would still be required of FDRs under their contracts with plan sponsors, we are concerned that this change would inadvertently increase the burden on PBMs that contract with multiple Part D plan sponsors who are likely to have a wide range of different requirements with which the PBMs would have to comply, rather than just one federal training requirement. Likewise, the burden could increase inadvertently on PBMs enforcing compliance training with downstream entities such as pharmacies, who would now also have to comply with a wide range of varying compliance requirements. We believe that the current rules already serve to reduce the burden on FDRs. Thus, CMS should maintain the current rules which further the standardization of the compliance program training requirements.

PCMA Recommendation: We recommend that CMS not make this change as it inadvertently increases burden to FDRs.

4. (§423.128) Revisions to Timing and Method of Disclosure Requirements

CMS Proposal: CMS proposes a change to a timeline that Part D plan sponsors must meet in disclosing certain types of information to enrollees. Specifically, CMS proposes to require that Part D sponsors provide plan information (Evidence of Coverage, provider or pharmacy directory and, for Part D plans, the formulary) by the first day of the annual enrollment period (AEP) instead of 15 days before. CMS states that the large volume of information provided before enrollment confuses enrollees who find the Annual Notice of Change (ANOC) to be a much more useful document.

CMS also proposes to modify §422.111(h)(2)(ii) to permit MA and Part D plan sponsors to provide the EOC, Summary of Benefits, formulary, and provider network information on the plan's website or electronically, with hard copies to be made available "upon request."

Discussion: PCMA supports the proposal for Part D sponsors to provide plan information by the first day of the AEP instead of 15 days before. This change will give plan sponsors an adequate amount of time to meet this requirement, particularly for Medicare beneficiaries who make their coverage decisions at the end of the AEP.

In order to facilitate disclosure to enrollees of the option to receive documents electronically, we recommend as an alternative to sending a separate notice to enrollees, the ability of Part D plan sponsors to update the model ANOC to include an optional page for plans to explain how enrollees can access important documents, including the formulary. Allowing Part D plan sponsors to include this pertinent information within the ANOC ensures that all information is contained in one document for easy enrollee accessibility.

PCMA Recommendation: We support the proposal to allow Part D sponsors to provide plan information by the first day of the AEP instead of 15 days before. We also recommend that Part D plan sponsors be given the option to update the model ANOC to include an optional page for plans to explain how enrollees can access important documents, including the formulary.

5. Revisions to Parts 422 and 423, Subpart V, Communication/Marketing Materials and Activities

A. (Subpart V) Revising the scope of to include Communications and Communications Materials

CMS Proposal: CMS proposes to incorporate the concept of "Communications materials" into the rules, which would be a broader set of materials that would include marketing materials. Certain materials currently considered to be marketing materials would, under the proposed rules, instead be included as communications materials and as such would not be subject to the same level of scrutiny as marketing materials. Thus, under the proposal, marketing materials would encompass a more narrow set of activities and materials compared to communications materials.

"Communications" would be defined as activities and use of materials to provide information to current and prospective enrollees. "Communications materials" would be defined as materials that include all information provided to current members and prospective beneficiaries.

CMS proposes to make the following changes to §423.2264:

- Delete paragraph (a)(3): "Written explanation of the grievance and appeals process" – which CMS states would be considered to be communications material instead of marketing material;
- Delete paragraph (a)(4): "Other information necessary to enable beneficiaries to make an informed decision about enrollment."
- Move paragraph (e), which requires plan sponsors to provide translated materials in certain areas where there is a significant non-English speaking population to the general communication standards in new §423.2268(a)(7). The material would now be included as communications materials instead of marketing materials. The statement "as defined by CMS," would be added to allow CMS the ability to define the significant material that would require translation.

Discussion: PCMA supports narrowing the definition of marketing materials and introducing the concept of communication materials that would be subject to less stringent requirements. We agree that the level of scrutiny currently required for several documents is unwarranted. We believe the proposed new definitions appropriately safeguards prospective and current enrollees, while not placing an undue burden on Part D plan sponsors.

In addition, we also recommend that CMS limit the current filing requirements, which currently apply to all materials, whether for approval or as file and use. The current requirement creates a

significant volume of materials to be submitted to CMS, even if those materials do not influence the enrollment decision or pose risk of confusing or misleading beneficiaries about their current benefits or premiums. Limiting the number of materials plan sponsors are required to file will create efficiencies for plans to deliver materials to beneficiaries.

We also seek clarification about how this new process may impact Fully Integrated Dual Eligible special needs plans (FIDE-SNPs) and Dual-Eligible SNPs (D-SNPs) that have integrated marketing materials related to both the Medicaid and Medicare programs. For example, it is unclear how the amended requirements will align with state marketing requirements and thus affect joint marketing efforts with states. CMS may need to review both Medicare and Medicaid marketing requirements and provide guidance to states and plans for further alignment, including examples of specific approvable marketing methods.

We also appreciate that CMS proposes to add the statement "as defined by CMS" to allow the agency the ability to define the significant material that would require translation. In that regard, we believe it is appropriate to once again ask CMS to define the significant material that would require the Section 1557 notice and tagline requirements. We have repeatedly asked the Department to adopt a narrow definition of "significant" so as not to create an unmanageable, unhelpful and costly requirement to include virtually all communications between an individual and a covered entity.

As we have noted several times, the burdens and costs associated with the nondiscrimination notice and taglines are particularly acute for PBMs, which handle millions of claims, operate in many different states, and thus face multiple, diverse notice and tagline requirements across their portfolio of plans.

Although the text of the regulations refers to "significant publications," neither the regulation nor the preamble defines what constitutes "significant." Instead, the Office of Civil Rights (OCR) defined "significant" through subregulatory guidance in the form of a series of FAQs that were published on the agency's website.

According to PCMA research that we have shared with the Department many times, the resulting burden imposed upon PBMs— and ultimately borne by all participants in the marketplace, including enrollees— by the nondiscrimination notices and taglines is estimated to cost the industry between $500 million to nearly $5 billion in 2017 alone.

PCMA, along with other industry stakeholders, has provided the Department with a draft FAQ, which would stay faithful to the intent of the nondiscrimination rule, while significantly reducing the burden imposed on covered entities.

Since the Department has not acted on this common sense solution, we ask CMS to take the lead on this issue in the interim and permit Part D plan sponsors to defer to its own standards in the Medicare Marketing Guidelines for compliance.

Finally, we urge CMS to consider greater support of electronic materials and communications and even consider electronic channels to be the default with the ability for beneficiaries to continue to receive print. The significant number of Medicare eligible members enrolling in Medicare plans today is engaged, ready and open to receiving materials electronically. While saving CMS money and addressing the concerns with notice and tagline requirements, this is also a great member experience that allows plans to further engage members on maximizing health outcomes.

***PCMA Recommendation*: PCMA supports narrowing the definition of marketing materials and introducing the concept of communication materials that would be subject to less stringent requirements; PCMA recommends that HHS take steps immediately to reduce the administrative burdens related to the nondiscrimination notice and tagline requirements, and urges CMS help achieve that goal by adopting a narrow definition of "significant" as it pertains to the Medicare Marketing Guidelines for compliance with the nondiscrimination notice and tagline requirements.**

6. (§423.590) Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

CMS Proposal: CMS proposes to change the adjudication time frame for Part D standard redetermination requests for payment. Under existing rules, if the Part D plan sponsor makes a redetermination that is favorable to the enrollee, it must issue its redetermination (and effectuate it as specified in §423.636) no later than 7 calendar days from the date it receives the request. CMS proposes to change that time frame so that such decisions are issued and effectuated within 14 calendar days from the date the plan sponsor receives the request. The 14 calendar day time frame would also apply to IRE reconsiderations under §423.600(d) by existing cross reference.

Discussion: PCMA supports this proposal and agrees with CMS that this change would increase consistency in Part D coverage and appeals processes and reduce burden because it would reduce the number of untimely payment redeterminations that must be auto-forwarded to the IRE. As CMS moves toward implementation of the proposal, we recommend that the agency issue new protocols to adjust the timeliness calculations for applicable data universe fields.

Though not addressed in the proposed rule, CMS should take this opportunity to make other changes to increase efficiency and reduce burden with appeals process. Specifically, PCMA is concerned that a large number of requests that require prescriber outreach for additional information are ultimately denied because the prescriber does not respond within the required timeline. Furthermore, completing the necessary information in the required time frame is especially exacerbated when requests are initiated by members or near the close of day before a weekend or holiday. When enrollees submit the request, there is usually significant time involved with identifying the prescriber to complete the necessary information.

PCMA has previously provided suggestions on the Part D appeals process in our response to the CMS request for comments on improving the appeals process[74] and in our comments to the CMS Part D 2017 Transformation Ideas request for information. As noted in these prior comments, we recommend that CMS adopt an integrated appeals process that incorporates the time frames and elements of Medicare Part C, which would reduce the number of requests denied due to unsuccessful prescriber outreach and an expiring timeline. For example, the first level of the Medicare Part C appeals timeline includes 72 hours for an expedited review and 30 days for a standard review, while the Part D time frames are 72 hours for an expedited and 7 days for a standard review determination.

As an alternative, CMS could provide that the timeline is triggered once there is sufficient information from the prescriber to make a decision. This would provide the needed time to obtain the necessary information and would likely result in fewer denial decisions.

[74] PCMA Dec 22, 2017 Comments on the Open Door Forum on the Medicare Part D Appeals Process

We believe these options provide adequate beneficiary protections while also aligning with the series of Executive Orders designed to ensure that regulatory agencies are regulating in a way that minimizes the economic burden on stakeholders.[75]

***PCMA Recommendation*: PCMA supports the proposal to lengthen the adjudication time frame for Part D payment redeterminations and IRE reconsiderations and recommends that the agency also issue new protocols to adjust the timeliness calculations for applicable data universe fields. PCMA also recommends that CMS adopt an integrated appeals process that incorporates the time frames and elements of Medicare Part C or allow Part D plan sponsors to begin the appeals timeline once there is sufficient information from the prescriber to make a decision.**

[75] Executive Order entitled "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs," published on January 30, 2017; Executive Order entitled "Presidential Executive Order on a Comprehensive Plan for Reorganizing the Executive Branch," published on March 13, 2017

8. §423.160 - Updating Part D E-Prescribing Standards (p. 56438-56440)

CMS Proposal: CMS proposes to implement a new standard developed by the National Council for Prescription Drug Programs (NCPDP), the NCPDP SCRIPT version 2017071 for certain specified new transactions. CMS would retire the previous version, NCPDP SCRIPT 10.6, beginning on January 1, 2019 and would make other conforming changes.

Beginning on or after January 1, 2019, NCPDP SCRIPT version 2017071 would apply, if finalized, to a set of prescription transactions that include the following additions:

- 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 and REMS initiation response, and
- REMS request and REMS response.

CMS proposes that the NCPDP Version 2017071 would become the official Part D prescribing standard for communicating medication history information (at §423.160(b)(4)) and to retire NCPDP SCRIPT version 8.1 and 10.6 for medication history transactions communicated on or after January 1, 2019. CMS indicates that it expects that transitioning to the new standards will impose minimal costs on the industry.

CMS proposes to limit usage of NCPDP SCRIPT version 10.6 to transactions before January 1, 2019 and to provide that NCPDP Version 2017071 must be used to conduct the covered transactions on or after January 1, 2019. CMS also proposes to name NCPDP SCRIPT Version 2017071 for the applicable transactions, and to incorporate NCPDP SCRIPT version 2017071 by reference in regulation.

Discussion: In the preamble, CMS notes that the rulemaking process is used to retire, replace or adopt a new e-prescribing standard. CMS indicates that it also provides 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. PCMA notes that some of the prescription transactions included in NCPDP

SCRIPT version 2017071 are new transactions, not previously included in NCPDP SCRIPT 10.6. Therefore, the "backward-compatible" allowance does not provide operational relief from the January 1, 2019 implementation date requirement.

Version 2017071 supports communications regarding multi-ingredient compounds, thereby it will allow compounded medication to be prescribed electronically. Prescriptions for compounds are handwritten currently and sent via fax to the dispenser, which often requires follow-up communications between the prescriber and pharmacy. PCMA looks forward to improvements that will lead to all prescriptions being transmitted electronically and the elimination of paper prescriptions.

While CMS does not propose mandating its use, 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 (LTC). The Census feature would trigger timely notification of a beneficiary's absence from a LTC 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. PCMA believes this new information will be useful to Part D plan sponsors.

CMS indicates its belief that transitioning to the new 2017071 versions of the transactions already covered by the current Part D e-prescribing standard will impose de minimus cost of the 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. CMS is proposing adoption of version 2017071 of the NCPDP 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. PCMA looks forward to a standard that decreases the need for manual processes. Because this would be a new process for Part D plan sponsors, and based on the timing of the proposal and eventual passage of the regulations and standard IT implementation time frames, we recommend at minimum a 24-month implementation of the NCPDP transaction standard from the date the final rule is published.

PCMA questions why CMS has not mentioned electronic prior authorization (ePA) in this discussion of modernizing e-prescribing standards. Electronic prior authorization is the electronic transmission of information between a prescriber and payer to determine whether or not a prior authorization (PA) can be granted. The NCPDP has developed technical standards to support this electronic transmission and accelerate the exchange of PA information. Several states have adopted the mandatory use of ePA under the NCPDP standard. By automating the

process and connecting all industry participants, ePA provides real-time information to support e-prescribing and more rapid PA decision-making. If fully implemented, ePA could reduce administrative costs and burdens, improving efficiency and ultimately ensuring patients receive clinically appropriate medications timely.

Additional reasons to adopt the NCPDP ePA standard at this time include: 1) ePA expedites the ability of beneficiaries to get the prescriptions they need and, therefore, supports the proposed measures for the 2021 Star Ratings in which the plans will be scored on how easy it is for members to get the prescriptions they need; 2) The inclusion of the NCPDP SCRIPT Standard ePA transactions helps CMS achieve the intent of supporting innovative approaches to improving program quality, accessibility and improvement in the CMS customer experience; 3) ePA transactions would also support CMS's intent of establishing a framework and addressing the opioid crisis, under Part D, in which plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug misuse; and 4) There is an unbalanced process right now at the state level, adopting NCPDP SCRIPT ePA at the Federal level could help stabilize adoption in the states.

The time is now for CMS to take action and leadership on the transition to ePA. CMS should take this opportunity to include in regulation the NCPDP ePA standard. PCMA recommends that CMS amend §423.160(b) by adding: (7) Prior authorization. The NCPDP SCRIPT Standard Version 2013101 PA adopted July 22, 2013 as the adopted standard for the exchange of PA information between prescribers and processors for the pharmacy benefit.

***PCMA Recommendation*: PCMA supports the CMS proposal to implement the NCPDP SCRIPT version 2017071 for certain specified new transactions, as identified by CMS in the proposed regulation. We recommend at a minimum a 24-month implementation of the NCPDP transaction standard from the date the final rule is published.**

CMS should take this opportunity to include in regulation the NCPDP ePA standard. PCMA recommends that CMS amend §423.160(b) by adding: (7) Prior authorization. The NCPDP SCRIPT Standard Version 2013101 Prior Authorization adopted July 22, 2013 as the adopted standard for the exchange of PA information between prescribers and processors for the pharmacy benefit.

10. § 423.120(c)(6)— Preclusion List – Part D Provisions (pp. 56441-56447)

CMS Proposal: CMS proposes to rescind the 2015 IFR provisions at § 423.120(c)(6) that "require physicians . . . 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"[76] (hereinafter "provider enrollment").

In place of provider enrollment, CMS proposes an alternative approach to create a risk-based "preclusion list" that targets "demonstrably problematic prescribers," "rather than require the enrollment of Part D prescribers regardless of the possible level of risk posed[.]" Under this proposal, "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[.]'"

The preclusion list would be defined in § 423.100 and would consist of "certain prescribers who are currently revoked from the Medicare program under § 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."[77]

In order to preserve beneficiary access to Part D covered prescription drugs, CMS is also proposing "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."*[78]

The effective date of CMS's proposed prescriber preclusion approach is currently set for January 1, 2019.

Discussion: PCMA commends CMS for proposing to retract the requirement for mandatory prescriber enrollment in Part D. As previously communicated to CMS by PCMA, such a requirement would have resulted in a significant decline in the number of eligible prescribers, harming beneficiary access and driving up programmatic costs. In general, PCMA supports the concept of a "preclusion list" as a way to ensure beneficiary safety and safeguard the program.

[76] 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, 82 Fed. Reg. 56336, 56340, November 28, 2017 (hereinafter "proposed rule").
[77] *Id.*
[78] *Id.* Emphasis added.

However, PCMA is very concerned by CMS's proposed implementation of the new provider preclusion list requirements, which, if implemented without revisions, could unnecessarily increase complexity in the Part D program, expose Medicare beneficiaries to problematic prescribers, and perpetuate a cycle where there is insufficient time to implement complex new requirements that have substantial operational challenges. We have commented extensively on some of these concerns when CMS first proposed provider enrollment as part of the 2015 Part D NPRM proposed in 2014, and again with respect to the 2015 IFR, and then during numerous ongoing stakeholder discussions held by CMS since then. We urge that CMS's new preclusion list requirements not be implemented until these concerns, and the many other issues raised by stakeholders, are fully addressed. Our comments on specific issues raised by the proposal are set out below.

1. *Adopting a separate standard from the revocation/exclusion criteria under § 424.535 creates unnecessary complexity and operational challenges in the Part D program*

    a. PCMA supports CMS's goal of ensuring that Part D drugs are prescribed only by qualified prescribers and appreciates CMS's recognition of the problems with its previously proposed prescriber enrollment program. However, PCMA remains very concerned about the complexity of the program if CMS creates a list that utilizes substantially different standards from the already-established Office of the Inspector General's (OIG) List of Excluded Individuals/Entities ("OIG exclusion list") as currently set forth at 42 C.F.R. § 424.535.[79] Specifically, we are concerned with how CMS intends to identify prescribers for inclusion onto the list, which will have major implications for Part D plan sponsors and PBMs with regard to how they incorporate and process the two separate files.

    b. Currently, when an excluded provider is included on a claim, the claim is rejected at POS with no override or additional fills provided. In the scenario described in the new proposed rule, a provisional fill would be provided to allow the beneficiary an opportunity to find a new provider. Although this has the potential to reduce beneficiary disruption, we believe that the potential for confusion associated with the conflicting messages this sends outweighs the benefits to the enrollee and is substantially inconsistent with the excluded provider and other prescriber validation processes.

    c. CMS's proposed standard for "preclusion" is technically a higher standard than the criteria for OIG "exclusion" from the Medicare program, as detailed in regulation at § 424.535. We understand that CMS proposes to add individuals to the preclusion list only if (i) they are either revoked or could have been revoked if they had been enrolled as a provider; **and** (ii) CMS

[79] *See generally* https://exclusions.oig.hhs.gov/. *See also* the Medicare Exclusion Database (MED), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/MED/Overview-MED.html.

determines that the underlying conduct that led to/would have led to the revocation is "detrimental to the best interests of the Medicare program." CMS proposes to utilize a "targeted" and "risk-based" approach to identify these prescribers, which will be done on a case-by-case basis. CMS's basis for this higher standard is as follows:

"All grounds for revocation under § 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."[80]

d. While we appreciate that CMS may come across a "variety of factual scenarios" as part of operationalizing the preclusion list, it remains unclear why a heightened standard is necessary for the preclusion list, provided that revocation under § 424.535(a) (the OIG list) is permissive (i.e. not mandatory). In other words, not everyone that has violated one of the 14 reasons for being revoked under § 424.535(a), will be revoked. Thus, if the same criteria were to be used for the preclusion list, not every provider that violated one of the 14 criteria would have to be precluded. We believe more transparency on how CMS is going to identify providers for inclusion in the preclusion list would help clarify why a heightened standard is necessary. For example, in what cases is a prescriber rightfully on the OIG exclusion list, but the conduct is not "detrimental to the best interests of Medicare program"?

***PCMA Recommendation*: CMS should create and manage a single prescriber preclusion list that is modeled after the OIG excluded provider list so the two files can be handled in a similar manner. Operationally, the precluded list could cross-reference the providers listed on the OIG exclusion list, and CMS could update the list and add prescribers utilizing its proposed targeted risk-based procedure approach but applying the criteria for revocation from the Medicare program under § 424.535. The provider preclusion file layout should be the same as the exclusion file and be placed in the**

[80] *Id*. at 56444.

same location as the exclusion file, in a machine-readable file format. By taking these steps, CMS would help ensure that implementing the preclusion list uses uniform standards in the Part D program that will increase predictability and make it easier for PBMs to implement and update software and claims processing systems.

2. *Proposed effective date is not feasible in light of the increased burden on Part D plan sponsors and added complexity to Medicare Part D program*

    a. Based on past experience since provider enrollment was first proposed in 2014, PCMA does not believe CMS's proposal to implement the new requirements for a prescriber preclusion list on January 1, 2019 is realistic. The proposed changes will add significant complexity to the current Part D program and stakeholders will need time to overcome operational challenges during the implementation phase of the new requirements. Implementing these requirements in a rushed manner will challenge Part D plan sponsor operations and cause potential harm to beneficiary access. Beyond an extension on the effective date, more clarity is needed in order for successful implementation of this new approach. It will be critical for CMS to release very clear guidance that takes into account the range of operational issues that stakeholders have discussed with them over this time period, including the detailed points specific to precluded prescribers (as we previously discussed in detail with CMS in 2016).[81] CMS must provide ample guidance, and *then* provide ample time for testing and implementation.

    b. Importantly, CMS fails to explain the interaction between the provider exclusion file and the new prescriber preclusion file. As stated above, PCMA is concerned that the proposed rule fails to provide adequate guidance to understand what the differences are between the OIG exclusion file and the preclusion file, how the two "interact," which file should take precedence in instances when the drug is not covered by Medicare but is covered by Medicaid, and how the notification requirements for the exclusion and preclusion lists should be reconciled. For example, because the exclusion file requires a specific beneficiary notification process, PBMs need guidance on whether a separate letter will be required for beneficiaries whose prescribers are on the preclusion file or whether a combination letter may be used. If a combination letter is to be used, CMS will need to update the current model template prior to implementation. To limit beneficiary confusion, we strongly recommend that the rejections for OIG and preclusion be similar; in other words, a reject with no override or provisional fill would be most appropriate and least confusing to the member. Having two separate operational processes not only introduces complexity into plans' operations, it also provides an added opportunity for beneficiary disruption when challenged with understanding the distinction between precluded and excluded. So, too, in the

[81] *See* Exhibit B, Notes on Industry Stakeholder Call with CMS as distributed by CMS, December 1, 2016.

preamble to the proposed rule CMS repeatedly refers to the preclusion process as applying to both "providers" and "prescribers," failing to distinguish between these two categories of individuals, and also failing to explain the degree to which the universe of providers and suppliers to which the exclusion file applies does or does not overlap with the universe of prescribers impacted by preclusion.

c. As it pertains to various state sanction files, the logic for assessing the presence/absence on these lists must be addressed. While a prescriber may present on multiple lists, they likely will not be present on all lists. Clarification regarding the presence on one, or more, but not all lists, would be essential.

d. Regarding dually eligible individuals (individuals dually eligible for both Medicare and Medicaid), we urge CMS to clarify that a prescriber's presence on the preclusion files will mean that any prescriptions written by this prescriber for beneficiaries enrolled in a Medicare-Medicaid plan or Special Needs Plan (SNP), regardless of the ultimate program providing coverage, will be ineligible for a fill pursuant to CMS's policy. In other words, regardless of whether Medicare or Medicaid is the ultimate payer of the drug, the precluded prescriber should be deemed a precluded prescriber for all scripts for the enrollee.

   To ensure plans/PBMs understand the differences and similarities between the exclusion and the preclusion files, CMS should provide a descriptive comparison flow chart to detail how providers on each list are to be handled operationally. This should include scenarios where 1) a prescriber is on both the excluded and precluded list, 2) a prescriber is precluded but is not excluded, and vice versa, and 3) a beneficiary is a dually eligible for both Medicare and Medicaid.

   ***PCMA Recommendation**: We urge CMS to provide that a prescriber's designation as a precluded prescriber will mean that any prescription written by such prescriber for beneficiaries enrolled in a Medicare-Medicaid or SNP will be ineligible for a fill pursuant to CMS's precluded prescriber policy.*

e. Based on previous conversations with CMS on the prescriber preclusion approach, we reiterate our concerns about the rule not taking effect before CMS is able to release the file layout needed for PBMs to conduct testing and proper coding.[82] Moreover, as we reiterated with CMS, it is critical that once the file is provided, CMS must provide assurance that it will not be subject to

[82] Id.

further changes. CMS previously acknowledged the industry reality that assessments of the file layout would take a year to test once CMS issues a file that is not subject to further changes. We appreciate that CMS now requests public comment on a "reasonable time period for Part D sponsors/PBMs to incorporate the preclusion list into their claims adjudication systems." As such, we strongly urge CMS to honor prior understandings with the industry to provide stakeholders with adequate time to conduct proper testing, coding, and IT infrastructure development, once a file layout is released that is not subject to further changes. Our PBM members continue to anticipate that it will take at a minimum of 12 months, depending on the file lay out and complexity of final standards adopted by CMS, to incorporate the preclusion list into claim adjudication systems.

***PCMA Recommendation*: We recommend that as soon as possible after issuance of the final rule, CMS release the file layout for Part D plan sponsors and PBMs to test and provide comment. CMS should also provide for an effective date that will be triggered at a date that is at least one year after a final file format has been released, and allow at least 12-18 months for implementation so that Part D plan sponsors and PBMs have sufficient time to conduct necessary testing and implementation of the file.**

f. More clarity is needed on CMS's process for updating the preclusion list. PCMA is concerned that CMS's current proposal to update the list on a monthly basis will cause excessive disruption to claims processing and daily operations. For example, if the file is updated only monthly, this opens the door to the potential for retroactivity. Retroactivity is already a concern for plan sponsors during any type of audit associated with excluded providers, in part due to the monthly updates to the file and also because it takes so long for a prescriber to be sanctioned. We strongly urge CMS to update any preclusion file more frequently than monthly to limit any potential for retroactivity and to establish clear, current effective and end dates to avoid any confusion over when a prescriber is truly precluded. More frequent updates would also more closely align to current National Plan & Provider Enumeration System (NPPES) and DEA number file updates.

***PCMA Recommendation*: CMS should update the prescriber preclusion list at a minimum every two weeks or more frequently if necessary to reduce adjustments and member access issues.**

g. Finally, PCMA urges CMS to carefully develop a timeline for it to educate prescribers about the new requirements prior to implementing the prescriber preclusion list. We believe that proper implementation of the preclusion list requirement will depend greatly on the level of transparency in the program

and level of education provided to prescribers and beneficiaries. We believe that this is ultimately the responsibility of CMS as part of promulgating the new requirements, and urge CMS to ensure that the final timeline for implementation provides adequate time for CMS to provide prescriber and beneficiary education. Part D plans, of course, would be willing to work in partnership with CMS to help educate their enrollees.

***PCMA Recommendation*: We strongly urge the preclusion list requirements be postponed to no earlier than January 1, 2020 to ensure that all programmatic issues are addressed prior to implementation.**

3. *CMS's provisional fill requirement runs counter to CMS's goal of protecting Part D beneficiaries from bad actors*

CMS proposes to maintain the provisional coverage requirement with the adjudication/notice that was first proposed in the 2015 IFR. However, CMS is proposing to change to a 90-day provisional coverage instead of the current three-month/90-day time period drug supply. In other words, a PBM now need only track a single 90-day period from the date a drug is first dispensed pursuant to a prescription written by an individual on the preclusion list. While PCMA appreciates CMS's proposal to switch to a 90-day supply as opposed to the current regulations that provide for a 3-month drug supply *or* a 90-day supply,[83] PCMA continues to be strongly opposed to the provisional supply requirement and urges CMS not to proceed with this requirement. There are a number of reasons we believe the provisional fill requirement is problematic and actually no longer needed. Our concerns are detailed below.

a. While PCMA commends CMS's desire to minimize member disruption to access of Part D drugs, it is important to note that under current CMS policy, if a prescriber has an active sanction with OIG (and is listed on the Medicare Exclusion Database sent on a monthly basis), *there is no provisional supply provided*. There is therefore no rational support for a policy which provides for anything other than a straight POS reject for a prescription submitted by a precluded provider.

b. Indeed, the inclusion of provisional fill in the original 2015 IFR proposal was based on whether a prescriber was enrolled in Medicare or not – in other words, CMS wanted to provide beneficiaries temporary coverage if their prescriber was not enrolled in the program. CMS has now proposed to

[83] 82 Fed. Reg. at 56445 ("We are proposing a 90-day provisional coverage period in lieu of a 3-month drug supply/90-day time period established in existing § 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.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.") (emphasis added).

dramatically change the universe of claims subject to provisional fill from un-enrolled prescribers, to those that, not only that are revoked or could be revoked, but also meet the higher standard of having conducted themselves in a way that is detrimental to the best interests of the Medicare program. Stated differently, these are bad actors and provisional fill rights should not apply for prescriptions written by these prescribers. PCMA believes it is unnecessary to provide these individuals with prescribing rights. CMS acknowledges that "individuals on the preclusion list are demonstrably problematic," and further acknowledges the problem with these prescribers in the context of opioids – but does not extend this same idea to all drugs they prescribe.

c. Importantly, under current law, when a beneficiary comes to the pharmacy counter with a prescription written by an excluded provider, there is no provisional fill authorized, nor does NCPDP permit as SCC override for such claims. As such, we see no reason why a provisional fill be allowed for the preclusion list when it could further perpetuate beneficiary harm (particularly considering that individuals on the proposed preclusion list are arguably even more problematic for purposes of program integrity given the higher standard proposed). Thus, it remains unclear how the provisional fill requirement would work in instances where a provider is listed on both the preclusion list and the exclusion list. We assume the presence on either list would prohibit the claim from being processed under Part D and would like confirmation from CMS.

d. We think this is an important consideration as CMS's current provisional supply mandate may still be interpreted broadly to provide a patient with up to a six-month supply of product from a prescriber who has been precluded from the Part D program. Here is an example to illustrate this point:

> Example: Under CMS's proposal, "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.[84]

[84] *Id.* ("[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.").

Based on this language, it could be interpreted that a beneficiary may get any drug no matter the day supply within this 90-day period. Thus, consider the following scenario: On 01/01/19 enrollee fills a 90-day supply of drug X from a precluded prescriber. As the language is currently proposed, the 90-day provisional supply period would end on 03/31/19. With the refill thresholds allowed on many plans, the enrollee can get another 90-day supply of drug X on 03/20/19. We urge CMS to acknowledge the ambiguity that currently exists with its proposal as to this issue. If it retains the provisional supply, CMS, in
the final regulations, needs to address this type of scenario to provide guidance on how the 90-day supply should be filled.

e. In the context of opioids, a 90-day fill seems completely counterproductive to recent efforts to fight the opioid crisis in the U.S. Additionally, the notion of a provisional fill of any controlled substance has the potential to impede states' autonomy in enforcing their own controlled substances requirements and, depending upon how frequently pharmacies are required to report dispensing of controlled substances within a given state, may also impede the function of prescription drug monitoring programs (PDMPs).

f. An alternative that CMS could consider would be to build in a 90-day time period prior to adding a particular prescriber to the preclusion list. In other words, if CMS determines a particular prescriber should be considered precluded, then CMS sends that prescriber a notice advising that they will be placed on this preclusion list and providing their appeals rights and time frame. Once the appeals time frame is exhausted and CMS has concluded that the prescriber is going to be placed on the preclusion list, CMS would then notify beneficiaries that receive prescriptions from this particular prescriber advising them that the prescriber will no longer be allowed to prescribe prescriptions for Medicare D due to the "precluded" determination. Once the beneficiary notification is sent, CMS would date the preclusion effective date to be 90 days later, thus building the 90-day time frame into when the preclusion effective date takes effect. For example, if the beneficiary notice is sent 01/01/2019, CMS would not add this prescriber to the preclusion list until 04/01/2019, thus building in the 90-day time frame after beneficiary notification. This is essentially the same concept of the 90-day provisional fill, but it would make the 90-day time frame the same across the industry for a particular precluded prescriber, and not require PBMs to track the 90-day per beneficiary and ultimately to have to change their systems to ensure the provisional supply is integrated into other program constructs such as transition fill.

***PCMA Recommendation*: We strongly urge CMS not to proceed with the provisional supply requirement. There are better alternatives to address the concern about minimizing member disruption without exposing beneficiaries to potential bad actors.**

4. *If CMS intends to proceed with a provisional supply requirement, CMS needs to provide substantial additional guidance on the issues regarding relationship of provisional supply to transition fill*

    a. As currently proposed by CMS, it remains unclear how the provisional coverage proposal should interact with transition requirements in the Medicare program and how the two should be reconciled during real-time operations. CMS has recognized this issue and is requesting feedback on whether it should propose that transition fill would not apply when the provisional fill is applicable in order to simplify the process and reduce beneficiary confusion. Normal Part D rules (e.g., prior authorization) apply during provisional coverage, but again CMS asks if different limits should apply for opioids, particularly if the reason for the prescriber's preclusion relates to opioids. Frankly, the uncertainty over the relationship between provisional supply and transition fill is another compelling reason for CMS to drop its provisional supply mandate.

    b. In order to understand this interaction, we would need specific examples provided by CMS that explain those instances in which either transition fill or provisional supply takes precedence over the other. Likewise, CMS needs to explain how the provisional supply requirement will interact with transition letters. For example, the new provisional supply language does not address whether PBMs have to provide a combination letter to beneficiaries, and if there is a need for a combination letter, how that would work since provisional supply only requires one letter from the initial fill. Below are some illustrative examples of when this issue arises:

        Example 1: Initial claim 01/01/19 from precluded prescriber, drug PA and the claim is transition fill eligible. Therefore the claim pays as both transition fill and provisional supply. It is unclear whether PBMs must send a combination letter to explain the situation around both the prescriber and the drug, or whether the lettering and notification process should be kept separate.

        Example 2: Initial fill 01/01/19 from precluded prescriber, drug is payable on plan. Claim pays as provisional supply and a letter is sent to the beneficiary explaining the prescriber is precluded. A different script is filled 01/15/19, where the drug requires PA but is transition fill eligible. While the claim pays as both provisional supply and transition, it is

unclear whether plans and PBMs have to send only the transition fill letter since the 01/01/19 claim already included the provisional fill letter. We are very concerned that sending multiple correspondences will confuse the enrollee.

***PCMA Recommendation*: CMS should provide that transition fill will not apply when provisional fill is applicable, in order to simplify the process and reduce beneficiary confusion. Because the relationship between the transition fill policy and provisional fill remains inconsistent and unclear in the proposed rule, CMS should keep them as independent program requirements and provide illustrative examples for the industry to understand how the two requirements interrelate to each other.**

5. *Beneficiary Medicare Part D appeal rights are not appropriate for the preclusion list*

   a. In the preamble, CMS states "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." PCMA has several concerns with respect to this position. First, the right to appeal will confuse beneficiaries as they will not understand that the only aspect they can appeal is whether there was an alleged error in applying the preclusion list. Moreover, CMS is not clear as to whose error may be appealed. Specifically, to the extent there are errors, we believe most errors would be those made by CMS, not the PBM. If the Part D plan sponsor relies on a name that CMS has erroneously included on the file, it is not clear how the plan would reply to the appeal. If anything, the beneficiary should be appealing to CMS. It is not fair to penalize the plan (e.g., through lowered star ratings) due to its reliance, as required, on the CMS file. As an alternative, we suggest that the beneficiary be provided a dedicated call-in line manned by CMS if they have concerns as to whether or why a prescriber is on the preclusion list and the implications for the beneficiary's prescriptions written by the prescriber. Another option that could be established along with the dedicated call-in line would be for CMS to provide for beneficiary appeal rights directly to the Agency and not the plan sponsor, since CMS is the source of truth for the original precluded prescriber decision. Of course, CMS would need to make sure such appeal process was transparent to Part D plan sponsors and their PBMs.

   b. Importantly, under CMS's appeal regulations at 42 CFR Part 423, subpart M, denial of a beneficiary's access to a covered Part D drug on the basis that the provider is excluded *is not* a coverage determination under existing regulations, and thus does not trigger any appeal or grievance rights.[85] In applying the preclusion list, a Part D sponsor is not declining to "provide or

[85] See 42 CFR 423.566(b).

pay for a Part D drug … that the enrollee believes may be covered under the plan." [86] Instead, the plan is making a finding that the drug is prescribed pursuant to an invalid prescription. Under current exclusion regulations, such a determination does not trigger any beneficiary appeal rights. We believe the same considerations for beneficiary appeal rights are applicable in the case of precluded prescribers.

c. If CMS intends to pursue beneficiary appeal rights to challenge the preclusion list applicability, PCMA strongly believes that CMS must first engage in rulemaking to amend the Medicare Part D appeal regulations, including a proper notice and comment period. The current proposal fails to detail the procedures and exact provisions in the Medicare Part D appeal regulations that would apply to the preclusion list. While CMS's current proposal is limited to "alleged errors in applying the preclusion list," there is no language proposing to limit beneficiary appeal rights in any way. As a result, more guidance would be needed on how the current Medicare Part D appeal rights apply to the preclusion list, and we believe CMS would be required to undergo rulemaking to accomplish this.

***PCMA Recommendation*: CMS should clarify that beneficiaries do not have appeal rights to whom the appeal would be directed with respect to any aspect of the application of the preclusion list as is the case with respect to the exclusion list. In the event CMS proceeds with its position, further guidance is needed on the appeals process for beneficiary challenges and confirmation that CMS, who made the original decision to place the prescriber on the preclusion list, would have to be the entity handling the appeal as they would be the source of truth for the original decision.**

6. *Provider Appeal Rights*

CMS proposes to allow prescribers placed on the preclusion list to appeal their placement on the list in accordance with 42 C.F.R. Part 498, which generally provides procedural due process for individuals affected by any of a number of CMS "initial determinations," such as whether a prospective provider qualifies as a provider or whether a supplier meets the conditions for coverage. *See, e.g.* 42 C.F.R. 498.3(b). Appeal rights would, CMS proposes, be limited to appealing inclusion on the list. However, the proposed rule also solicits comment as to "whether a different appeals process is warranted." PCMA is concerned that use of the 42 C.F.R. Part 498 to govern appeals of placement on the preclusion list may not be appropriate given the regulatory uncertainties posed by the fact that: (1) CMS' proposal applies to all "prescribers," and not just Medicare providers; and (2) CMS is proposing to move away from mandatory enrollment, and yet Part 498 explicitly applies to Medicare participating providers.

[86] Id. at 423.566(b)(1).

***PCMA Recommendation*: PCMA is concerned that use of the 42 C.F.R. Part 498 to govern appeals of placement on the preclusion list may not be appropriate and urges CMS to address the regulatory uncertainties as to the scope of these appeals.**

7. *CMS's proposal adds inefficiencies to the Medicare program and runs counter to policies promulgated by the Trump Administration to reduce regulatory burdens and costs*

    a. While we recognize that CMS has broad authority to promulgate regulations "as may be necessary to the efficient administration of the functions" [87] of the Medicare program, we are concerned that the current proposal fails to accomplish CMS's goal and instead increases inefficiencies, as detailed above. As such, we urge CMS to work to administer consistent standards across its programs. For example, the preclusion list requirements are absent in both the Medicaid and Part C programs, but will obviously be included in the Part D program. Adopting uniform standards across all Federal programs would facilitate administering the programs as a comprehensive system, which in turn, facilitates ease of operations for Part D plans and PBMs and results in cost savings.

    b. The resulting program cost savings from a consistent approach would be in line with Executive Order (EO) 13771, *Reducing Regulation and Controlling Regulatory Costs*, signed by President Donald Trump on January 30, 2017. The EO directs agencies that, for any new regulation, two existing regulations must be repealed and any new regulation must be implemented in such a way that the total cost of regulations is net neutral. Stated differently, we interpret that the cost of implementation of the new requirements must be less than or equal to zero. However, as we detailed above, the operational challenges that are likely to result from this program will not only increase operational burdens for PBMs (as well as for CMS) but also increase costs. In light of this, this proposal runs counter to the current policies of this Administration and should be carefully scrutinized prior to implementation.[88]

***PCMA Recommendation*: CMS should consider implementing precluded prescribers/providers across the Part D, Part C, and Medicaid programs as one system in order to increase ease of administrability and implement consistent standards across all of its programs to minimize regulatory burden and costs.**

[87] *See* Section 1102; 42 U.S.C. 1302 ("[T]he Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this Act, **as may be necessary to the efficient administration of the functions with which each is charged under this Act**.")(emphasis added).
[88] *See also* Exec. Order No. 13813, 82 Fed. Reg. 48385 (Oct. 17, 2017) (instructing regulatory agencies to incentivize "high-quality care at affordable prices for the American people" and minimize "burdens on affected plans, providers or payers").

C. IMPLEMENTING OTHER CHANGES

1. Reducing the Burden of the Medicare Part D Medical Loss Ratio Requirements

A. (§422.2430) Fraud Reduction Activities

CMS Proposal: CMS is reconsidering its medical loss ratio (MLR) policy by proposing the following changes to the treatment of expenses for fraud reduction activities in the Medicare MLR calculation:

- Include all expenditures in connection with fraud prevention activities as quality improvement activity (QIA)-related expenditures, even if those expenditures exceed the amount recovered through fraud reduction efforts;
- Expand the definition of QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery; and
- No longer include in incurred claims in the MLR numerator the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses.

Discussion: Given the central and increasing role of fraud, waste and abuse (FWA) reduction efforts in the Medicare program, we strongly support the proposal to include all expenditures in connection with fraud prevention activities as QIA-related expenditures. As Medicare plans are subsidized by the government, CMS has an obligation to ensure these subsidies go towards providing the best value. We agree that limiting or excluding amounts invested in fraud reduction undermines efforts to combat fraud in the Medicare program, and reduces the potential savings that robust fraud prevention efforts in Part D programs may provide. Fraud reduction activities clearly bear a direct relation to patient-centered quality and safety initiatives, and as such, should not be subject to exclusion under §423.2430.

With regards to the types of activities that should be included as fraud reduction activities, we believe that CMS should include all plan FWA reduction activities. Among such activities, we recommend that CMS specifically include the full scope of drug utilization management activities, including retrospective and concurrent drug utilization review, in the designation of activities that reduce FWA and improve health care quality. In the Part D program, currently only prospective drug utilization review (DUR) activities are included in the definition of QIA and not retrospective or concurrent review. As CMS is aware, DUR activities play a vital role in assisting to prevent overutilization of frequently abused drugs. Perhaps no better example of this exists than PCMA member initiatives to address the opioid epidemic. After a patient has filled a prescription, PBMs continuously monitor drug claims data and conduct case management to determine whether a patient's drug pattern is consistent with the medical service. Considering the

increasing complexity and potential toxicity of drug therapies, it is more important than ever to avoid the dispensing of inappropriate therapies. DUR activities performed in the context of a prescription drug benefit differ from those in a medical benefit. While the primary goal of such activities in a drug benefit is to protect enrollees from significant harm related to over-prescribed and inappropriately monitored prescriptions, such as opioids, the secondary goal of these programs is to reduce FWA. Given the goals, characteristics, benefits, and outcomes of DUR activities in drug benefit programs, we believe such activities should be included in the numerator of the MLR calculation.

There are several different ways that CMS could recognize Part D FWA costs in the MLR numerator. One would be to revise the definition of incurred claims at §423.2420(b) (2) (viii) to delete the limit "not to exceed the amount of fraud reduction expenses." Another would be to add a specific element to a new subsection under §423.2420(b) that would include FWA costs in the numerator. Yet another option would be to revise the definition of activities that improve health care quality at §423.2430 (as discussed below) to include mandatory Part D FWA activities. A combination of these approaches would allow for appropriate recognition of Part D FWA costs.

***PCMA Recommendation*: PCMA supports including all expenditures in connection with fraud prevention activities as QIA-related expenditures; and PCMA recommends that drug utilization management activities be included in the numerator of the MLR calculation, given their role in improving health care quality and reducing FWA.**

B. (§423.2430) Medication Therapy Management

CMS Proposal: CMS proposes to amend its regulation to specify that all medication therapy management (MTM) programs offered by Part D sponsors (including MAOs offering MA-PD plans) that comply with §423.153(d) are QIA. CMS notes that is concerned that Part D sponsors may be limiting the number of qualified enrollees in MTM programs by restricting eligibility criteria, and the agency believes that including MTM expenditures as QIA will incentivize the elimination of these restrictions.

Discussion: We support including all MTM-related activities that comply with §423.153(d) as QIA. The program's comprehensive approach to improving medication use and adherence directly aligns with the definition of QIA since these programs improve patient-centered education and counseling leading to improved patient safety related to drug use. The ability of MTM programs to improve care coordination is a key component of health care system integration. It is designed for meeting the needs of the patient, and can be measured and evaluated to assess improvements.

<u>PCMA Recommendation</u>: PCMA supports the proposal that all Part D MTM program activities be included in the definition of QIA.

C. (§423.2460) Regulatory Changes to Medicare MLR Reporting Requirements

<u>CMS Proposal</u>: Concerned that health insurance issuers complete substantially different forms for Medicare MLR purposes and for commercial purposes, CMS proposes to reduce the minimum amount of information necessary for MLR reporting by MAOs and Part D plan sponsors. CMS would only require reporting for the following data elements: (i) organization name, (ii) contract number, (iii) adjusted MLR (which would be populated as "Not Applicable" or "N/A" for non-credible contracts), and (iv) remittance amount.

CMS emphasizes that while this proposal represents a significant reduction in reporting burden, the agency retains its authority to carry out audits to ensure accurate reporting and to impose sanctions. Part D plan sponsors would still be required to retain documentation supporting the MLR figure reported to the agency.

<u>Discussion</u>: PCMA supports the proposal to reduce the burden of the current Medicare reporting requirements. We agree that this change is consistent with the directive in the January 30, 2017 Executive Order on Reducing Regulation and Controlling Regulatory Costs to manage the costs associated with the government imposition of private expenditures required to comply with Federal regulations.

<u>PCMA Recommendation</u>: PCMA supports the proposal to reduce the burden of the current Medicare reporting requirements.

Request for Information (RFI)

PART TWO

17. Request for Information (RFI) Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale (pp. 56419 – 56421)

A. Legal Assessment of the RFI

1. Introduction

In conjunction with the Proposed CY 2019 Policy and Technical Rule, CMS has issued a Request for Information ("RFI") regarding the application of manufacturer rebates and pharmacy price concessions at point-of-sale ("POS"). If formally adopted, the content of the RFI would violate at least *four* separate provisions of the Part D statute, as enacted in the Medicare Modernization Act.[89] Moreover (and regardless of its legality under Medicare Part D), if CMS were to adopt some the policies in the RFI in future rulemaking, it would raise significant concerns under both the Trade Secrets Act and the Administrative Procedure Act (APA). The proposal also runs counter to the Administration's goal of reducing, not increasing, the regulatory burden imposed on industry. Finally, should CMS proceed to adopt the policies in the RFI through some pathway other than a proposed rule, it would violate the very clear requirements of both the APA and the Medicare statute itself that CMS first formally propose this type of policy change through formal notice-and-comment rulemaking. These legal arguments are addressed below.

2. Statutory Violations

i. The Proposals in the RFI Violate the Non-Interference Clause (42 U.S.C. § 1395w-111(i)

Under the Part D statute, CMS is explicitly prohibited from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and Part D plan sponsors."[90] Preventing such interference was very clearly the intent of Congress when it created the Part D program, as evidenced by multiple Conference report statements. This provision has long been understood as prohibiting CMS from interfering in payment negotiations between both Part D plan sponsors and pharmacies, and Part D plan sponsors and manufacturers.[91] Indeed, CMS has long taken an appropriate view of the non-interference clause's applicability to negotiations between Part D plan sponsors and pharmacies and manufacturers, reflecting the understanding that the Part D program's success is built upon free market competition. In the 2005 final Part D rule, for

[89] See generally Title XVIII of the Social Security Act.
[90] 42 U.S.C. § 1395w-111(i)(1).
[91] See House Conference Report No. 108-391 at 461 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 1840 ("In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and Part D plans.") See also *id.* at 748-9 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 2105 ("[t]hese negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.")

example, CMS interpreted the non-interference clause as prohibiting CMS from "interfer[ing] with negotiations between drug manufacturers and pharmacies and PDP sponsors, and [] requir[ing] a particular formulary or [] a price structure for the reimbursement of covered Part D drugs."[92] This free market approach (and CMS's past willingness to abide by the statute and not to step in between negotiations) is generally credited for the overwhelming success of the program.[93]

In the RFI CMS states that it is contemplating significant limits on the degree to which Part D plan sponsors can negotiate pharmacy price concessions and manufacturer rebates outside of those applied at the POS. As explained below, under a proposal that would require that all or a certain percentage of rebates or price concessions be passed through at POS, Part D plan sponsors and their PBMs will lose nearly all bargaining power in the negotiation of manufacturer rebates. They would also lose the ability to negotiate upside and downside incentives with pharmacies tied to performance or quality targets as well as suffer significant impairment in their ability to negotiate rates with pharmacies. In particular, Part D plans currently utilize rebates and price concessions as negotiating tools – to lower drug prices, develop formularies that respond to consumer needs, reduce pharmacy costs, and improve the beneficiary experience at the pharmacy counter. In addition, by requiring all pharmacy price concessions to be passed through at POS, Part D plans would lose nearly all significant negotiating leverage in pharmacy negotiations, resulting in billions in excess costs to the Part D program, and to beneficiaries, as CMS has explicitly acknowledged in the RFI.[94]

In a 2014 final rule in which CMS *declined* to reinterpret the non-interference clause, the agency reiterated its position that "the intent of 1860D–11(i) is to ensure that we do not create any policies or become a participant in any discussions that could be expected to interfere with negotiations leading to the selection of drug products to be covered under Part D formularies."[95] Yet, only three years later, CMS is now proposing to step directly in between manufacturers and Part D plans, and pharmacies and Part D plans, and dictate the very details of the pricing arrangements between the parties. This clear interference will have the very obvious result of impacting drug formulary placement.

Thus, to the extent the RFI would mandate that certain kinds of concessions or rebates be passed through at POS, as opposed to being reflected as direct or indirect remuneration (DIR), *it would*

[92] 70 Fed. Reg. 4,194, 4,396 (January 28, 2005). See also 69 Fed. Reg. 46,632, 46,681 (August 3, 2004) (where CMS stated that the MMA "envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations would take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers" and that "price negotiation would be conducted by the private drug benefit managers and plans that are already familiar with negotiating prices of prescription drugs on a local, regional or national basis.")

[93] "In beginning with the words ''In order to promote competition under this part and in carrying out this part. . .'' we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition." 79 Fed. Reg. 29,874 (May 23, 2014).

[94] 82 Fed. Reg. at 56,425.

[95] 79 Fed. Reg. 29,844, 29,874 (May 23, 2014).

clearly constitute interference in Part D plan sponsor negotiations. Such allocation of rebates and price concessions are appropriately the subject of business negotiations between Part D sponsors and manufacturers. CMS's previous statements have correctly recognized that mandating particular pricing features—as opposed to a requirement about how payments must be reported—would constitute interference in pharmacy-Part D sponsor negotiations.[96] Under the statute, CMS may not interfere in those negotiations.

ii. The RFI Proposals Also Institute a Price Structure (42 U.S.C. § 1395w-111(i))

The Part D statute also states that CMS may not require "a particular formulary or institute a price structure for the reimbursement of covered part D drugs."[97] Yet, by suggesting potential policies which would, if adopted, create a structure around pharmacy prices and manufacturer rebates – with some or most price concessions and rebates required to be included at POS – CMS would also clearly be violating the prohibition against instituting a price structure for the reimbursement of covered Part D drugs if it were to adopt the proposals suggested in the RFI.[98]

As with its interpretation of the non-interference clause, with respect to the prohibition against instituting a price structure, CMS has previously carefully balanced the competing goals of pharmacy access and Part D plan flexibility, ensuring neither of these requirements is read out of the statute. While neither Congress nor the agency has ever formally adopted a definition of "price structure," the meaning of the clause is clear: CMS is prohibited from not only specifying a "standard" (e.g., what is paid or how payments are calculated), but also imposing any "structure" (e.g., any rules around the elements of that pricing). This meaning is evident both from the plain language of the statute (i.e., the term "structure" is commonly defined as an arrangement or organization of elements or parts[99]), as well as other language in the Part D statute. For example, the significance of the clause is evident when one compares it to how Congress phrased the limitation on CMS activity involving formularies. In particular, section 1860D- 11(i)(2) prohibits CMS from requiring a "particular" formulary. The statute does not use the same modifier "particular" in front of the price structure language.

Thus, CMS's proposal very clearly implicates, and would, if adopted, violate, the prohibition on establishment of a price structure. In particular – and by way of example – if CMS were to seek to implement concepts in the RFI and average or weight rebates across a particular drug category or class – manufacturers would be driven by simple laws of economics to move toward a standard rebate to avoid any "free rider effect" whereby manufacturers with high rebates subsidize manufacturers with low rebates. In other words, if CMS proceeds with its proposal to

[96] See 79 Fed. Reg. at 29,873 ("In practice we have generally invoked the spirit of this provision in declining to intervene in negotiations or disputes involving payment-related contractual terms between participants in the drug distribution channel.")
[97] 42 U.S.C. § 1395w-111(i)(2).
[98] See 70 Fed. Reg. 4,194, 4300 (January 28, 2005).
[99] Merriam-Webster Dictionary (online); available at http://www.merriam-webster.com/dictionary/structure.

take the "weighted averages" of manufacturer rebates for covered Part D drugs in the same therapeutic category or class (the alternative to this – a drug-specific rebate – has seemingly already been ruled "out of hand" by the agency on the grounds that it would violate the confidentiality of manufacturer pricing),[100] then manufacturers will lose all incentive to negotiate higher rebates given the fact that their rebate amounts will ultimately be "averaged" with their competitors for purposes of POS calculations. We provide detailed illustrations of this reverse engineering in section (b)(5)(a), below. So, too, by requiring that all pharmacy price concessions be passed through at POS, CMS is effectively instituting a price structure for pharmacy payment whereby plans are forced to negotiate only on the lowest possible price/rates with each and every pharmacy with which they contract. Inevitably, such a single variable negotiating system will result in standard rates across all pharmacy lines of business.

In sum, the ideas articulated in the RFI would, if adopted, effectively result in a standardized rebate across manufacturers and standardized payment rates to all pharmacies, effectively instituting a "price structure" for the reimbursement of covered Part D drugs, in clear violation of the statute.

iii. The RFI Would Eviscerate Preferred Pharmacy Networks, In Violation of the Pharmacy Access Provisions of the Part D Statute

CMS has long supported a Part D plan sponsor's (statutorily vested) ability to reduce cost-sharing for certain preferred pharmacies meeting a Part D plan sponsor's special terms and conditions.[101] The pharmacy access provision of the Part D statute contains two independent requirements, each which has always been supported and enforced by the agency:

> "(1) Assuring pharmacy access.—
>
> (A) Participation of any willing pharmacy.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.
>
> (B) Discounts allowed for network pharmacies.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D-15 to a plan."

[100] 82 Fed. Reg. at 56,422 (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.")
[101] 42 U.S.C. § 1395W-104(b)(1).

Since the first Part D rule was proposed in 2004, CMS has taken great care to ensure that the entirety of the pharmacy access provisions are enforced, simultaneously requiring "any willing pharmacy" to participate in the plan (subparagraph A), while permitting Part D plan sponsors to offer differential cost-sharing for preferred pharmacies (subparagraph B). Indeed, in the preamble to this proposed rule, CMS reiterates its goal of "ensur[ing] that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement."[102] Yet, by interfering in the negotiations between Part D plan sponsors and manufacturers and pharmacies, and by requiring all or some rebates or price concessions be passed through at POS, CMS would significantly hinder the ability of Part D plan sponsors to craft preferred networks.

Simply put – CMS has long interpreted the pharmacy access provisions as "allowing Part D plans to reduce cost-sharing differentially for network pharmacies"[103] – but now considers proposing to place severe limits on this flexibility by requiring some or all rebates or price concessions be passed through at POS, regardless of a pharmacy's ability to meet a Part D plan sponsor's special terms and conditions. Moreover, by forcing Part D plans to negotiate with pharmacies only on the lowest rate, CMS may limit Part D plan sponsors in their ability to negotiate lower rates for preferred pharmacy participation. Under the policies in the RFI, Part D plans would no longer be granted the full authority granted to them in statute to establish pharmacy networks, which promote quality, reduce fraud and abuse, and lower costs.

Under current practice, Part D plans and their PBMs successfully utilize preferred pharmacy networks (deemed such by the reduced cost-sharing available to the beneficiaries they serve) to reduce pharmacy costs, improve beneficiary access and quality of care, and drive down overall Part D prices (including premiums and cost-sharing). CMS now suggests in the RFI a policy under which *all* pharmacy price concessions would be passed through at POS to the beneficiary in the form of reduced cost-sharing, in direct conflict with a Part D plan sponsor's statutorily vested right to create preferred networks with reduced cost-sharing. The unintended consequences of this policy are innumerable (higher pharmacy costs, reduced network access, etc.) and the legal barriers are clear. Under existing law, CMS cannot adopt the policies in the RFI without violating the longstanding pharmacy access provisions of the Part D statute.

iv. Policies in the RFI are Incompatible with the Coverage Gap Discount Program

In the RFI, CMS notes a major legal hurdle in adoption of its proposal: for purposes of calculation of manufacturer liability under the coverage gap discount program, the statute references the term "negotiated price" as it was defined in regulations at the time of the passage

[102] 82 Fed. Reg. at 56,371.
[103] 70 Fed. Reg. 4,194, 4,254 (January 28, 2005).

of the Affordable Care Act. Notably this regulatory definition enacted in 2010 references only the price concessions that the Part D sponsor had elected to pass-through at POS. As such, if CMS were to adopt the policies in the proposal, it would be de facto adopting two different definitions of "negotiated price" for purpose of the Part D program. CMS is therefore (rightly) concerned that it does not have the legal authority to require Part D plan sponsors to include pharmacy price concessions in the negotiated price that is used by manufacturers for purposes of determining their coverage gap discounts.

3. ***The RFI Contemplates Disclosing Confidential Information in violation of the Trade Secrets Act***

In discussing possible methodologies for calculating an "applicable average rebate amount" for purposes of rebates at POS, CMS notes that such rebates could be calculated "based on the plan's 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-sponsored/PBM pricing relationship with respect to an individual drug."[104]

Under the Part D statute, Part D plans are required to provide CMS with information about prescription drug price concessions and rebates.[105] This provision applies the confidentiality protections that apply in the Medicaid prescription drug rebate program (at 42 U.S.C. § 1396r-8(b)(3)(D)) to all such information submitted to CMS. Specifically, these protections preclude disclosure of information submitted to CMS "in a form which discloses the identity of a specific manufacturer or wholesaler [or] prices charged for drugs by such manufacturer or wholesaler,"[106] subject to five exceptions. Only one exception allows CMS to make a public disclosure:

> to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with [42 U.S.C. § 1396r-8(f)].

42 U.S.C. § 1396r-8(b)(3)(D)(v).

The SSA's designation as "confidential" information from which "prices charged for drugs" can be derived makes disclosure of such information a crime unless specifically authorized by statute. In particular, the Trade Secrets Act at 18 U.S.C. § 1905 prohibits "disclosure of confidential information" by any "officer or employee of the United States or of any department or agency thereof."

The arrangements contemplated by the RFI would be contrary to the confidentiality provisions in the Part D program, and thus violate the Trade Secrets Act, because they would require public

[104] 82 Fed. Reg. at 56,422.
[105] 42 U.S.C. § 1395w-102(d)(2).
[106] 42 U.S.C. § 1396r-8(b)(3)(D)

disclosure of "confidential" information. The RFI explicitly acknowledges this with respect to at least certain drugs, noting that CMS is "particularly interested" in how to calculate an "average rebate" "for a drug that is the only rebated drug in its category or class."[107] Although the RFI seeks "alternative" proposals for such drugs, fundamentally, there is no way to apply a known portion of the "average rebate" to the lone drug in a class or category without facilitating an interested party or parties discerning what the actual rebate is/was.

Even as to drugs that are not the only drugs in a category or class, the arrangements contemplated by the RFI call for the disclosure of confidential information. Under 42 U.S.C. § 1396r-8(b)(3)(D), information reported by a Part D sponsor to CMS which allows a member of the public to derive "prices charged for drugs" to a Part D sponsor is confidential.[108] Though the RFI suggests "that rebate rates are typically negotiated at the individual drug level," the statute evinces a confidentiality concern broader than a single drug price, applying even to "*aggregate* negotiated price concessions" in 42 U.S.C. § 1395w-102(d)(2) and to "*prices* charged for drugs by" any individual manufacturer in 42 U.S.C. § 1396r-8(b)(3)(D). Class or category-specific pricing information is much more granular than these broader categories and thus is likewise protected as confidential. This is particularly so where a category or class is larger than one, but still small. For example, if there are only two drugs in a given class, the manufacturer of the first drug – knowing the rebates it offers – could easily determine the rebates given by the manufacturer of the second, and vice versa. The statute does not contemplate CMS or Part D sponsors attempting to envision all of the ways in which manufacturers or others may "reverse engineer,"[109] pricing arrangements; rather, it takes a precautionary approach of applying a broad protection to Part D sponsors' (and manufacturers') sensitive business information.

In discussing various proposals, CMS acknowledges these limitations, and yet fails to provide answers or solutions. It is clear to us that any such proposal that requires even a portion of manufacturer rebates to be passed through at POS will expose confidential information, in direct violation of the Trade Secrets Act. Indeed, attached as Exhibit C makes clear (and as discussed in more detail below in Section (B)(5), competitors will be able to deduce rebates provided on competitor products quite easily in certain instances.

4. ***The policies in the RFI are inconsistent with the Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs***

On January 30, 2017, President Trump issued an Executive Order directing agencies "to be prudent and financially responsible in the expenditure of funds, from both public and private sources. In addition to the management of the direct expenditure of taxpayer dollars through the

[107] 82 Fed. Reg. at 56,422.
[108] The statutory exceptions to that protection would not apply to categories and classes; it applies to weighted averages of multiple source drugs, and is deliberately structured to avoid disclosure of the price or prices paid by any individual Part D sponsor.
[109] 82 Fed. Reg. at 56,422.

budgeting process, it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations."[110] Requiring Part D plans sponsors to pass through at POS manufacturer rebates and pharmacy price concessions would increase plan and CMS program costs.

While CMS details some of the direct costs associated with the RFI in Table 10, CMS does not provide cost estimates for the (what we believe is significant) burden associated with the regulatory concept in the RFI or in the "Supporting Statement Medicare Advantage Program and Supporting Regulations" document.[111] However, the coverage gap discount program (CGDP) represents a historical program similar to a POS rebate. At a high level, the coverage gap discount is a type of POS rebate, but for a statutorily defined percentage and for the non-low income subsidy (LIS) population only. In the April 15, 2011, rule implementing the CGDP, CMS estimated a one-time plan implementation cost of $50.4 million and 12,000 burden hours.[112] For subsequent years, CMS estimated the total annual cost would be $1.05 million and 250 burden hours per claims processor. While CMS does not report administrative spending by program, a review of CMS budget and contract documents indicates that at least $1 million is spent per annum on CGDP activities.[113] Since the CGDP represents a smaller and less complicated version of a POS rebate, it is reasonable to assume the costs outlined above would represent a low-end estimate of the administrative burden and costs for a full Part D POS rebate regulation. Adding these burdens and costs without a Congressional mandate is clearly inconsistent with the Executive Order on Reducing Regulation and Controlling Regulatory Costs.

5. ***In addition to the substantive flaws in CMS's RFI proposals, such policies also raise significant APA concerns***

PCMA is concerned that CMS is planning to finalize policy changes, without further notice-and-comment rulemaking, requiring that a certain portion of manufacturer rebates and pharmacy price concessions (together referred to as "negotiated price concessions") be passed to the consumer at the POS. We are concerned CMS may do this either through finalizing these policy changes as part of the Part C & D Technical Changes final rule, or through a separate Interim Final Rule ("IFR") or other guidance document (such as the annual Call Letter.) PCMA believes without question that to the extent CMS pursues any changes in this topic area, the agency must undergo a completely new round of notice-and-comment rulemaking, and demonstrate due consideration of public comments received during that new round, because such policy changes would have the force and effect of law. In addition, prior to finalization, all relevant subregulatory guidance would need to be developed with adequate public feedback, and all

[110] 82 Fed. Reg. 9,339 (February 3, 2017).
[111] CMS-R-267, OMB 0938-0753
[112] 76 Federal Register 21,545 (April 15, 2011).
[113] Centers for Medicare & Medicaid Services, Justification of Estimates for Appropriations Committees, CY2018 and CMS contract awards data regarding Palmetto and other contractors involved with the CGDP available online at www.usaspending.gov

documents subject to the Paperwork Reduction Act of 1995 (e.g., reporting forms, bid tools) would require clearance from the Office of Management and Budget. We discuss the application of Administrative Procedure Act's ("APA") and SSA's ("SSAs") substantive and procedural requirements in further detail below.

i. The Statutory Definition of "Negotiated Price" Prohibits the Proposed Policies in the RFI (42 U.S.C. § 1395w-102(d)(1)(B))

The Part D statute clearly requires that negotiated prices "shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations." PCMA is concerned that the policy changes discussed in the RFI would be substantively flawed under the APA as arbitrary and capricious and not otherwise in accordance with law. In particular, the underlying statutory language ("take into account") unambiguously indicates Congress did not intend that Part D sponsors be required to pass on manufacturer rebates and pharmacy price concessions to the consumer at the POS. Indeed, as CMS readily admits in the RFI, the agency's ability to require all or a portion of rebates or price concessions to be passed through at POS is "limited."[114] Moreover, even if the statutory language was found to be ambiguous, CMS's policy changes would be inconsistent with Congress' intent to provide Part D sponsors with flexibility in administering the Part D prescription drug benefit as a private market model. As such, a reviewing court is likely to find such policy changes as substantively invalid because they would be promulgated *ultra vires* and/or would be "arbitrary, capricious, or manifestly contrary to the statute."[115]

As explained in more detail below, because the policy changes discussed in the RFI would constitute legislative rules, they would be entitled to *Chevron* deference.[116] Under *Chevron*, a court reviewing an agency's construction of a statute which it administers must examine two questions. The first is whether "Congress has directly spoken to the precise question at issue" ("*Chevron* Step One").[117] If the statute is unambiguous, then that is the end of the inquiry and the unambiguous text of the statute must be followed.[118] If, however, "the court determines Congress has not directly addressed the precise question at issue…the question for the court is whether the agency's [interpretation] is based on a permissible construction of the statute" ("*Chevron* Step Two").[119]

Here, a reviewing court is likely to find that CMS's finalization of any of the RFI policies discussed in this comment letter would fail *Chevron* Step One as being promulgated beyond the

[114] 82 Fed. Reg. 56,421 (November 28, 2017)
[115] *See Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984).
[116] *See Nat'l Mining Ass'n*, 758 F.3d at 251 ("Legislative rules generally receive *Chevron* deference….").
[117] *Chevron U.S.A., Inc.*, 467 U.S. at 842.
[118] *Id.*
[119] *Id.* at 843.

agency's delegated authority, given the narrow definition of "negotiated prices," and therefore not be entitled to deference. As the D.C. Circuit observed in *Arent v. Shalala*,[120]

> Chevron is principally concerned with whether an agency has authority to act under a statute. Thus, a reviewing court's inquiry under Chevron is rooted in statutory analysis and is focused on discerning the boundaries of Congress' delegation of authority to the agency; and as long as the agency stays within that delegation, it is free to make policy choices in interpreting the statute, and such interpretations are entitled to deference…In such a case, the question for the reviewing court is whether the agency's construction of the statute is faithful to its plain meaning, or, if the statute has no plain meaning, whether the agency's interpretation "is based on a permissible construction of the statute. (internal citations and quotations omitted) (alterations made).

In this instance, CMS does not have the statutory authority to require that manufacturer rebates and pharmacy price concessions be passed through to the consumer at the POS. Congress has spoken to the issue of negotiated price concessions in the Medicare Part D program. More specifically, Congress has stated that negotiated prices "shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations…."[121] If Congress intended to dictate that negotiated price concessions must be passed through to beneficiaries at the POS, it would have surely foreclosed the possibility that Part D sponsors could report negotiated price concessions used to reduce costs under the plan in other ways. As CMS previously noted, "had the Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than "take into account" in the definition of term 'negotiated prices.'"[122] However, Congress clearly did not do this.[123]

Therefore, it is entirely unclear under what statutory authority CMS would justify its interference with Part D sponsors' management of plan costs. CMS seems to suggest that requiring plans to pass through a "portion" of negotiated manufacturer price concessions, as opposed to all of them, somehow confers the agency with "just enough" statutory authority to justify its suggested interpretation. In other words, CMS suggests that CMS's statutory authority to regulate in this space is a "matter of degrees." But this distorts whom Congress had in mind to answer the question of "degrees:" Congress unambiguously gave Part D sponsors, not CMS, the prerogative of determining how much negotiated price concessions are appropriate to pass through at the

[120] 70 F.3d 610, 615 (D.C. Cir. 1995).
[121] 42 U.S.C. § 1395w-102(d)(1)(B).
[122] 70 Fed. Reg. at 4194, 4244 (Jan. 28, 2005) (*supra* n. 3).
[123] *See id.* at § 1395w-102(d)(2).

POS. In short, CMS cannot, *sua sponte*, create statutory authority out of thin air by juxtaposing itself with Part D sponsors in the management of negotiated price concessions.[124]

Even assuming *arguendo* that CMS's suggested policies could advance to *Chevron* Step Two, a reviewing court would likely find them to be arbitrary, capricious, or manifestly contrary to the statute. The appropriate inquiry under *Chevron* Step Two is whether CMS's suggested requirement that a portion of negotiated price concessions be passed at the POS is a "reasonable" interpretation of the statute.[125]

At the outset, there is a critical difference between requiring that Part D sponsors pass through negotiated price concessions at the POS, and imposing on Part D sponsors a specific methodology for doing so. In this instance, CMS's interpretation of the statute would impose a specific methodology for passing through negotiated price concessions at the POS either by requiring a specified minimum percentage of the cost-weighted average of rebates for drugs in the same therapeutic category or class, or imposing the POS requirement only for certain high-cost drugs.

For the purposes of assessing whether CMS's suggested policies are consistent with congressional intent, the distinction between CMS imposing an obligation on a Part D sponsor to pass through negotiated price concessions at the POS and dictating precisely how the Part D sponsor is going to implement such a requirement is critical. As we have noted earlier in these comments, Congress fundamentally intended the Medicare prescription drug benefit to be a private market model.[126] For example, Congress gives Part D sponsors significant flexibility in designing their prescription drug plans, as long as they can show it is actuarially equivalent to standard prescription drug coverage.[127] As discussed above, Congress also prohibits the Secretary from interfering in "negotiations between drug manufacturers, and pharmacies and PDP sponsors", reinforcing once again the private market focus of the Part D program.[128]

Yet it is against this statutory scheme and legislative history that CMS suggests that its interpretation, which involves dictating how Part D sponsors must manage their negotiated price concessions, is reasonable. CMS's argument here is similar to HHS's unsuccessful argument in *Cent. United Life Ins. Co.* v. *Burwell.*[129] In that case, the court invalidated an amendment to the regulatory criteria for fixed indemnity plans to be considered an "excepted benefit" under the

[124] *See Railway Labor Executives' Ass'n v. National Medication Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (finding that the agency was not entitled to deference because "Congress has directly spoken to the precise question at issue in this case, so there is no gap for the agency to fill.").
[125] *See generally Chevron U.S.A. Inc.*, 467 at 844; *Texas v. United States*, 497 F.3d 491, 506 (5th Cir. 2007) ("[C]hevron step two compels a judicial evaluation of congressional intent.")
[126] *See United States ex. rel. Spay v. CVS Caremark Group*, 913 F. Supp. 2d 125, 132 ("[M]edicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans.").
[127] *See* 42 U.S.C. §1395w-102(a)(1)(B); *see also* 42 U.S.C. 1395w-104(b)(3) (providing PDP sponsors wide flexibility to develop formularies within certain parameters).
[128] 42 U.S.C. § 1395w-111(h)(i)(1).
[129] *Cent. United Life Ins. Co.* v. *Burwell*, 827 F.3d 70 (D.C. Cir. 2016).

Public Health Services Act ("PHSA").[130] According to the court, that Congress explicitly listed the criteria for fixed indemnity plans in statute foreclosed HHS's addition of another criterion through regulations.[131] Although HHS couched its amendment as a reasonable interpretation of the PHSA's second criterion,[132] the court rejected this characterization by noting that "ambiguity [] is a creature not of definitional possibilities but of statutory context."[133] The court asserted that, viewed in its proper context, HHS misread the PHSA and therefore was not entitled to *Chevron* deference.[134] Similarly here, CMS takes a perceived ambiguity regarding whether Part D sponsors are required to pass through negotiated price concessions at the POS, and then hurls forward to the conclusion that it must dictate how Part D sponsors must pass through these price concessions. Simply put, this interpretation is inconsistent with Congress' intent to leave such decisions to the discretion of Part D sponsors.[135]

ii. Changes to CMS's "negotiated prices" policy requires notice-and-comment rulemaking to comply with the APA.

As a threshold matter, even assuming *arguendo* that CMS can change its negotiated prices policy to require that negotiated price concessions be passed on at the POS (as discussed above, we believe the agency lacks the authority to do so), doing so would require that the agency undergo notice-and-comment rulemaking because such a change constitutes a legislative rule.

At the outset, CMS has already engaged in rulemaking to implement section 1860D-2(d)(1)(B) of the SSA, which requires that Part D sponsors provide beneficiaries with access to negotiated prices for covered Part D drugs.[136] Although CMS defines the terms "negotiated prices" and establishes a requirement that qualified prescription drug coverage include access to negotiated prices in its implementing regulations, the agency has never required that negotiated price concessions be passed to beneficiaries at the POS.[137] Indeed, from the earliest days of Medicare Part D, CMS has explicitly acknowledged that under the Part D statute, Part D plans are permitted, but not required, to pass through rebates and price concessions at POS.[138] As a result, even assuming solely for purposes of these comments on the RFI, that the statute permitted CMS to adopt such a change, imposing it would be effectively introducing a new condition that Part D sponsors must satisfy in order to offer qualified prescription drug coverage.

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[130] *Id.* at 72-73.
[131] *Id.* at 74.
[132] That a fixed indemnity plan must offer "independent, noncoordinated benefits." *See* 42 U.S.C. 300gg-63(b). HHS argued that this implied "there's something the benefits must be independent from or not coordinated with, and Congress's silence left room for HHS to read that unspoken 'something' as though it meant 'minimum essential coverage.'")
[133] *Id.* at 74 (quoting *Brown v. Gardner*, 513 U.S. 115, 118 (1994)).
[134] *Id.* ("[The] agency's rule was an act of amendment, not interpretation").
[135] *See MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear."); *see also Jordan v. Sec'y of Educ.*, 194 F.3d 169, 171-72 (D.C. Cir. 1999) (concluding, under similar circumstances, an agency's decision to "add an obligation that is not in the statute . . . changed the nature of the statute" and that the "Secretary may not rewrite the statute").
[136] 42 C.F.R. 423.100 (defining the term "negotiated prices"); 42 C.F.R. 423.104 (requiring that Part D sponsors provide Part D enrollees with access to negotiated prices for qualified prescription drug coverage).
[137] CMS itself acknowledges this much in the RFI. *See* 82 Fed. Reg. at 56420.
[138] *See, e.g.*, 70 Fed. Reg. , 4244 (Jan. 28, 2005) (noting that "[h]ad Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than 'take into account' in the definition of the term 'negotiated price.'") (emphasis added).

The APA distinguishes between "rules" that must be issued pursuant to notice-and-comment, (also referred to as "legislative rules") from those that do not require notice-and-comment, (known as "interpretive rules").[139] The APA does not further define "interpretive rules," but the Supreme Court has stated that a "critical feature" of an interpretive rule is that it is "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers."[140] Importantly, however, interpretive rules "do not have the force and effect of law…."[141] By contrast, "an agency action that sets forth legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements—is a legislative rule."[142] Notably, courts have applied the same standard for determining rules subject to the SSA's procedural requirements.[143]

Requiring Part D sponsors to pass through all or some manufacturer rebates and pharmacy price concessions at POS would clearly, under this definition, constitute a legislative rule and fall subject to the APA's and SSA's notice-and-comment rulemaking procedures. This type of requirement would effectively impose a "legally binding obligation" on Part D sponsors to pass through at least a certain portion of negotiated price concessions at the POS in order to participate in the Medicare Part D program. Stated differently, a Part D sponsor that chose not to comply with this requirement would be prohibited from offering *any* type of Part D plan to beneficiaries. Because such a requirement would have the "force and effect of law," CMS would need to adhere to the APA's and SSA's procedural strictures before finalizing it.

iii. Finalizing any policies discussed in the RFI in a final rule, without first issuing a proposed rule, violates the procedural requirements of the APA and SSA.

PCMA firmly believes that any formal proposed changes to manufacturer rebates and pharmacy price concessions at the POS should be preceded by robust stakeholder engagement. To that extent, we appreciate that CMS has solicited feedback on this topic "for consideration in future rulemaking."[144]

However, we want to take this opportunity to reinforce that CMS has not in fact proposed a discrete change in policy through its RFI. In particular, it would be a procedural violation of the APA and the SSA for the agency to finalize any policy on this topic in the CY 2019 Part C & D Technical Changes final rule, or through the upcoming Call Letter.

[139] *See* 5 U.S.C. § 553(b)(A) (stating that the notice-and-comment process "does not apply" to "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.").
[140] *See Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (internal citations omitted).
[141] *Id.*
[142] *See Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251-52 (D.C. Cir. 2014).
[143] *See Clarian Health West, LLC v. Burwell*, 206 F. Supp. 3d 393, 408 (D.D.C. 2016) ("As a general matter, courts use the APA's standards for determining whether or not a particular Medicare rule is a "substantive" one for notice-and-comment purposes").
[144] *See* 82 Fed. Reg. at 56419 (emphasis added).

The APA requires an agency to provide published notice of its proposed rulemaking. In doing so, the agency's notice must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[145] That is, the agency must describe "the range of alternatives being considered with reasonable specificity."[146] "Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making."[147]

This requirement is satisfied where an agency's final rule is a "logical outgrowth" of its rulemaking proposal.[148] A final rule is a "logical outgrowth" when stakeholders, *"ex ante*, should have anticipated that such a requirement might be imposed."[149] When analyzing whether a final rule is a logical outgrowth of the proposed rule, courts apply the "standard functionally by asking whether the purposes of notice and comment have been adequately served…that is, whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule."[150] In other words, '[t]he essential inquiry focuses on whether interested parties reasonably could have anticipated the final rulemaking from the draft [rule]."[151]

In this instance, CMS cannot support finalizing policies discussed in the RFI as a "logical outgrowth" of a proposed rule. At the outset, CMS explicitly preceded its discussion regarding both the application of manufacturer rebates and pharmacy price concessions at the POS with the clear statement that "feedback received will be used for consideration in future rulemaking on this topic."[152] Indeed, and as addressed in detail in Section B below, CMS's discussion of negotiated price concessions reflects only a preliminary understanding of the issues as evidenced by CMS's vague proposals,[153] admitted ended legal barriers, open-ended solicitations for "ideas", and request for "quantitative analytical support" to accompany submitted feedback.[154] Given CMS's own indecisiveness on the topic and its representation that it would consider feedback in "future rulemaking," stakeholders do not know which of the numerous policies discussed in the RFI are "on the table."[155] Therefore, a reviewing court would likely find that it

[145] *See* 5 U.S.C. § 553(b)(3).
[146] *See Small Refiner Lead Phase-Down Task Force v. United States Environmental Protection Agency*, 705 F.2d 506, 549 (D.C. Cir. 1983).
[147] *See Home Box Office v. Federal Communications Commission*, 567 F.2d 9, 36 (D.C. Cir. 1977).
[148] *See United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1221 (D.C. Cir. 1980).
[149] *See Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549.
[150] *See American Water Works Ass'n v. EPA*, 40 F.3d 1266 (D.C. Cir. 1994) (emphasis added) (internal quotations and citations omitted).
[151] *See Anne Arundel County v. EPA*, 963 F.2d 412, 418 (D.C. Cir. 1992) (internal quotations and citations omitted).
[152] *See* 82 Fed. Reg. at 56419 (emphasis added).
[153] For example, under CMS' first proposed approach wherein the agency would require Part D sponsors to include in their reported negotiated prices a specified minimum percentage of the cost weighted average of expected rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class, *see id.* at 56421, CMS acknowledges many unknowns, such as whether to use historical rebates or expected rebates to set the minimum percentage for POS rebates, or whether to use a weighted average of total drug costs incurred rather than a simple average to determine the average rebate amount reported to CMS. *Id.* at 56422. Similarly, CMS is also undecided in how to regulate pharmacy price concessions. Although the agency believes all pharmacy price concessions should be passed through to beneficiaries at the POS, the agency acknowledges that it needs additional information to determine whether requiring that negotiated prices include the lowest possible pharmacy reimbursement is consistent with recent developments in industry practices. *Id.* at 56427.
[154] *See generally* 82 Fed. Reg. at 56421,56426.
[155] *See Anne Arundel County v. EPA*, 963 F.2d 412, 417-18 (D.C. Cir. 1992) (holding that the EPA did not provide adequate notice because the County "had no reason to anticipate, on the basis of the proposed rule alone, that the [EPA would finalize its determination])

is

not reasonable to anticipate that the agency could then turn around and summarily finalize policies on this topic.[156]

CMS also cannot rely on an argument that "general" discussions of policy considerations, such as the ones in the RFI in question, constitute notice that the agency is in fact proposing policy changes.[157] Furthermore, it would also be inappropriate for CMS to argue that stakeholders responding to the RFI should have "actual notice" of proposed changes simply because other commenters may have anticipated a change in policy.[158]

In addition to the APA, the SSA also imposes separate procedural requirements on HHS before it "prescribes [] regulations as may be necessary to carry out the administration of the insurance programs under this title."[159] The SSA provides that "no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the…eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation…"[160] Moreover, final rules published by the agency that are not the logical outgrowth of a previously published rule "are treated as a proposed regulation" and may not take effect until the public is given an opportunity to comment and the rule is republished.[161]

Here, CMS's suggested policies in the RFI clearly implicate the SSA's procedural requirements. First, CMS's suggested policies requiring negotiated price concessions be passed through at the POS constitute a "requirement" imposed on Part D sponsors because they do not have a choice regarding compliance with these policies. Second, this requirement represents a change in long-standing policy, as CMS itself acknowledges. Finally, the requirement governs the "substantive legal standard" for plan eligibility to furnish services to Part D beneficiaries. Accordingly, CMS must issue a proposed rule and engage in notice-and-comment before finalizing any of the policies described in the RFI.[162]

So, too, is CMS prohibited from attempting to propose and finalize any of the policies in the RFI through the Call Letter process. As CMS has already made clear, it is considering putting forth the policies in the RFI in "future rulemaking," and not in something less substantive. The annual

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[156] *See id.* at 418; *see also* 5 U.S.C. § 553(b) (requiring that "rule making" start with a general notice of proposed rule making).
[157] *See AFL-CIO v. Donavan*, 757 F.2d 330, 340 (1985) (rejecting the Department of Labor's contention that the final rule "grew out of competing suggestions during the comment period" because there was "no indication [] to be found" that the regulation in question was subject to change).
[158] *See id.* at 340-41 (dismissing the agency's proposition that commenters may anticipate changes in policy based on the comments of other stakeholders, stating that "As a general rule, [an agency] must *itself* provide notice of a regulatory proposal."); *see also Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549 (stating that an agency "cannot bootstrap notice from a comment.").
[159] 42 U.S.C. § 1395hh(a)(1).
[160] *Id.* at §1395hh(a)(2); *see also Clarian Health West, LLC v. Burwell*, 206 F. Supp. 3d 393, 408 (D.D.C. 2016) ("As a general matter, courts use the APA's standards for determining whether or not a particular Medicare rule is a "substantive" one for notice-and-comment purposes").
[161] *Id.* at §1395hh(a)(4).
[162] *See Allina Health Servs. v. Price*, 863 F.3d 937, 943-44 (D.C. Cir. 2017) (holding that HHS violated the procedural requirements of the SSA in including Part C days in 2012 Medicare DSH fraction).

Call Letter *is not* rulemaking for purposes of compliance with the APA's notice-and-comment rulemaking procedures (and, moreover, CMS must first address and give due consideration to the ideas articulated in response to this RFI). The annual Call Letter is designed for minor, non-substantive changes to the Part D program (such as updates to rates and minor policy concerns), and is not the appropriate venue for substantive policy changes which would fundamentally reshape the Part D program. As noted above, given the scope of the changes considered, any rule addressing rebates and price concessions at POS would require "legislative rulemaking" – and the Call Letter, a limited comment period guidance document that is not published in the Federal Register, is very clearly *not* a sufficient vehicle for such proposals.

In short, we want to make it clear that by CMS's own admission, the policies discussed in the RFI are not in compliance with the APA's or SSA's rulemaking process, and therefore it would be a procedural violation of the APA and SSA were CMS to mislead stakeholders by making changes to regulations that the agency clearly impressed would remain unchanged and not "on the table."[163]

iv. Relying on the RFI to issue an IFR would violate the procedural requirements of the APA and SSA

We are also concerned that CMS may, in the alternative, be planning to use the information obtained from the RFI and then, through an IFR, adopt a brand new policy regarding rebates and price concessions without going through notice-and-comment rulemaking

We want to make clear that feedback solicited by the RFI cannot be used as the basis for an IFR. CMS indicates in the RFI portion of the proposed rule that it "solicit[s] 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."[164] CMS states that feedback from the RFI "will be used for consideration in future rulemaking on this topic," arguably leaving ambiguous whether CMS intends to use the information to formulate a proposed rule for notice and comment, or to issue an IFR on the subjects of the RFI. Applicable precedent is clear that, under the APA and SSA, CMS may do the former but not the latter.

As discussed above, the APA and the SSA require CMS to follow the normal course of proposed rulemaking, receipt of public comment, and final rulemaking. The agency may bypass these procedures only in limited cases where it finds "good cause (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon

[163] *See Anne Arundel County*, 963 F.2d at 418.
[164] 82 Fed. Reg. at 56419.

are impracticable, unnecessary, or contrary to the public interest."[165] None of these factors would support a finding of "good cause" to issue an IFR with respect to any issue addressed in the RFI.

Courts are reluctant to uphold agencies' use of exceptions to the typical course of APA rulemaking:

> It should be clear beyond contradiction or cavil that Congress expected, and the courts have held, that the various exceptions to the notice and comment provisions of section 553 will be narrowly construed and only reluctantly countenanced. S.Doc. No. 248, 79th Cong., 2d Sess. 19, 199, 258 (1946); *American Bus* [*Association v. U.S.*, 201 U.S. App. D.C. 66, 627 F.3d 525 (D.C. Cir. 1980)]; *Humana of South Carolina v. Califano*, 191 U.S. App. D.C. 368, 590 F.2d 1070, 1082 (D.C.Cir.1978); *National Nutritional Foods Association v. Kennedy*, 572 F.2d 377, 384 (2nd Cir. 1978); *National Wildlife Federation v. Snow*, 561 F.2d 227, 232 (D.C.Cir.1976).[166]

Indeed, Congress' intentions are clear in the comments of the Senate committee responsible for the APA's drafting:

> The exemption of situations of emergency or necessity is not an "escape clause" in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published. "Impracticable" means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings.[167]

The same committee called upon courts to cast a stern eye upon use of the exceptions:

> It will thus be the duty of reviewing courts to prevent avoidance of the requirements of the bill by any manner or form of indirection, and to determine the meaning of the words and phrases used. For example, in several provisions the expression "good cause" is used. The cause so specified must be interpreted by the context of the provision in which it is found and the purpose of the entire section and bill. Cause found must be real and demonstrable.[168]

[165] 5 U.S.C. § 553(b)(3)(B); 42 U.S.C. § 1395hh(b)(2)(c) (incorporating the "good cause" exception under the APA).
[166] *New Jersey, Dep't of Environmental Protection v. United States Environmental Protection Agency*, 626 F.2d 1038, 1045-46 (D.C. Cir. 1980).
[167] S. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).
[168] *Id.* at 207.

Accordingly, courts have held that the exceptions are "an important safety valve to be used where delay would do real harm," and are not to be used "to circumvent the notice and comment requirements whenever an agency finds it inconvenient to follow them."[169]

Here, none of the three exceptions would support "good cause" to use feedback obtained in the RFI to create an IFR without first offering a proposed rule. As a threshold matter, the

"unnecessary" exception cannot apply; CMS in the RFI makes plain the necessity for input to be used as part of a "future rulemaking." If such input is required in the first instance to formulate a proposed rule, comment on CMS's use of such input cannot be "unnecessary."

Nor would normal, notice-and-comment rulemaking be "impracticable" or "contrary to the public interest." Nothing in the proposed rule indicates that CMS faces "a situation in which due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings."[170] Indeed, the "background" portion of the RFI section notes that CMS has considered the issues in the RFI at least as early as "the Part D final rule that appeared in the January 28, 2005 Federal Register (70 FR 4244),"[171] and that part of CMS's interest arises from trends in negotiating price concessions going back at least as far as 2010.[172] Nothing in the RFI indicates that various regulatory actions CMS is "considering" are so vital that their delay would preclude CMS from undertaking its "due and required execution of agency functions."

Similarly, promulgation of an IFR would not be justified as such a rule would not address an "emergency" situation affecting the public interest.[173] Again, nothing in the RFI indicates that CMS confronts an "emergency" or situation in which, failing quick action by CMS, the public interest would be prejudiced. An IFR would be required to demonstrate a pressing, genuine public interest even if limited to discrete portions of the issues addressed by the RFI.[174] Likewise, that such a rule would be "interim" would not justify a lower showing of public interest to justify jettisoning normal APA procedure,[175] nor does preceding such an IFR with an RFI justify dispensing with notice-and-comment.[176]

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[169] *U.S. Steel Corp. v. United States Environmental Protection Agency*, 595 F.2d 207, 214 (5th Cir. 1979); *See Pennsylvania v. Trump*, No. 17-4540, 2017 U.S. Dist. LEXIS 206380, at *40 (E.D. Pa. Dec. 15, 2017) (rejecting the agency's argument supporting an IFR that no notice-and-comment rulemaking was needed because the agency received significant comments on the same topic in previous rounds of rulemaking).
[170] S. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).
[171] 82 Fed. Reg. at 56336.
[172] *Id*. at 56335.
[173] *See, e.g., American Fed'n of Gov't Employees v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981).
[174] *See, e.g., Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 582 (D.C. Cir. 1981) ("the limited nature of the rule cannot in itself justify a failure to follow notice and comment procedures").
[175] *See, e.g., American Fed'n of Gov't Employees*, 655 F.3d at 11158 (citing cases holding "even interim regulations invalid without public procedures").
[176] *See Dialysis Patient Citizens v. Burwell*, Civil Action No. 4:17-CV-16, 2017 U.S. Dist. LEXIS 10145 at *16 (E.D. Tex. 2017) (holding the IFR procedurally invalid because "the RFI (1) did not give Plaintiffs notice that HHS was considering promulgating a rule; (2) was not specific to ESRD; (3) disclosed no information regarding the provisions that made the Rule so damaging; and (4) was "[t]oo open-ended to allow for meaningful comment" on key aspects of the Rule actually adopted.").

Indeed, we remind CMS that the U.S. District Court of Eastern Texas only last year enjoined the agency's IFR regarding third-party premium assistance for end-stage renal disease (ESRD) patients earlier this year.[177] In that case, the Department of Health and Human Services (HHS) also issued an RFI prior to issuing an IFR.[178] The RFI noted HHS's concerns that dialysis providers were offering charitable premium assistance to steer patients towards private plans, which offered higher reimbursement than Medicare and Medicaid.[179] The court noted that in the RFI, HHS stated the RFI was for "'information and planning purposes' only and did not propose a new rule."[180]

On December 14, 2016, HHS issued an IFR requiring, among other things, that dialysis providers disclose to patients that they are contributing to charities and to receive assurance from insurers that they will accept charitable premium assistance.[181] The plaintiffs, which consisted of patient groups and dialysis providers, argued that the IFR violated the APA because it was unlawfully promulgated without notice and comment and was arbitrary, capricious, and contrary to law.[182] HHS retorted by arguing, among other things, that it articulated a reasonable explanation for the IFR, had good cause to issue the rule, and that any procedural errors were harmless.[183]

The court flatly rejected HHS's contentions, and in particular its contention that emergency rulemaking was necessary to prevent further harm to dialysis patients.[184] The court reiterated the D.C. Circuit's position that NPRM should only be disposed of where "announcement of proposed rule would enable the sort of…manipulation the rule sought to prevent."[185] The court stated that speculation that some patients would be harmed was not enough, and that purely economic harm does not supply good cause.[186] In particular, the court observed that:

> The RFI (1) did not give Plaintiffs notice that HHS was considering promulgating a rule; (2) was not specific to ESRD; (3) disclosed no information regarding the provisions that made the Rule so damaging; and (4) was "[t]oo open-ended to allow for meaningful comment" on key aspects of the Rule actually adopted. It is not 'clear that the petitioner was not prejudiced by APA deficiencies." In fact, when combined with the shortcomings

[177] *See Dialysis Patient Citizens v. Burwell*, Civil Action No. 4:17-CV-16, 2017 U.S. Dist. LEXIS 10145 (E.D. Tex. 2017).
[178] *See* "Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and/or Medicaid Benefits to Individual Market Plans," 81 Fed. Reg. 57,554 (Aug. 23, 2016).
[179] *See id.*
[180] *Dialysis Patient Citizens*, at 5.
[181] *See id.* (citing "Third-Party Payment," 81 Fed. Reg. 90, 211 (Dec. 14, 2016)).
[182] *See Dialysis Patient Citizens*, at 7.
[183] *See id.*
[184] *Id.* at 10.
[185] *Id.* at 10 (citing *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 775 (D.C. Cir. 2001) (internal quotations omitted).
[186] *See Dialysis Patient Citizens*, at 12.

and deficiencies of the Rule itself, the Court finds Plaintiffs were clearly prejudiced by HHS's decision to violate the procedures of the APA.[187]

Considering the stark procedural parallels between the *Dialysis Patient Citizens* case and the fact pattern at issue here, we expect that, to the extent it pursues regulatory changes on this topic (and we reiterate our strong believe that adoption of any of the policies in the RFI would violate the statute), CMS will adhere to the NPRM process as required by the APA (including addressing all of the considerations raised by commenters through this RFI process, including those of PCMA, as set forth below) and issue a new proposed rule.[188]

B. Policy Assessment of the RFI

1. Introduction (p. 56419)

CMS Proposal: CMS notes that price concessions have grown significantly in the last five years with manufacturer rebates accounting for the largest share of price concessions. Pharmacy price concessions have grown faster than any other category of DIR and "now buy down a larger share of total Part D costs than ever before." Beneficiaries do not see the benefit of these price concessions at POS (regardless of lower premiums). CMS further asserts that the POS "negotiated" price on the PDE is both less transparent and less representative of actual costs and that this distorts incentives for sponsors from what CMS intended in 2005. Therefore, CMS requests comments on considerations related to "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." (p. 56419) CMS notes that feedback received will be used for consideration in future rulemaking on this topic.

Discussion: As noted in Section A above, PCMA believes that implementation of the policies articulated in the RFI are beyond the legal authority of CMS. Regardless of the legality of this initiative, however, we also have extensive policy, operational, regulatory, cost, market competition, and other concerns with the RFI content. We urge CMS to carefully consider the extensive range of concerns set forth below as it contemplates whether to proceed. Highlights of the adverse repercussions of the RFI proposal, as discussed in more detail below, include:

- *The approach provides incentives for collusion and gaming by manufacturers*

[187] *See id.* at 16 (internal citations omitted).
[188] Additionally, we note that to the extent CMS has previously discussed these policies with stakeholders in previous rulemakings, it does not absolve CMS from complying with notice-and-comment rulemaking in this instance. *See Pennsylvania v. Trump*, No. 17-4540, 2017 U.S. Dist. LEXIS 206380, at *40 (E.D. Pa. Dec. 15, 2017) (rejecting the agency's argument that no notice-and-comment rulemaking was needed because the agency received significant comments on the same topic in previous rounds of rulemaking).

Regardless of how the weighted average is calculated (broad vs. narrow), the RFI construct creates a "false pricing transparency" because manufacturers with higher rebates will be subsidizing manufacturers with lower rebates. This cross-subsidization would not only decrease transparency, but also create major market distortions in manufacturer rebates. New entrants will have every incentive to be "free riders," and over time, this will incentivize manufacturers to move towards a lower, standard rebate level (thus losing segmentation price negotiation and increasing overall drug pricing). As noted in our legal discussion above, such incentives also raise significant anti-competitive concerns.

- *CMS does not consider the potential for adverse selection*

When Part D started, plans were competitive based on premiums, but under the RFI scenario, plans would now be competing based on individual drug cost-sharing, under which plans are exposed to adverse selection and distortion of the risk pool. Competing on a disease specific level may well impact the utility of the program; it will also raise premiums in the process and potentially drive sponsors out of the market due to adverse selection over time.

- *There could be a major, detrimental impact on preferred pharmacy networks*

Another important facet of Part D not considered by CMS in the RFI proposals is the disruption of the highly popular and cost-effective preferred pharmacy network offerings. The elimination of pharmacy DIR may undermine the value of preferred networks, reducing enrollee access to lower cost-sharing.

- *CMS would be extensively regulating Part D sponsors and their PBMs, and not regulating wholesalers, pharmacies, or manufacturers*

If CMS is serious about regulating Part D sponsors and their PBMs as envisioned by the RFI, and is serious about addressing the high cost of drugs by regulating Part D sponsors and their PBMs as envisioned by the RFI, it needs to develop an approach to regulate all supply chain entities. Regulations addressing only one player in the supply chain fail to recognize the multiple components of the supply chain.

- *There are major unaddressed implementation issues*

From a practical perspective, the RFI proposals cannot be properly implemented until 2020. CMS would need to provide detailed guidance on significant, unaddressed issues that would materially impact sponsor IT systems, bid development, reporting, contracting with manufacturers and pharmacies, beneficiary notices and other material seeking to explain this

approach to beneficiaries, beneficiary appeal rights (e.g., how would tiering exceptions requests for drugs in a rebated class work?), Medicare Plan Finder, etc. As CMS is aware, Part D plan sponsors are already well into the process of developing their 2019 bids and it would be virtually impossible to accommodate the RFI changes by the submission deadline in June of 2018.

- *There are many other alternatives available under current law for CMS to address high drug costs and their impact on affordability*

As PCMA has commented to the Agency many times before, there are significant and meaningful opportunities for CMS under current law to seek to address the problem of high drug costs, without disrupting the Part D program. While this topic is beyond the scope of this RFI, we refer CMS to our comments filed in response to the RFI the agency issued on Part D improvements. To provide just one of many examples, CMS itself recognized in the 2015 NPRM released in 2014, that the current protected class requirements significantly limit rebate opportunity on some of the most expensive conditions for members.[189]

***PCMA Recommendation*: Beyond the legal impediments to proceeding, CMS should not pursue any policy based on the content of the RFI. If CMS wants to lower beneficiary payments at POS, it should consider alternatives aimed at getting manufacturers to lower their drug prices.**

2. Background (pp. 56419-56421)

CMS Proposal: CMS notes that while under current law, Part D plan sponsors may choose whether to reflect price concessions in negotiated prices at POS, sponsors generally include all price concessions in DIR.

Discussion: We assume that CMS, by referencing current law, is referring to the option allowed under DIR guidance for Part D plans to pass through estimated rebates at POS, which has been permitted by CMS since 2008.[190] While this currently is an option, there are many reasons that it is not widely utilized. First, plan contracts, IT systems, PDE submissions and beneficiary materials are not set up to implement estimated rebates at POS. Second, there is no guidance from CMS on the estimation process and how that is to be conducted, and thus, there remain major concerns about false claims exposure for estimates that are not accurate. Third, if a plan passes the estimated price concessions through at POS, and then it later turns out that the estimate was too high or too low, there is no provision or guidance about how to collect the underpayment from the beneficiary or credit them with the difference. Any effort to do so would result in significant administrative costs given the need to reprocess claims, recalculate TrOOP, and adjust total drug cost accumulation.

[189] 79 Fed. Reg. 1,918, 1,937 (January 10, 2014).
[190] Hutchinson, T. (June 1, 2007) *Reporting Estimated Rebates Applied to the Point-of-Sale Price* [Memorandum]. Baltimore, MD; Centers for Medicare and Medicaid Services.

Further, from a policy perspective, one reason this option has not gained traction is because beneficiaries prefer to shop for health coverage based on premiums. The Part D market-based model is based on premium competition. Indeed, many parts of the Part D program are based on the premium metric (e.g., auto-assignment for the LIS population is based on the premium structure). Absent changes to the statute and the underlying program, it is difficult to envision how CMS can take a system based on premiums, and change only one aspect to seek to make it about competing only on individual drug prices.[191]

Finally, another reason that the "estimated" option may not be widely adopted is that it could decrease the generic dispensing rate (GDR), because if cost-sharing decreases significantly for a brand, beneficiaries may switch away from generics.[192] This, in turn, would further increase premiums and government spending.

PCMA Recommendation*: *CMS should assess all the barriers to plans relying on the current guidance which allows pass-through of estimated rebates at POS, to better understand programmatic disruptions and barriers to the policy changes it proffers in the RFI.

3. Background – Premiums and Plan Revenues (p. 56420)

CMS Proposal: CMS acknowledges that the main benefit of applying price concessions as DIR is lower premiums for all beneficiaries. However, CMS then proceeds to assert that any DIR received above the amount factored into a plan's bid largely goes to plan profits. CMS references its analysis that shows that DIR amounts received by plans/PBMs have consistently exceeded bid projections. CMS notes that to capture the advantages of price concessions as DIR, "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," which in turn could drive up drug pricing.

Discussion: We are concerned that this discussion of premiums and plan revenues presents a distorted view, not only of how the Part D program works, but also the impact of the approach presented in the RFI.

[191] "How a Part D sponsor nets out negotiated prices is at the discretion of the Part D sponsor, but we expect that competition will create incentives for Part D sponsors to offer reasonable negotiated prices." 70 Fed. Reg. 4,194, 4,245 (January 28, 2005).

[192] "Brand-name discounts lower relative prices for brand- name drugs. For therapeutic classes in which an enrollee has a choice of both brand-name and generic alternatives, the policy makes brand-name drugs appear less expensive than they would otherwise."
Medicare Payment Advisory Commission (MedPAC), Chapter Six: Improving Medicare Part D, Report to the Congress: Medicare and the Health Care Delivery System, June 2016, p. 178.

a. Higher DIR does not largely go to plan profits

From a pricing perspective, underwriting is a rolling wave, and it is not valid to look only at one year. A plan may get more DIR than projected one year, and then its premium can be lower the next year. While CMS seems to be looking at this as a one year period for calculating profits, the wave of constant underwriting balances out over time. There is just no "runaway" profit opportunity in Part D. There are multiple mechanisms in place to prevent abuse of the system, and it is unreasonable for CMS to argue that POS rebates are needed to prevent such abuse. Some of the many other programmatic features that limit Part D plan sponsor profits include the MLR provisions and bid review. Further, the CMS Office of the Actuary will not approve a bid if the plan sponsor is consistently off with its projections. Likewise, CMS performs audits to ensure proper bid protocols are followed.

It is worth reviewing in detail how the Part D risk corridor program penalizes plans if they under-project DIR in their bids. Under the program, plan sponsors may share a portion of savings or losses with the federal government. Total savings or losses are calculated as the difference between a plan's "target amount" (what the plan was actually paid through the direct subsidy plus enrollee premium related to the standardized bid amount) and its actual allowable costs. The target amount reflects the plan sponsor's expected costs as projected in the bid. Both the target amount and actual allowable costs exclude administrative expenses and are net of DIR.

- Plans retain 100% of savings or losses within 5% of the target amount. Plans share 50% of the savings or losses that are 5%-10% different from the target amount, and share 80% (retain 20%) of the savings or losses that are more than 10% different from the target amount.

- The Part D risk corridor program incentivizes plan sponsors to accurately project DIR in their bids. Consider the following example (amounts per member per month):

    - Projected DIR in bid = $10
    - Target amount gross of DIR = $100
    - Target amount (net of DIR) = $100 - $10 = $90
    - Actual DIR = $20
    - Actual allowable costs gross of DIR = $100 (assume same as projected target)
    - Actual allowable costs (net of DIR) = $100 - $20 = $80

    Since the plan's actual allowable costs ($80) are more than 5% lower than the target amount ($90), the plan must share a portion of the savings with the federal government. Had the plan accurately projected $20 of DIR in the bid, it would not have to share any

savings with the government, and could have instead used that savings to reduce the member premium.

- The above example highlights how the risk corridor program penalizes plans for under projecting DIR in bids. Such under projection results in (1) sharing a portion of DIR with the federal government through risk corridors, and (2) having a less competitive premium. Plans may increase their profits when they accurately project DIR in the bid, as the lower resulting premium typically increases membership. Competitive premiums are especially important in the basic PDP market, where plan sponsors have strong incentives to reduce their bids to gain auto-assigned LIS membership.

- This risk corridor dynamic is not specific to DIR. Differences between actual and projected amounts for most cost-related bid assumptions have the same effect. For example, if a plan sponsor under-projects discounts, its target amount would be greater than its actual allowable costs, and it may end up sharing a portion of the discount "savings" with the government.

b. The RFI proposal is based on anecdotes about bad plan sponsor behavior

As with many of the provisions in the NPRM, the RFI proposal seems to be based on anecdotes that plans are somehow acting in a nefarious manner. In fact, most if not all of the DIR variance cited by CMS is due to new manufacturer products that are released midyear. Plans use tools such as rebate negotiation to manage new product entries, which could result in more actual received DIR than what was contemplated when the bid was submitted. Once again, CMS appears to be relying on imprecise anecdotal evidence to drive major structural changes that do not address the fundamental drug pricing problem – which is the high prices charged by manufacturers.

c. The CMS impact tables are incomplete and overestimates the beneficiaries helped and underestimates the impact on premiums[193]

CMS's crude impact tables 10A, 10B and 11 reflect only money transfers between limited parties and are not complete. Simply put, the impact analysis is static and needs to show additional program impacts that incorporate plan, manufacturer and beneficiary behavioral responses to the proposals discussed in the RFI. Indeed, MedPAC, in its comments filed with

[193] In addition to the range of issues cited herein on the tables, we also note our puzzlement about why the 10-year impact projection begins with 2019. Since this is an RFI, not a proposed rule, which would necessitate an actual proposal, there is no way the POS rebate approach could be in effect for 2019 so any assessment should begin with the year in which the approach could realistically take effect.

CMS on the RFI,[194] notes that the RFI proposal is unlikely to produce the result that the Administration is looking for, and that beneficiaries will see premium increases while manufacturers will face no additional pressure to lower pricing. Below we discuss some of the ways the CMS analysis is deficient in terms of both overestimating how many beneficiaries benefit and underestimating the premium impact.

i. The percent of beneficiaries that achieve net savings with POS rebates as outlined in the RFI, taking into account both the impact on cost sharing AND premiums, is overstated. It would not produce meaningful savings for the vast majority of beneficiaries.

- Overall, reflecting rebates at POS increases beneficiary premiums (or premium subsidies) for all beneficiaries and reduces beneficiary cost sharing when beneficiaries pay coinsurance (see Table 10A). However, approximately 35% of beneficiaries in the Part D market are low income individuals who receive government subsidies for both premium and cost sharing. Therefore, we assume low income beneficiaries are affected minimally, if at all, by the premium and cost sharing impacts that result from reflecting rebates at the POS.

- For the 65% of beneficiaries who are non-low income and do not receive government subsidies, the majority end the year in the deductible or initial coverage limit Part D benefit phases. Approximately 15% of non-low income beneficiaries have higher claims and end the year in the coverage gap or catastrophic phases. These non-low income beneficiaries that end the year in the coverage gap or catastrophic phases make up approximately 10% of the total Part D market (= 65% of Part D are non-low income – 15% of non-low income end in the coverage gap or catastrophic phase). In general, it is only these non-low income beneficiaries with higher claims whose cost sharing savings would outweigh the premium increase (i.e. would achieve net savings) if rebates were reflected at the POS.

- Under the RFI, CMS is considering limiting the application of POS manufacturer rebates to only drugs that receive a rebate. In this case, only beneficiaries taking rebated drugs would realize cost sharing reductions due to manufacturer rebates reflected at the

[194] See "Comments of Medicare Payment Advisory Commission on CMS-4182-P," filed January 3, 2018 at regulations.gov ("… we are concerned that CMS's proposed approach would be complex to implement, administratively burdensome and, for drug classes with few competing therapies, would risk disclosure of confidential rebate information. Further, the policy would not help beneficiaries who take expensive drugs with no post-sale rebates or discounts.")

POS, so the percentage of beneficiaries that realize net savings may well be lower than the 10% estimate.

ii. CMS has also underestimated the impact on premium growth. In Table 10B, CMS assumes that rebates would be perfectly substituted with the POS discount in all phases of the Part D benefit, including the coverage gap phase. But in actuality, POS rebates would be concentrated in the coverage gap and catastrophic phases. We understand from internal assessments prepared by some of our members that factoring in the concentration of rebates based on phases leads to a significantly different result where the ultimate impact to the beneficiary is less than half of what Table 10B indicates.[195] We urge CMS to secure an independent analysis of the premium impact, including whether such a policy would produce meaningful savings for the vast majority of beneficiaries.

d. *CMS should consider less complex alternatives*

It is incumbent on CMS to consider alternatives that are less complex, less burdensome, do not involve disclosure of confidential rebate information, as well as that don't increase beneficiary costs nor result in manufacturer windfalls. We believe that the actuarial types of approaches, as suggested by MedPAC in its comments, may be a reasonable place to start.

> However, "we are concerned that CMS's proposed approach would be complex to implement, administratively burdensome and, for drug classes with few competing therapies, would risk disclosure of confidential rebate information. (emphasis added) Further, the policy would not help beneficiaries who take expensive drugs with no post-sale rebates or discounts. **We strongly encourage CMS to search for alternative policies that are less complex but could help to achieve similar aims. For example, CMS may want to consider requiring plan sponsors to reflect a portion of expected DIR in cost sharing amounts when they submit their bids.**
>
> In general, given the growth in the disparity between gross and net prices, a model based on gross prices may no longer be appropriate for demonstrating actuarial equivalence to the defined standard benefit. This is because cost sharing amounts calculated to be actuarially equivalent to the defined standard benefit based on gross prices would, in effect, have beneficiaries pay a higher share of the actual costs than is set by the defined standard benefit. Therefore, "the agency may want to evaluate whether that actuarial model (i.e., the current bid-pricing tool) could

[195] Indeed, we further understand that appropriately allocating POS rebates by phase could also result in estimated gap discount payments paid by manufacturers being approximately half as much as estimated by CMS.

incorporate a portion of expected DIR so that cost sharing reflects some of the rebates."[196]

e. CMS has alternatives if it is worried about malfeasance

If CMS has proof about inappropriate behavior (e.g., Part D plan sponsors directing manufacturers to increase their prices so they can get a bigger rebate), CMS should use its compliance authority to deal with the specific situations, instead of seeking to implement broad scale changes that will disrupt the entire Part D program.

PCMA Recommendation: CMS should reconsider the many inaccurate and missing assumptions that appear to underlie its assessment of the impact of price concessions at POS on premiums and plan revenues, including the impact on plan sponsors, PBMs and pharmacies. CMS should also consider alternatives to high drug prices that are less complex and more beneficial to beneficiaries and the federal government.

4. Background – Cost-Shifting (pp. 56420-56421)

CMS Proposal: CMS is concerned with the negative impact of higher cost-sharing, which moves beneficiaries more quickly through to the catastrophic phase, on beneficiary access. CMS notes that sponsors are able "to offset their already limited liability" in the catastrophic phase by capturing additional rebates. Under current rules, plans "may have weak incentives, and in some cases even no incentive to lower prices at POS or to choose lower net cost alternatives to high cost-highly rebated drugs when available." (p.56421)

Discussion: We are perplexed by CMS's criticism here of Part D sponsors as it appears to reflect a fundamental misunderstanding of the business of insurance. In particular, CMS seems to believe that the Part D program (contrary to Congressional intent, including recent amendments to the Coverage Gap Discount Program in the ACA) should be a 100% accounting exercise, operating as a fee-for-service program. Yet, the Part D program has never been meant to be a dollar-for-dollar program. Under the MMA, CMS does not have the authority to restructure the risk in the program, which is established statutorily.[197] Instead, the whole purpose of the MMA was to establish a balanced risk pool. We are concerned that this "balance" could be unraveled very quickly under the RFI. For example, there are a lot of enrollees that are currently taking only a few generic drugs. If their premiums go up under these proposals, they might not bother to either enroll in, or remain in Part D in the first place. We note this to illustrate another type of

[196] "Comments of Medicare Payment Advisory Commission on CMS-4182-P," filed January 3, 2018 at regulations.gov (page 15).
[197] See 42 U.S.C. § 1860D-11(b).

behavioral change which we believe CMS should model if it seeks to obtain a realistic assessment of the impact of its proposal.

***PCMA Recommendation*: If CMS is truly concerned about the incentive structure in the Part D program, it should develop a legislative proposal for consideration by Congress.**

5. Manufacturer Rebates to the POS (pp. 56421-56426)

CMS Proposal: CMS is seeking comments on how to most effectively design a policy to require pass-through at POS of a share of rebates in order to mitigate effects of the DIR construct. CMS specifically seeks comment on how to do this without increasing government costs, or reducing manufacturer payments under the CGDP. Specifically, the policy under consideration is to require the negotiated price to include a specified minimum percentage, but not 100%, of the cost-weighted average of rebates for drugs in the same therapeutic category or class.

Discussion: We do not believe that this is a viable proposal that will deliver the value and goals CMS claims it is trying to achieve. Most importantly, the proposal discussed in the RFI will increase program and beneficiary costs. While a minority of beneficiaries will pay less for certain drugs, a vast majority will pay higher premiums. As noted above, a blended rebate approach will mean that manufacturers that don't provide rebates benefit, while those that provide the biggest rebates disproportionately lose. As a result, we believe that the outcome of such a policy would be reduced and standardized rebates that approach the mean across all drug classes.

a. Disruption caused by reverse engineering

Below we set forth how providing an estimated minimum rebate percentage at POS (and related concepts/alternatives outlined in the RFI) could lead to competitors "reverse engineering" rebate levels.[198] Under the arrangement proposed by CMS where a minimum rebate percentage is reflected at POS, POS drug costs for a given plan benefit package (PBP) and therapeutic class would be reduced by the average POS rebate for the PBP and class. The average POS rebate is the gross cost weighted average of the rebates of each rebateable drug in the class. This arrangement could yield instances in which stakeholders may be able to reasonably estimate the rebate levels of others in the market. Given that rebate levels are highly proprietary information that contributes to the financial success of multiple stakeholders, such a policy would create disruption in the market.

[198] A detailed chart of this impact is also included as Exhibit C to the legal discussion above, to illustrate how the disclosures under the design would violate the Trade Secrets Act.

Specifically, competitors may be able to "reverse engineer" rebate levels as follows:

- *One Rebateable Drug in a Class*

In the case that there is only one rebateable drug in a given class, the average POS rebate would equal the rebate of that individual drug. If a competitor has access to the final POS price for that drug, they may be able to back into the rebate value by estimating the POS price prior to rebates. Multiple entities have access to final POS drug prices, including pharmacists, internal health plan staff, and consultants. The POS price prior to rebates could be estimated by applying a range of potential discount terms to the average wholesale price (AWP) of the drug. Industry experts have the means to identify which drugs are rebateable and thus may recognize classes with only one rebateable drug.

- *Two Rebateable Drugs in a Class*

Since the average POS rebate would be the same for all rebateable drugs in a class, competitors would only need to know the final POS price for one rebateable drug to calculate the average POS rebate. A competitor may then estimate the drug-specific POS rebates using the average POS rebate and one of two approaches:

(1) If the competitor's product is one of the two rebateable drugs in the class, they can use the average POS rebate, the claims associated with each drug in the previous year, and the known rebate for their product to determine the POS rebate for the other product.

(2) If the competitor's product is not one of the two rebateable drugs in the class, they likely would not know the POS rebate for either product. In this case, they could estimate POS rebates for each drug using the average POS rebate, the claims associated with each drug in the previous year, and the relativity between the rebates (e.g., one drug may typically receive a rebate that is 2x the rebate of another drug). While this method requires multiple assumptions and may not yield exact rebate values, competitors would be able to produce a reasonable range of estimates.

- *Two or More Rebateable Drugs in a Class*

The same method outlined in the two-drug scenario could be used with any number of rebateable drugs in a class. This would require estimating the claims associated with each drug, and additional relativities between the rebates of each drug (e.g., Drug A rebate is 2x Drug B, Drug B rebate is 3x Drug C). The number of assumptions required increases with the number of drugs in

the class. As a result, a competitor's rebate estimates may be less accurate in classes with many rebateable drugs.

b. Strategic implications of release of rebate information

CMS also needs to take into account the potential strategic implications of revealing manufacturer rebate terms:

- Manufacturer rebate contracts are among the most closely guarded information in the pharmaceutical industry. For example, many insurers that provide other contracting information (e.g., discount terms) to trusted consultants prefer to keep drug-specific rebate terms confidential, even if sharing would create cost efficiencies in consulting engagements. A change from this level of confidentiality could create market disruption.

- If manufacturer rebate terms were revealed, pharmaceutical manufacturers would benefit from knowing the rebate levels associated with competing products from other manufacturers. For example, if Manufacturer A's Drug A had an average rebate of 30%, and Manufacturer B's therapeutically equivalent Drug B had an average rebate of 20%, then Manufacturer A would know it may not have to provide as strong of a rebate for formulary inclusion or tier placement. Or, if Drug B had an average rebate of 40%, then Manufacturer A would know if might be able to obtain greater market share by setting a higher rebate level on Drug A.

- In general, increased cost transparency reduces negotiation leverage, which would result in higher overall Part D program costs. Respected government bodies and universities have established that confidential negotiations result in more competition and lower costs for patients and plan sponsors. The Federal Trade Commission has stated that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors … then tacit collusion among manufacturers is more feasible … Whenever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely."[199] And researchers at the University of Pennsylvania find that, "[t]ransparency requirements that attempt to set actual reimbursement for drugs at the pharmacy's or PBM's actual cost or acquisition price may have unintended consequences, leading to higher real costs and/or manipulated prices."[200]

- These changes could potentially result in significant formulary and market disruption. For example, if plan sponsors used transparent manufacturer cost rebate information to

[199] U.S. Federal Trade Commission and the U.S. Department of Justice, Improving Health Care: A Dose of Competition (July 2004)
[200] Danzon, P. "Pharmacy Benefit Management: Are Reporting Requirements Pro or AntiCompetitive?" (April 2015) https://bepp.wharton.upenn.edu/files/?whdmsaction=public:main.file&fileID=9696

change formulary tier placement or coverage for high-utilization products, members taking those products may either switch products or switch plans.

***PCMA Recommendation*: We oppose any mandate to pass through manufacturer rebates at POS. The RFI proposal will lead to reverse engineering, which will incentivize manufacturers to go to lower, standardized rebates. CMS must further factor in to any proposals in this arena the implications of revealing manufacturer rebate terms and the dampening effect this would have on the use of plan tools to compete and lower drug prices.**

A. Specified Minimum Percentage (pp. 56421-56422)

CMS Proposal: CMS is considering setting the minimum percentage of what must be passed through at less than 100%. This percentage would not change by drug category or class by year. CMS acknowledges this would result in larger premium increases for all beneficiaries and less plan flexibility. CMS also recognizes that this may result in weaker incentives for plans to participate in Part D. CMS is looking for an appropriate balance, and seeks comment on the minimum percentage and how often, and based on what factors, it should be updated, as well as the impact on competition for rebates under Part D.

Discussion: Unfortunately, as shown in the CMS impact tables, even if CMS considered a 33% rebate policy, manufacturers will receive a free ride. As previously stated, weighted average rebates are problematic because some drugs carry very little rebate benefit while those that provide meaningful rebate benefits lose, thus incentivizing manufacturers with relatively high rebate offers to lower or abandon rebates all together.

***PCMA Recommendation*: PCMA urges CMS to recognize that its specified minimum rebate approach is unworkable.**

B. Applicable Average Rebate Amount (pp. 56422-56423)

CMS Proposal: CMS sets out a methodology to calculate the applicable average rebate amount as follows:

- *Rebate Year*. Expected for current year, not historical.
- *Rebated Drugs*. Only for drugs where manufacturers provide rebates, and drug products with unique NDC codes considered separately.

- *Plan Level Average*. This would be calculated at the plan benefit level (e.g., separately for each plan).

- *Drug Category or Class*. The amount would be calculated on average amount at category/class level, and not drug specific. This would "prevent reverse engineering the particulars of any proprietary pricing arrangement." CMS is seeking feedback on what drug classification system Part D sponsors should be required to use.

- *Weighting*. CMS considering weighting by total drug costs for each drug, and seeks input on the relevant time period (e.g., month, quarter, year).

- *Timing*. CMS is also considering having plans recalculate the applicable average rebate on a time period to be determined.

Discussion: We do not believe there is any way for CMS to structure the methodology without facilitating the reverse engineering or free rider scenario, as detailed above. Some specifics on each aspect of the methodology are noted below.

- *CMS's Rebated Drugs Definition.* As noted above, the overarching concern is that blending causes manufacturers to aggregate reduced rebates because the manufacturers with aggressive rebates will not receive as much benefit, and manufacturers with smaller rebates get the most benefit. However, on a per drug basis, there are rebate transparency problems. In either event, the outcome is unacceptable.

- *Plan Level Average.* Doing this on an individual plan basis is problematic as a particular Part D sponsor may work with scores of Medicare Advantage entities at a time. Moreover, working with plans at a plan level would have implications for collusion. We also query as to how the Medicare Plan Finder would even work in this type of environment in terms of accuracy issues.

- *Drug Category or Class*. Requiring a specific drug classification system could readily go down the slippery slope of requiring the use of the USP model drug classification system and thus essentially mandating a formulary. As CMS knows, under Part D, the role of USP in establishing categories and classes has significantly diminished over time, to the point where very few Part D plan sponsors utilize the USP safe harbor. Instead, the Agency has developed an outlier approach to the review of formularies which appropriately balances beneficiary access with P&T committee formulary development. The idea of relying on USP, or AHFS, or any other third-party entity to determine categories and classes is counterproductive to best practices, the important functioning of

duly established P&T committees, and the competitive marketplace. In addition, it would be costly for the government and plans and would take significant time to establish the categories and classes. Moreover, USP is not planning its next update to the Medicare Model Guidelines until 2021. On a related note, over time, manufacturers have pushed USP, AHFS, and others to seek more granular classes to secure coverage. It is not clear why CMS would want to drag all the problems and uncertainties with drug categories and classes, under Part D, into the mandatory rebates at POS.

- *Weighting*. With regard to post-rebate costs or pre-rebate costs, it is very unclear what CMS is intending. Our questions include: How would a value-based rebate contract average into this? If a drug doesn't work, and the Part D plan sponsor gets a refund, does the beneficiary get their money back? How would that work? Would Part D plan sponsors be expected to front the money for the payment at POS because it's not collected from manufacturers at real time POS? Having to front the money would likely increase plan costs and therefore premiums. We assume Part D plan sponsors may seek to negotiate with the manufacturers to have them front the money in certain circumstances, but those negotiations could not take place until all of the issues identified herein are addressed.

- *Timing*. With regard to timing, CMS should consider a one-time, midyear adjustment (e.g., July 1). However, there would need to be a range of considerations factored in, including what happens to the timing if there are new drugs released midyear, or other major midyear changes (e.g., generic becomes available) that reduce the number of rebateable drugs in the class).

There also are significant other operational issues that CMS needs to consider. These include: What options are there other than using the historical rebate? What would the reconciliation process look like? What happens when final numbers are in and the beneficiary was given too much or too little of a rebate? Will the beneficiary owe any money? How will it impact TrOOP calculations for the beneficiary? What will be the administrative costs of repricing claims? How will that affect the plan's medical loss ratio?

Finally, as noted above regarding why estimates at POS are not currently used, there could be significant false claims exposure here for estimates that turn out to not be accurate. There would need to be unambiguous Agency guidance as to acceptable parameters for rebate estimations issued which are provided and subject to stakeholder input, significantly in advance of implementation, to alleviate this exposure.

PCMA Recommendation: ***We are not aware of any methodology that would address the free rider and other critical issues noted above.***

C. POS Rebate Drugs (p. 56423)

CMS Proposal: CMS hypothesizes that the rebate at POS policy would likely apply only to rebated drugs. CMS is also considering a more targeted approach which would require POS rebates only for drugs or classes that most directly contribute to increasing Part D drug costs. CMS wants comments on the more limited approach and criteria for determining which drugs to target.

Discussion: We assume that CMS seeks classes for this approach that are already highly rebated. If CMS were to consider implementation of a targeted approach, it should be limited only to a narrow subset of drugs to limit the disruption on Part D. We appreciate the idea to target more narrowly, but we still believe this violates non-interference. That said, if CMS were to define a very small subset of drugs where this could be tested or done in a way that doesn't bring up all the issues we have identified herein including the free rider concern, we would be glad to engage in discussions as to the viability of proceeding.

An alternative here may be for CMS to identify the most egregious class that contributes to cost and then consider piloting a manufacturer POS rebate on a demonstration basis. We think it may be difficult for a POS rebate approach to be able to coexist with a traditional approach, but with a limited set of drugs and making participation optional, there may be some insights gained.

PCMA Recommendation: ***If CMS addresses relevant issues including the free rider concern, it might be worth considering a demonstration through CMMI of a limited drug manufacturer rebate at POS.***

D. Additional Considerations (p. 56424)

CMS Proposal: CMS would leverage existing reporting mechanisms to review plan calculations (e.g., estimated rebates field at POS in PDE). Sponsors would be required to certify the accuracy, completeness and truthfulness of all data. This likely would be extended to POS rebate data, as well as PDE reopenings. CMS seeks comments on what other enforcement and oversight mechanisms should be instituted to ensure compliance with the POS rebate requirement. Specifically, it is seeking feedback on how to ensure accurate amounts when rebate agreements are structured with contingencies that would be unclear at POS. CMS seeks

comments on impact of applying the POS rebate requirements to EGWPs. CMS notes lack of clarity on to what extent the potential POS rebate should be included in determining the manufacturer's CGDP obligation.

Discussion: It is critical that CMS understand that there will not be a way for sponsors to make the certifications proposed since rebates are, by definition uncertain, and especially here where rebates would change over time and the program would be replaced with incentives to "game" the rebate levels. If CMS proceeds with implementation, there would have to be a period of enforcement discretion; frankly, we just do not understand how certification could work with all of the uncertainty that stems from this proposal.

With respect to the impact of applying the POS rebate requirements to EGWPs, while we strongly oppose the rebate at POS initiative, we think it would be chaotic in the marketplace if any such policy applied to some Part D plan offerings but not others. For example, how would beneficiaries be able to compare with the individual market? While we would consider the imposition of this policy to be interference with contracting between Part D sponsors/PBMs and employer groups, we also believe that CMS should have a consistent policy. Also, CMS should consider that Part D EGWPs receive additional revenue with increases in the Part D national average direct subsidy. As with the individual plans, reflecting DIR at the POS would increase the direct subsidy, thereby increasing EGWP revenue (and thus the federal government's EGWP program costs).

CMS also does not address the impact of the RFI proposals on copayments. Since the RFI states that DIR would be used to reduce the POS drug cost (rather than directly reduce member cost-sharing), it would reduce beneficiary cost-sharing only in cases where the enrollee's liability depends on the POS drug cost. Therefore, enrollees paying coinsurance, which is based on the POS drug cost, would see cost- sharing reductions. In most cases, enrollees paying fixed copays would not see cost-sharing reductions, since the fixed copay typically does not vary with the POS drug cost. We understand that the RFI does not specifically differentiate between copayments and coinsurance. However, as mentioned above, POS cost reductions would not typically affect fixed copays, so the proposal primarily applies to coinsurance. There could, however, be rare cases when enrollees paying copays may also realize savings with a lower POS drug price. In Medicare Part D, enrollees paying copays pay the lesser of the copay and the POS drug price. For example, if an enrollee's copay is $15 for a $10 POS-price drug, the enrollee would pay $10. If the POS drug price were reduced under the proposed "DIR at POS" arrangement, this enrollee would realize cost-sharing savings (e.g., the copay is $15, the $10 drug is now $8, and the enrollee would pay $8). This scenario may be unlikely to occur, as CMS is considering limiting the application of POS manufacturer rebates to only drugs that receive a

rebate, and price of a rebated drug is likely more expensive than a copay. However, it illustrates yet another aspect of the proposal that needs to be addressed.

***PCMA Recommendation*: If CMS proceeds on the concepts embodied in the RFI, it must provide detailed measurable requirements and guidance so there is no ambiguity in the marketplace. Otherwise, there could be major market disruption, let alone enforcement and oversight issues.**

E. Impacts of Applying Manufacturer Rebates at the POS (pp. 56424-56426)

CMS Proposal: Table 10, A-C summarizes the 10-year impact (2019-2028) of the policy. CMS notes that the data does not account for changes in sponsor behavior regarding drug pricing that would further reduce the cost of Part D (e.g., reduce the incentive to favor high cost-highly rebated drugs). CMS seeks comment on the extent to which a POS rebate would further align incentives for beneficiaries, plans and taxpayers.

Discussion: Under the Trump Administration policy set forth at Executive Order 12866 regarding offsets and new regulations, requiring costs to be offset to keep Medicare sustainable, CMS will need to offset the substantial costs of this undertaking. As noted above, we believe the costs to the beneficiary and the government has been underestimated. Moreover, the POS rebate construct is highly burdensome to the industry, and the whole concept is counter to reducing costs for the industry which will spend significant amounts to implement this.

***PCMA Recommendation*: PCMA is not aware of any way that the POS rebate concept in the RFI can possibly align incentives for beneficiaries, plans, and taxpayers. If CMS proceeds, it must offset the billions in costs (over $81 billion for the manufacturer rebate along with the pharmacy POS change discussed below) that it has identified. In any event, the costs – properly determined – need to be offset.**

F. Pharmacy Price Concessions to POS (p. 56426)

CMS Proposal: CMS states that an increasing share of pharmacy reimbursement is adjusted after POS based on pharmacy performance and an increasing share of pharmacy payments are recouped after POS based on poor performance, significantly more than paid out for good performance. These trends started after 2012 when preferred networks were launched. CMS tried to address this in the 2015 Parts C and D rule, which was issued in 2014, in the definition of negotiated price, requiring pass-through at POS with a narrow exception (if amount cannot reasonably be determined at POS). At that time CMS did not have data which reflected the pharmacy reimbursement trend noted above. CMS now realizes that the "reasonably determined"

exception is used so broadly that it "prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs." Stakeholders tell CMS that the exception is being applied to all performance-based payment adjustments. CMS seeks comments on how to update requirements to better reflect current pharmacy payment arrangements "to ensure that the reported price at POS includes all pharmacy price concessions." (emphasis added) CMS puts forth a possible approach and seeks comments on the merits.

Discussion: We have many of the same concerns articulated elsewhere in our NPRM and RFI comments here as well, including:

- CMS again relies on anecdotal evidence that no performance-based pharmacy payment adjustments are passed through at POS. We do not believe that is an accurate assessment and urge CMS to reassess the issue and to engage with all stakeholders before seeking to base a major new policy on anecdotes.

- If CMS were to proceed with its proposed approach, it would incentivize Part D plans to drop pay-for-performance standards. We think that would be counterproductive to a value-based Part D program and contrary to the direction of all other components of Medicare which are seeking to be more value-based.

- With respect to preventing the shifting of costs to taxpayers and beneficiaries. We ae not aware of any way to prevent the cost-shift which, as identified in Table II, is additional billions over ten years.

PCMA Recommendation: CMS clearly does not have the legal authority to make this change, as discussed in Part Two, section A above. We further urge CMS to consider a process involving all stakeholders to help it better understand current pharmacy arrangements, including the role of pay-for-performance.

1. All Pharmacy Price Concessions (pp. 56426-56427)

CMS Proposal: CMS is considering removing the reasonably determined exception and requiring that all price concessions be applied at POS, even if they are contingent. CMS lays out the case that it has legal authority to do this since the statutory language on rebates does not address entities other than manufacturers. Plus, the approach would still allow plans to "take into account" at least some price concessions (e.g., those from manufacturers).

Discussion: CMS clearly does not have the legal authority to make this change, as discussed in detail in the legal section above. Both the noninterference provision and the prohibition against setting a benefit structure bar it from adopting this policy.

PCMA Recommendation: In light of the clear impermissibility of the proposal, we urge CMS to reassess its RFI policy.

2. Lowest Possible Reimbursement (p. 56427)

CMS Proposal: CMS is considering requiring the negotiated price to include the lowest possible reimbursement that a network pharmacy could receive. The price at POS would exclude any additional contingent payments to pharmacies (e.g., incentive fees). Any such amounts ultimately paid to pharmacies would be reported as negative DIR. CMS seeks comment on whether this approach would address issues raised above about current industry practices. Would it standardize treatment of unknown amounts? Would it maximize cost-sharing savings for beneficiaries? Would it be operationally clearer to follow for Part D plans? Would it improve consistency? Would it improve the quality of pricing information available to the public (and therefore improve competition and cost-efficiency)? CMS seeks comments on whether this will help achieve meaningful price transparency. CMS again notes that it has heard that under the current system, pharmacies basically only suffer penalties. CMS seeks comments on whether the proposal will avoid the unintended consequence where the pricing differential creates a perverse incentive for beneficiaries to choose a lower performing pharmacy to take advantage of a lower price.

Discussion: As noted in the legal section above, this proposal is a clear violation of non-interference. Even if it were permissible, however, we do not understand how this would help pharmacies, who apparently regularly complain to CMS that they don't know what they are going to get paid. Ironically, the approach suggested by CMS will give pharmacies more certainty that they will be paid the lowest amount possible.

We are also concerned that this proposal will inhibit future innovation in the program by dictating the way plans must contract. The CMS construct underlying the policy seems to imply that there is a market rate for reimbursement that is somehow different from what is currently paid. Yet, CMS provides no evidence that this is the case – what is clear is that although the actual mechanics of the payment arrangement may change, the aggregate payment will not.

PCMA Recommendation: In light of the clear impermissibility of the proposal, we urge CMS to reassess its RFI policy.

3. ***Additional Considerations (p. 56428)***

CMS Proposal: CMS would like to use the existing estimated rebates field at POS on the PDE record and DIR reporting to collect data. CMS wants comments on whether this approach would make bids more comparable and more reflective of relative plan efficiencies, and whether it will make the Part D market more competitive and efficient. Finally, CMS notes that it is not sure if it has the legal authority to change the definition of negotiated price for purposes of the CGDP and that it will consider this in future rulemaking.

Discussion: We detail below the problems and unintended consequences of requiring the negotiated price to reflect the lowest possible pharmacy reimbursement.

a. Pharmacy cash flow

Many pharmacy DIR arrangements are currently structured such that the plan pays the full POS drug price when a drug is dispensed, and the pharmacy potentially reimburses the plan for a portion of the drug cost after the POS**.** From a cash flow perspective, this is advantageous to the pharmacy, since they benefit from collecting revenue earlier and get the float on the funds. However, under the proposed "lowest possible reimbursement" arrangement, pharmacies would lose this cash flow advantage.

The following simplified scenario illustrates this dynamic using investment income to quantify the different cash flow timing.

> Assume an initial drug price of $100 on January 1st, with a provision that the pharmacy pays the plan 0% to 5% of the drug cost at the end of the year based on quality metrics. Assume the pharmacy expenses for the drug are $90, and the pharmacy ends the year paying 4% of drug costs to the plan, having missed most, but not all, of its metrics on quality.

	[A]	[B]	[C] = [A]-[B]	[D] = 3%*([A]-$90)	[E] = [C]-$90+[D]
	POS drug price (plan to pharmacy)	**Post-POS DIR (pharmacy to plan)**	**Final reimbursement to pharmacy**	**Assumed 3% investment income**	**Pharmacy profit**
Current	$100	$4	$96	$0.30	$6.30
Proposed	$95	-$1	$96	$0.15	$6.15

In the above example, the "Proposed" POS drug price of $95 is the lowest possible reimbursement for the drug. The pharmacy collects investment income on the full spread ($100 POS price less $90 drug expense) in the current environment, but would collect only on the spread at the lowest possible price ($95 POS price less $90 drug expense) in the proposed scenario, reducing their ultimate revenue. In addition, the lower upfront pharmacy reimbursement under the RFI approach may pose challenges for small, independent pharmacies that do not have a lot of capital.

b. Preferred network disruption

The innovation of preferred networks has significantly reduced Part D program costs, including government costs and enrollee premiums, and provided enrollees access to reduced cost-sharing at preferred pharmacies. Post-POS DIR is a key driver of preferred network savings for many plan sponsors. The "lowest possible reimbursement" pharmacy price concession proposal would eliminate DIR payments from pharmacies to the plan sponsors, resulting in preferred network arrangements based on discount differentials alone. The elimination of pharmacy DIR may deteriorate the value of preferred networks, which may result in reduced cost-sharing differentials between preferred and non-preferred pharmacies (i.e. reduced enrollee access to lower preferred cost-sharing). In addition, some plan sponsors may realistically no longer be able to offer preferred network arrangements.

c. Member premium increase

Under the RFI policy, only *negative* pharmacy DIR would be allowed. This is because the "lowest possible reimbursement" approach prevents plans from collecting any pharmacy DIR after the POS, but may result in plans paying post-POS DIR adjustments to pharmacies. Therefore, Part D plan sponsors would need to account for expected negative DIR as additional costs in the bids submitted to CMS. This may increase bids, thus increasing member premiums.

d. Determination of drug-level "lowest possible reimbursement" amount

Many pharmacy DIR arrangements are based on aggregate, rather than drug-level, metrics. For example, payments may be based on an overall percentage of ingredient cost or per script amount. These aggregate metrics may not be appropriate to apply at the drug level. This could result in yet another set of contracting and operational challenges as plan sponsors and pharmacies work to implement a new drug-level approach.

PCMA Recommendation*: *CMS does not have the legal authority to change the definition of negotiated priced for purposes of the CGDP. There are significant unintended consequences

of the proposal, including for pharmacies, which CMS should consider as it revisits what it wants to do here.

4. Impacts of Applying Pharmacy Price Concession at POS (p. 56428)

CMS Proposal: CMS notes that the impact of applying all pharmacy price concessions at POS will largely affect beneficiary, government, and manufacturer costs the same as for the manufacturer rebate approach. The difference is the magnitude of the impact is much less. CMS does not address the impact on pharmacies, plan sponsors, or PBMs.

Discussion: The impact table ignores the money flow consequences for Part D plan sponsors and their PBMs. Indeed, nowhere in the impact table does it show any money flowing into, or out of, Part D plans or PBMs, which suggests that CMS agrees that Part D plans are passing along these rebates in the form of reduced premiums and cost-sharing via benefit design.

PCMA is concerned that the proposal would increase premiums and program costs. The proposal to eliminate DIR from pharmacies as a method to reduce beneficiary costs would result in higher premiums for all enrollees and would increase costs for the government and taxpayers. According to CMS's own analysis of POS pharmacy price concession impacts, in Table 11 (p 56428), enrollees are expected to experience a $5.7 billion increase in premium costs and the government a $16.6 billion increase in total costs over 10 years. Post-POS DIR price concessions cause a greater reduction in federal Medicare spending than equivalent drug discounts reflected at POS. Such amounts are reflected in lower plan premiums and are allocated to reduce federal direct subsidy payments.

Additionally, performance based pharmacy price concessions paid to sponsors through DIR do not increase Part D program costs as long as they are used to reduce premium. Furthermore, DIR allows sponsors to pass pharmacy savings through to all plan enrollees, ensuring that all beneficiaries benefit from the savings. Many PDP beneficiaries have a preference for experiencing savings through lower premiums and reduced cost-sharing rather than through lower negotiated prices at the pharmacy counter.

The RFI would also undermine preferred pharmacy networks. CMS has long supported a PDP sponsor's statutory ability to reduce cost-sharing or co-insurance for certain preferred pharmacies meeting a PDP sponsor's special terms and conditions. Indeed, CMS reiterates its goal of "ensur[ing] that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement." 56,371. Yet, by interfering in the negotiations between PDP sponsors and pharmacies, and by requiring all price concessions be included in the negotiated price, CMS would significantly hinder the ability of PDP sponsors

to craft preferred networks. Simply put – CMS has long interpreted AWP as "allowing Part D plans to reduce cost-sharing differentially for network pharmacies" (70 Fed. Reg. 4,194, 4,254 (January 28, 2005) – but now proposes to place severe limits on this flexibility by requiring all price concessions be passed through at POS, regardless of a pharmacy's ability to meet a PDP sponsor's special terms and conditions.

The RFI approach would result in decreased reimbursement rates for all pharmacies and therefore reduce pharmacy network size. As a result, the reimbursement rates offered to all pharmacies in the future could be significantly decreased. This decline in reimbursement rates, along with performance based quality no longer being incentivized, could result in contracting terms that may not be financially favorable to pharmacies. Many pharmacies may decide to no longer participate in the network therefore the current network of 60,000 pharmacies will likely contract, thus reducing consumer access to broad pharmacy networks. Moreover, if CMS finalizes its proposed AWP changes, the result will basically be much higher costs for everyone.

***PCMA Recommendation*: PCMA recommends that CMS continue to permit post-POS performance based pharmacy price concessions under the current requirements and allow such amounts to be reported as DIR (as opposed to being reflected in the negotiated price).**

List of Exhibits

Exhibit A: Any Willing Pharmacy Economic Impact Analysis by The Moran Company

Exhibit B: Notes on Industry Stakeholder Call with CMS, as distributed by CMS, December 1, 2016

Exhibit C: Rebate Reverse Engineering