BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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Mr. Demetrious Kouzoukas, Esq.
Principal Deputy Administrator and Director, Center for Medicare
U.S. Department of Health and Human Services
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model and Advance Notice of Methodological Changes for CY 2019 for MA Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter

Dear Deputy Administrator Kouzoukas:

The Blue Cross Blue Shield Association ("BCBSA") appreciates the opportunity to provide comments on the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model and Advance Notice of Methodological Changes for CY 2019 for MA Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter, "Advance Notice and Draft Call Letter" as issued on December 27, 2017 and February 1, 2018.

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans that collectively provide healthcare coverage for one in three Americans. For more than 80 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid. Today Blue Plans serve millions of Medicare beneficiaries in Medicare Advantage (MA) and Stand-Alone Part D (PDP) options.

Overall, we support many of the provisions in the Advance Notice and Draft Call Letter and thank CMS for its continued attention to policies that create more efficiencies for plans and providers, promote flexibility, innovation, and transparency, and improve the value of MA and Part D for Medicare beneficiaries.

We would like to highlight several issues, which are discussed in more detail, along with many other topics in our detailed comments. We recommend that CMS:

- **Maintain stable and accurate risk adjustment:** We appreciate CMS' adherence to the intention of the Cures Act. However, we find that the payment models proposed in the Advance Notice need more analysis before 2019 implementation. Bids are due in early June and the final Announcements will come in early March. There is a short window of time to assess the impact of the interactions among the new proposed model and the continued use of EDS and RAPS – all being phased-in at the same time. Therefore, we urge CMS to continue to work with stakeholders to develop a revised model or models that could be implemented in 2020, still meeting the timelines required by the Cures Act. At this time, BCBSA cannot endorse either of the new models proposed in the Advance Notice. In addition, BCBSA strongly recommends that CMS should maintain the current level of EDS for risk adjustment at 15 percent in 2019;
- **Ensure payment accuracy for ESRD beneficiaries:** BCBSA applauds CMS for its recalibration of the ESRD model and encourages CMS to recalibrate the ESRD model on a more regulator basis. We recommend that CMS consider phasing in the new, recalibrated model over time to smooth the impact and we request that CMS clarify in the final Rate Notice the impact of the new calibration on plans and the extent to which CMS will be providing further assessment of ESRD payment as required by the 21st Century Cures Act;
- **Create certainty in as to coding intensity:** CMS should not change its methodology for the coding intensity adjustment, until at least 2020, after providing detailed advance notice of contemplated methodologies to plans and other stakeholders and allowing sufficient time to provide meaningful and accurate feedback. CMS should conduct a robust stakeholders' inclusive evaluation to determine if this adjustment continues to be needed and, if so, what the right approach should be;
- **Ensure that all substantive updates to the Stars Rating program are proposed through formal notice and comment rulemaking with sufficient opportunity for public comment.** In the draft call letter, we provide feedback on CMS' discussion of measure changes for 2019, 2020, and beyond, but BCBSA would like to reiterate our support for the agency's direction proposed in the November 2017 MA and Part D rule, in which CMS would make substantive updates to the Star Ratings program through formal notice and comment rulemaking;
- **Ensure adequate funding for employer group waiver plans (EGWPs)** by maintaining the methodology applied 2017 and 2018 and including the new enhancement for PPO vs HMO membership; and
- **Provide additional flexibility for plans and value to beneficiaries:** BCBSA fully appreciates CMS' proposals to expand the definition of health-related supplemental benefits and provide additional flexibility in benefit uniformity, which will allow plans to innovate and provide high value coverage for beneficiaries. We thank the agency for these positive proposals which will enhance the value of MA for beneficiaries; and
- **Give full consideration to the attached communication from Triple S, our Blue Plan that operates in Puerto Rico,** outlining the current situation in Puerto Rico and the need to assure adequate funding for their Medicare Advantage options given the on-going challenges and unique issues facing Puerto Rico.

We appreciate your consideration of our detailed comments. If you have any questions or need additional information, please contact Jane Galvin, Managing Director, Regulatory Affairs at Jane.Galvin@bcbsa.com .

Sincerely,

Kris Haltmeyer
Vice President, Legislative & Regulatory Policy
Office of Policy & Representation

cc: Cheri Rice, Acting Deputy Director, Center for Medicare

DETAILED COMMENTS ON ADVANCE NOTICE OF METHODOLOGICAL CHANGES FOR CALENDAR YEAR (CY) 2019 FOR THE MEDICARE ADVANTAGE (MA) CMS-HCC RISK ADJUSTMENT MODEL AND ADVANCE NOTICE OF METHODOLOGICAL CHANGES FOR CALENDAR YEAR (CY) 2019 FOR MEDICARE ADVANTAGE (MA) CAPITATION RATES, PART C AND PART D PAYMENT POLICIES AND 2019 DRAFT CALL LETTER

Advance Notice Part I:
Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model

21st Century Cures Act

Issue #1: Addition of New Mental Health and Substance Abuse Diagnosis Codes

The 21st Century Cures Act (P.L. 114-255) requires CMS to evaluate whether other specified factors should be included in the risk adjustment model, (1853(a)(1)(C)(i)(IV)). Specifically, the Act directs CMS to evaluate mental health and substance use disorders.
CMS evaluated mental health and substance abuse diagnoses and proposes adding new hierarchical condition categories (HCCs) and adding new codes to existing categories to the CMS-HCC risk adjustment model for payment in 2019.

Recommendation #1:

BCBSA fully supports the inclusion of the aforementioned new mental health and substance abuse diagnosis codes and HCCs into the risk adjustment model for 2019.

Rationale #1:

These news codes will ensure accurate payment to treat beneficiaries with complex mental health and substance abuse disorders, especially as CMS and Plans work together to address the opioid epidemic.

Issue #2: Addition of New Chronic Kidney Disease Diagnosis Codes and Evaluation of ESRD Payment

The 21st Century Cures Act also directs CMS to evaluate the inclusion of new chronic kidney disease diagnosis codes into the risk adjustment model (1853(a)(1)(C)(i)(V)). The Act also allows all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021, in addition to those already enrolled in Medicare Advantage (MA) plans when they enter ESRD status or able to enroll in MA plans (42 CFR § 422.50). Related to these changes, Congress directs CMS to evaluate whether additional risk adjustment factors should be taken into consideration when computing ESRD payment; the initial evaluation is required to be complete by December 31, 2018 (1853(a)(1)(C)(i)(VI)).

Based on its analysis, CMS proposes to add one HCC for chronic kidney disease for payment in the CMS-HCC model for 2019.

Recommendation #2:

BCBSA supports the inclusion of the new chronic kidney disease diagnosis codes. We encourage CMS to continue to evaluate ESRD payment in a transparent, iterative way to ensure payment adequacy is improved before 2021, when more ESRD beneficiaries are expected to enroll in MA.

Rationale #2:

Several years ago, CMS removed multiple codes related to the early stages of chronic kidney disease, which negatively impacted the accuracy of payment for these patients and the ability of plans to invest resources in preventative measures to slow disease progression. Additionally, BCBSA has provided analysis to CMS to underscore concerns that the current ESRD risk adjustment and benchmark system is flawed and payment is inadequate to care for these complex patients. These concerns will be compounded in 2021 when all ESRD patients will have the choice to enroll in MA.

Issue #3: <u>Adjustments for Full-Benefit Dual Eligible Individuals</u>

The 21st Century Cures Act also requires CMS to makes adjustments for individuals dually eligible for Medicare and Medicaid (1853(a)(1)(C)(i)(III)).

CMS concludes that the agency's current policy of splitting the CMS-HCC model into six segments based on Medicare/Medicaid status, first implemented in payment year 2017, fulfills the directive established in the 21st Century Cures Act and thus proposes no change.

Recommendation #3:

BCBSA agrees with CMS's interpretation that the current sub-segmented model fulfills the spirit of the law. However, we encourage CMS to continue to evaluate the CMS-HCC model to ensure it accurately pays for individuals dually eligible for Medicare and Medicaid.

Rationale #3:

Dual eligible beneficiaries are the most complex Medicare beneficiaries and they represent an increasing proportion of the Medicare cohort. In order to effectively manage their care, MA plans must be able to address social determinants of health and other factors that impact the health status of these individuals. The increased flexibilities CMS is granting to tailor care can only be effectively leveraged when payment is adequate.

Issue #4: <u>Take Into Account Enrollee's Total Number of Diseases or Conditions</u>

The 21st Century Cures Act directs CMS to take into account the total number of diseases or conditions of an individual enrolled in an MA plan and states that CMS shall make an additional adjustment under such subparagraph as the number of diseases or conditions of an individual increases (1853(a)(1)(C)(i)(I)). Statute states that CMS must phase-in any changes to risk adjustment (including this change and previously listed changes, such as adding new codes), "over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years."

CMS considered two models and ultimately proposes to use the "Payment Condition Count Model". This model counts all HCCs in the 2017 CMS-HCC model (as opposed to the alternative model that was considered, which counted all payment and non-payment HCCs).

CMS interpreted the statute to mean that it must start to implement all changes to the model in 2019 to be completed in 2022. The proposed phase-in schedule is as follows:

- 2019: Payment Condition Count HCC model 25%/ 2017 CMS-HCC model 75%
- 2020: Payment Condition Count HCC model 50%/ 2017 CMS-HCC model 50%
- 2021: Payment Condition Count HCC model 75%/ 2017 CMS-HCC model 25%
- 2022: Payment Condition Count HCC model 100%/ 2017 CMS-HCC model N/A (fully phased-in)

Recommendation #4:

BCBSA urges CMS not to implement the "Payment Condition Count Model" in 2019. Plans conclude that this specific model does not effectively improve the accuracy of payment for beneficiaries with multiple chronic conditions, which was the intended provision in Cures. As an alternative to the proposed model and timeline, BCBSA recommends CMS evaluate potential new models that consider the total number of diseases or conditions of a beneficiary and announce them in the CY 2020 Advance Notice with a 60-day comment period. Such alternative models could include additional ways to consider the complexity of beneficiaries with a large number of confirmed diagnoses. To comply with statute, CMS could implement this alternative model in 2020 and phased it in over a 3-year period, from 2020 to 2022.

BCBSA encourages CMS to work with stakeholders, especially plan actuaries and financial managers, to improve the analysis and evaluation needed to effectively adopt a new model for risk adjustment that limits disruption. The 21st Century Cures Act did not offer a new payment model but a concept as to the need to address beneficiaries with multiple conditions. Therefore, CMS and Plans should work together to advance this concept into alternative models that are currently not under consideration.

Rationale #4:

A predictable risk adjustment model is crucial to a stable MA program. Adjustments and updates to the model are an inevitable part of the process. However, these changes must be made in a way that limits disruption to plans. We appreciate that CMS released the Advance Notice Part I earlier than in previous years, on December 27, 2017, in line with the goal of increased transparency and additional time for comment. However, the crosswalks were not released until a week later and the Normalization Factors and other payment elements actuaries need to effectively evaluate the model were not released until the announcement of the Advance Notice Part II on February 1, 2018.

Issue #5: Updating Data Years for Model Calibration

In conjunction with the implementation of the CMS-HCC model revisions required by the 21st Century Cures Act, CMS proposes to update the data years used to calibrate the current model to 2014 diagnoses predicting 2015 FFS costs.

Recommendation #5:

BCBSA supports CMS's proposal to update the data years used to calibrate the current model. However, BCBSA continues to remind the agency of the operational challenges and technical changes required each time the model coefficients are updated.

Rationale #5:

It is important that the risk adjustment model accurately reflect cost, which requires recurrent recalibration. However, these updates create operational disruption and implementation must be measured and transparent. These concerns are compounded when CMS is blending multiple models, as it did when implementing a new model (with removal of certain lower acuity codes) several years ago, when phasing-in the new model that segmented the model into six groups based on duals status and age, and once again when possibly enacting the changes required by the 21st Century Cures Act.

Encounter Data as a Diagnosis Source for Risk Adjustment

Issue #1: <u>Phase-In to Encounter Data System (EDS) for Risk Adjustment</u>

For 2019, CMS proposes to increase the proportion of the CMS-HCC model that is based on encounter data from 15% to 25%, resulting in a 25% EDS/75% RAPS blend in 2019. On average, BCBS Plans continue to face operational challenges and see a decrease in their risk scores and payment with the phase-in of EDS. Blue Plans reported an average difference between their EDS risk score and RAPS risk score in 2017 of -2.58%.[1] Impacts among those who responded to our survey ranged from -7.0% to -0.4%.

Recommendation #1:

BCBSA strongly urges CMS not to increase the EDS proportion and freeze it at the 2018 level of 15%. Though we support an eventual transition to encounter data as a source of diagnosis, we continue to have concerns about using EDS for payment purposes. We encourage CMS to allow for more time to ensure operational issues have been resolved and the completeness and accuracy of the data can be verified. However, we support the use of RAPS data, including inpatient data, in CY 2019 to support EDS data, though it is concerning that such supplemental data is necessary.

Rationale #1:

The Government Accountability Office (GAO) and Office of the Inspector General (OIG) have released multiple reports describing the implementation concerns with the phase-in of EDS as a source for diagnosis for risk adjustment.[2,3,4] Milliman recently issued an updated white paper

[1] Based on survey to all BCBSA Plans in January, 2018. Results based on 14 Plan responses to the questions "What is the percentage difference between your Plan's EDS risk score and RAPS risk score for payment year 2017?"
[2] OIG: "Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements are Needed." January 2018. https://oig.hhs.gov/oei/reports/oei-03-15-00060.asp

outlining the complexities and challenges of the transition to EDS and found that EDS-based risk scores continue to lag behind RAPS-based risk scores.[5] BCBSA also notes that a proposal in the FY 2019 President's Budget estimates that the transition to encounter data will reduce plan payments by approximately $11.1 billion over 10 years, suggesting that a too-fast transition before the EDS is stable and accurate could de-stabilize the MA market.

Additionally, we surveyed BCBS Plans on implementation of EDS. Thirteen Plans reported that they support freezing the current blend level at 15% EDS/85% RAPS, one Plan had no opinion, and no Plans supported increasing the blend to 25%/75%. Below are some specific comments:

- "There are higher volumes of errors on EDS than RAPS. EDS is mirroring PFFS claims submission requirements, which may not align with individual MA plan benefits or provider billing requirements. MA plans are still working trying to understand EDS error codes, identify missing data elements and waiting for additional guidance for error resolution recommendations from CMS to improve EDS acceptance rates. In addition, with CMS's proposal in the Advance Notice to supplement EDS risk scores with inpatient diagnosis codes from RAPs, it is clear not all allowable and necessary diagnosis codes are getting through on EDS, which directly affects MA payments and thus, the benefits we can offer our members. Lastly, Medicare Advantage Organization (MAO) reports are still changing which makes them difficult to rely on."
- "Yes, CMS should freeze at the current blend considering: (1) We know that plans continue to struggle with EDS, and the delay of the transition allows for more time to work through the complexities to getting an accepted 837 file through the EDS rules; and (2) The MAO-004s continue to have inaccurate data."

Issue #2: <u>Operational Improvements to EDS Implementation</u>

Even if the EDS phase-in is maintained at the current 15% EDS/85% RAPS blend, it is still crucial that improvements be made to EDS and that operational issues be resolved. BCBS Plans continue to experience issues with EDS, as detailed below.

Recommendation #2:

CMS should continue to work with plans to ensure there is a transparent, accountable process around EDS submissions. The EDS should be stable before it is solely relied upon as the basis for risk adjusted payments to plans. We encourage CMS to use the specific feedback provided below to improve the processes. BCBSA looks forward to facilitating discussions with Plans and CMS to ensure CMS has the operational feedback it needs to enact improvements.

Rationale #2:

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[3] GAO. "Medicare Advantage: Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments." January 2017. https://www.gao.gov/assets/690/682145.pdf

[4] GAO. "Medicare Advantage: CMS Should Fully Develop Plans for Encounter Data and Assess Data Quality Before Use." July 2014. https://www.gao.gov/assets/670/665142.pdf

[5] Milliman White Paper: "Medicare Advantage's transition from RAPS to EDS Risk Scores: 2017 impact". February 2018. http://www.milliman.com/insight/2018/Medicare-Advantages-transition-from-RAPS-to-EDS-risk-scores-2017-impact/

We conducted a survey of our Plans to give specific feedback to the agency on EDS implementation challenges. Please see the below table for a summary of the feedback:

BCBS Plan	In your experience has implementation of the EDS processes improved? Please include specific examples of how CMS could improve implementation.
Plan A	Yes, in our experience the EDS process has improved. The roll-back of EDS weighting has been an improvement for our blended risk scores and we expect the inclusion of RAPS inpatient data as an EDS supplement to improve our RAPS reconciliation process. However, it is very clear to us that, when compared to RAPS, EDS has a deficiency in data because of the inherent filtering rules. One suggestion we have is supplementing EDS professional and outpatient data with RAPS data.
Plan B	Yes, it has improved. Improvement opportunities include: 1) clearer communication about the edits, 2) reasons for rejection and 3) solutions to prevent rejections.
Plan C	In general the process has improved since 2012, but more is needed. The time lag between the MAO-002 report (the initial acceptance or denial of the claim) to the MAO-004 report (the report that shows what diagnoses were accepted for risk adjustment) is too long. The MAO-002 report generally comes back within a week of submission. The MAO-004 reports are generated monthly. However, depending on the timing of the initial submission of the claim, the plan may not know the full details of the claim/diagnoses for another 7-8 weeks.
Plan D	Yes, it has improved but our biggest concern is related to lab codes billed by physicians. These are accepted for RAPS because they are the result of a face-to-face office visit with an acceptable provider type. However, due to the physician billing the office visit and the lab service separately (even though they both occurred on the same day at the same site), we don't get credit under EDS for the conditions confirmed in the lab work. This occurs when the physician has his own lab, doesn't document the conditions on the office visit claim but waits and places them on a separate lab claim.
Plan E	Yes, the process has improved. However the monthly distribution of MA004 report should be release more frequently.
Plan F	From our vendor who handles the Risk Adjustment Submissions: "In my opinion the process has not improved. CMS is still delayed on releasing complete and accurate MAO-004 data. They have already had to have both a 2nd and 3rd phase of the layout. Phase III was supposed to correct the problems, but just after its release they said there would have to be a second version of Phase III to resolve all issues. After CMS released this Phase III Version 2, they announced in September 2017 that yet another version (Phase III Version 3) would be needed. As of yet they have not announced a release date for this."
Plan G	At this point, our biggest issue is inconsistent processing time. At some points during the year it took several days to a week to receive responses. Currently, we mostly get same day responses so we feel there have been improvements made this past year (There continues to be occasional unexplained times where responses become very delayed, so improvements need to continue to be made). It appears the inaccuracies on the MAO-004s are mostly fixed yet the file itself remains difficult to parse and work with. In addition, their delivery is extremely delayed. For example, we're still waiting to receive December 2017 and January 2018 files. In general, EDPS has seen many improvements and we look forward to them continuing to build on them.

BCBS Plan	In your experience has implementation of the EDS processes improved? Please include specific examples of how CMS could improve implementation.
Plan H	Yes, the process has improved and CMS has made some major changes based on commentary from Plans. However, we could still use improvement on the following: a. Inconsistent returns information – We submit data weekly, but we rarely receive all return files at the same time. Instead the results are spread out with no predictable pattern. b. MAO-004 return files are received only monthly, creating a difficulty during deadlines as well as when attempting to balance RAPS and EDPS. c. 277 Edits received at the billing provider hierarchical level do not include key information used to tie the record to a claim, and as a result cannot be identified and corrected. d. It would be helpful to have better information on how numbers on Report Cards are derived. There currently isn't sufficient information for Plans to derive the same numbers internally and therefore proactively monitor data. e. Fee for Service Rules appear to be applied to EDS edits, causing records to reject incorrectly.
Plan I	There has been some improvement. However, there are still plenty of opportunities to get better. Documentation needs to be centralized, simplified, and kept current. REGTAP is a good example of providing all three of these for the EDGE process; it is one place for all ACA EDGE-related material. EDGE has a specific document for all business rules and a separate Interface Control Document (ICD) for technical implementation. On the CSSC Operations website, EDS has three companion guides covering Institutional, Professional, and DME. These three documents overlap; they should be combined with the differences illustrated and specific business rules clearly called out. Also, like EDGE, an ICD document could contain all EDS inbound and outbound files. Documentation and memos need to be kept current. The most current HPMS memo related to EDS RA data deadlines is dated 2/17/2017. EDS needs a timeline like the 'EDGE Server Timeline' that is posted on REGTAP and is always current. The webinars and Q&A sessions are great and the EDS team has been providing better content. However, the business rules and changes that are being presented in the webinars need to make it into documentation, and not just a slide posted to a website. The content needs to make it into an official EDS process/program document like I mentioned above.
Plan J	CMS has improved the overall implementation. However, there are still issues. -CMS continues to issue multiple versions of EDS return files for plans to reprocess. These files are still not consistent, especially the MAO004s. -CMS does not issue a MOR for EDS until the final payment. EDS MORs should be issued on the same timeframe as RAPs MORs. -EDS user group calls are only held once a month. In many cases when questions are asked on the call (if there is time for Q&A) CMS states they will need to get back with plans on the answer. There is no real mechanism for them to get back with everyone. -It would be helpful if CMS would provide more information on small group interventions to work through filtering errors. -We would like to see more on how to use the MAO002 and MAO004 reports to reconcile the risk scores and payments at an EDS level. -On a recent EDS user group call CMS provided new guidance for populating NPIs. This was helpful. We would like to see more of this. For example, we would like CMS to provide more guidance on how to bypass errors for data elements that may not have been received from the provider for claims processing and/or enhanced benefits offered by MA plans not available with original Medicare (i.e. error code 21925 – conditions for swing bed SNF PPS claim are not met).
Plan K	CMS has resolved many operational headaches over time, so their implementation has improved. One process improvement that we recommend is improvements to the timeliness of data processing. It can take over a month for any data that is submitted to be processed and for us to receive the results.

BCBS Plan	In your experience has implementation of the EDS processes improved? Please include specific examples of how CMS could improve implementation.
Plan L	Our RAPS/EDS process is fully delegated to a vendor, which is further delegated to our vendor's sub-contractor, given the complexities and technical expertise of the area. It is our understanding, in our oversight role, that the process has gotten better since the onset. An area for improvement is accuracy in data from CMS, specifically correcting and re-issuing MAO-004 reports (which we know CMS is working on, with an expected delivery in April). Our vendor continues to find discrepancies in the MAO-004 whereby they expected to see an accepted record that does not show up on the MAO-004

Issue #3: <u>Establishing Milestones in EDS Implementation</u>

In response to the EDS implementation concerns listed above, BCBSA supports consideration of approaches, such as Encounter Data listening forums, monitoring and compliance activities, to ensure the problems are fixed before EDS is fully phased in for payment.

Recommendation #3:

BCBSA recommends that CMS and plans work together to establish a set of milestones—including the need for all testing of the filtering logic to be completed prior to bid submission—in order for the transition from RAPS to EDS to be successfully implemented. The following is an example of milestones that could be set by the agency to get to completeness and accuracy:

Milestone	Measure
Accurate data capture and intake by CMS	• Plan MAO-002 submissions match data input by CMS (this phase is largely complete). • CMS and plans address all issues with the new version of the MAO-004.
Accurate data processing in payment system	• Every submitted encounter that is eligible for payment must be accepted by CMS. Conversely, encounters that are not eligible for payment must be denied. Specifically, this standard has two vital parts: o Data Accuracy (6 to 12-month validation period): – Data must be retained throughout processing. All accepted encounter data needs to match submitted data to ensure integrity of the data and process. – For example: Eliminate mismatched Beneficiary HICNs. o Filtering logic programmed to accurately reflect payment policy: – All information that impacts MA payment needs to be accurately configured in the filtering logic. • CMS should share comparisons they have with each plan and/or mask a couple contracts and show results at a high level. • Plans should be involved in testing of the EDPS payments. Testing should use DOS 2015 or a model of focus on a particular contract.
Rigorous testing of filtering logic	• CMS should partner with plans and provide raps to EDPS compare reports by Payment Year. Plans have questions about DOS 2016 and have a level of doubt as there is delay in MAO-004 (~45 days) • All testing must be completed prospectively before the bid

Milestone	Measure
	submission deadline (i.e., for the 2019 bid cycle, CMS should complete all testing of the filtering logic by June 2018). • Plans rely on this information to form assumptions, which are then built into the bid submitted to CMS. Inaccurate information leads to significant beneficiary impacts, including the loss of value-added benefits.
Payment Validation	• Ensure a clear and complete outline of reconciliation process, including: ○ Method of payment validation, including models and examples ○ Data to be used in payment validation ○ Output from a test sample or contract ○ Timeline for payment and reconciliation ○ Appeals structure ○ Testing methodology
Increased Transparency; Transactional Reports Must be Available to Plans	• All RAPS based reports should be made available for EDPS data, with a 3 to 6-month testing period. • CMS should increase the rate at which MAO-004 will be issued.

While work towards achieving the above suggested milestones is ongoing, we stress that integrating performance metrics related to EDS submissions into potential compliance actions, negatively impacting plans, is premature.

We urge CMS to continue collaborating with stakeholders to develop sound, realistic standards that are representative of the issues important to CMS, sponsors, and providers before implementing any oversight and enforcement activities. This is a critical step that must be taken to ensure the ultimate success of an encounter data-based system

Recommendation #4:

The recommended milestones require plan engagement and CMS transparency—two elements that are key to a properly functioning, valid, and accurate system.

In regards to compliance actions, we understand the need for CMS to ensure that plan sponsors are actively engaged in making the transition to encounter data, and we support any efforts to improve both plans' and CMS' understanding of this data. While we agree that CMS should be monitoring this data, plan sponsors should not be penalized—whether through warning letters or Corrective Action Plans (CAPs) — with respect to the timeliness or quality of encounter data submissions until CMS' systems are consistently able to intake, process, and reconcile encounter data submissions with all sponsors.

Issue #4: <u>EDS Interaction with New Payment Condition Count Model</u>

As part of the phase-in to the new "Payment Condition Count Model", CMS is proposing to calculate the 25% EDS portion of the blended scores using the new "Payment Condition Count

Model" and calculate the 75% RAPS portion of the model using the current model (recalibrated with newer data and the newly added codes, as discussed above).

Recommendation #4:

BCBSA agrees with CMS that is makes sense – for operational simplicity – to pair EDS with the "Payment Condition Count Model" and RAPS with the current model. However, we have concerns about the intersecting complexities of increasing the use of EDS (explained above) with implementation of a new model (also explained above). In addition to delaying an increase of EDS and delaying implementation of a new model to 2020, we recommend that CMS speak to these concerns and provide more feedback on its plan for implementation of EDS, including tangible milestones, as well as any new model.

Rationale #4:

Tying a new model to EDS means that EDS phase-in will be locked into the same timeline that is in statute which directed the new model to be phased-in by 2022. This schedule will not allow for any course corrections that are needed. This rigidity gives us concern due to the challenges and reduced risk scores related to EDS phase-in, described above.

Advance Notice Part II:

Advance Notice Of Methodological Changes For Calendar Year (CY) 2019 For Medicare Advantage (MA) Capitation Rates, Part C And Part D Payment Policies

Attachment I: Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2019

Issue #1: MA Growth Percentage and FFS Growth Percentage (Non-ESRD & ESRD)

CMS' current estimate of the change in the national per capita MA growth percentage (NPCMAGP)/Total USPCC (Non-ESRD) for aged and disabled enrollees combined in CY 2019 is 5.44%. This estimate reflects an underlying trend change from 2018 to 2019 in per capita cost of 4.05% and the remaining change due to adjustments to the estimates for prior years due to higher than expected 2016 and 2017 MA spending. The proposed FFS United States per capita cost (USPCC) Non-ESRD update from 2018 to 2019 is 4.08%. The proposed update is higher than recent finalized FFS USPCC updates: 2018: 2.73%; 2017: 3.1%. The proposed FFS United States per capita cost (USPCC) for dialysis-only ESRD is 5.07%.

Recommendation #1:

BCBSA appreciates the updated data and insights into the changes in prior year data. We encourage CMS to continue to share details related to the underlying methodology and data trends in the growth percentages.

Attachment II: Changes in the Part C Payment Methodology for CY 2019

MA Benchmarks and Rebates

Issue #2: Benchmark Caps

No policy change was proposed. Though CMS shares the concerns stakeholders have raised, CMS has not identified an approach under section 1853(n)(4) of the ACA to eliminate application of the rate cap or exclude the bonus payment from the cap calculation.

Recommendation #2:

BCBSA continues to urge CMS to use its administrative authority to lift the caps on benchmarks so that contracts with high Star Ratings can access the full quality bonus payments (QBP) to which they are entitled. BCBSA has previously submitted a legal analysis that provides the agency with a pathway to accomplish this goal. We would be glad to have the agency review this analysis again for possible action on this issue.

Issue #3: Rebates

No policy change was proposed

Recommendation #3:

BCBSA has no comment.

Quality Bonus Payments

Issue #1: New Plan and Low Enrollment Plans Quality Bonus Payments (QBPs)

No policy change.

Recommendation #1:

BCBSA has no comment.

Issue #2: Contract Consolidations and QBP

CMS reiterated the policy change recently proposed in the MA/Part D regulation – (CMS-4182-P) (82 FR 56336). For the first year following the consolidation the QBP would be the enrollment weighted average 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.

Recommendation #2:

As stated in our comment letter to the recently released MA and Part D regulation (CMS-4182-P), BCBSA recommends that CMS finalize this approach as proposed, effective for the 2019 measurement year. The proposal seems fair and equitable to all stakeholders and we thank CMS for addressing this issue in a favorable manner.

Rationale #2:

BCBSA supports CMS's goal to ensure that Star Ratings are administered in a fair and equitable manner and "gaming" among contracts by organizations is not an acceptable practice for the sole purpose of being assigned a higher Star rating.

Issue #3: Double QBP Bonus Counties

No policy change was proposed

Recommendation #3:

BCBSA has no comment.

Calculation of Fee for Service Cost

Issue #1: Calculation of FFS Cost

The FFS cost for each county is a product of (1) the FFS USPCC, and (2) a county-level geographic index called the average geographic adjustment (AGA). For 2019, CMS is proposing to continue to incorporate refinements developed in prior years to update the claims data used to calculate the AGAs and to continue the repricing of historical data in the AGA calculation. Repricing historical claims, in conjunction with rebasing rates for 2019, ensures that the 2019 FFS rates for each county reflect the most current FFS fee schedules and payment rules. CMS did not adopt the MedPAC recommendation to base FFS costs only on beneficiaries with both Part A and Part B.

Recommendation #1:

BCBSA continues to encourage CMS to use only data from Fee-for-Service Medicare beneficiaries with Part A and Part B to set the FFS Growth Percentage used to set MA benchmarks. BCBSA was disappointed that this calculation was not in the Advance Notice. Our Plan in Hawaii, HSMA, has also raised issues in this area and we have presented their findings to CMS for future consideration.

Rationale #1:

MedPAC and others support this recommendation because it would promote equity in county benchmarks and reflects trends in certain counties with a large percentage of individuals in FFS only enrolled in Part A.

Issue #2: Average Geographic Adjustment (AGA) Methodology

CMS proposes to update the data using the same process as in previous years, by adding the 2016 cost and enrollment data, so the five-year rolling average will be based on FFS claims data from 2012–2016 and updating and repricing other data based on the most currently available data.

CMS also intends to continue to make special updates to the Puerto Rico AGA & Zero Claims Adjustment to only include claims and enrollment for beneficiaries with Part A eligibility and Part

B enrollment for all five years (2012–2016) in the AGA. In 2017 and 2018, the Secretary had directed the CMS Office of the Actuary (OACT) to adjust the FFS experience for beneficiaries enrolled in Puerto Rico to reflect the nationwide propensity of beneficiaries with zero claims. CMS is considering whether a similar adjustment should be applied for 2019. The OACT will perform an analysis that is similar to the analysis performed in 2017 and 2018, but with an updated five years of data: 2012–2016. CMS requests comments regarding a similar update to Puerto Rico's experience in the development of the 2019 FFS rate. CMS will review the results of this study and any comments they receive, and will specify in the Final Rate Announcement any adjustment determined necessary based on results and comments.

Finally, for CY 2019, CMS proposes two related changes to the adjustment to FFS per capita costs for beneficiaries dually enrolled in Veterans Affairs (VA) and/or the Department of Defense (DoD) health programs; 1) adjust the FFS rates by the VA ratios and the DoD ratios, using results from a study based on FFS data from calendar years 2011-2015; 2) address potential "double counting" of the effect by replacing the separate VA and DoD adjustments with a consolidated adjustment.

Recommendation #2:

BCBSA supports all proposed changes to the AGA. We continue to encourage CMS to make the appropriate adjustments to payments in Puerto Rico to account for the unique characteristics of their healthcare system and the beneficiary cohort in the territory. We have attached a separate communication from Triple S which speaks to their current issues and challenges as to payments. We urge CMS to give their communication every consideration given the unique features of their population. We regret the OACT analysis was not in the Preliminary Announcements which would have provided an opportunity for comment.

Rationale #2:

As CMS described in the Advance Notice, while most Medicare beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in Puerto Rico must take affirmative action to opt-in to Part B coverage. This leads to a differential enrollment rate in Puerto Rico than that in the mainland, leading to payment inaccuracy in Puerto Rico.

IME Phase Out, ESRD Rates, Clinical Trials, Location of Network Areas for PFFS Plans in Plan Year 2020

Issue #1: <u>Indirect Medical Education (IME) Phase Out</u>

No policy change.

Recommendation #2:

BCBSA has no comment.

Issue #2: <u>ESRD Rates</u>

CMS has recently incorporated enhancements to the ESRD data system and projection methodology, and will now be able to apply repricing adjustments to the CY2019 ESRD rates, similar to the non-ESRD rate methodology.

Recommendation #2:

BCBSA continues to be concerned with MA ESRD rates that need to ensure the ability of plans to sustain the high costs of these patients from year to year.

Rationale #2:

The Medicare Advantage program overall needs to be ready to be able to handle an influx of new ESRD patients in 2021. One critical step is to make certain that ESRD rates are fair and equitable and do not create new risks for plans that could lead to financial instability, especially in small plans.

Issue #3: Clinical Trials Adjustments and Location of Network Areas for PFFS Plans in Plan Year 2020

No policy changes.

MA Employer Group Waiver Plans

Issue #1: New EGWP Payment Methodology

CMS is proposing to complete the transition to the new payment methodology for 2019. Therefore, CMS intends to continue to waive the Bid Pricing Tool bidding requirements for all MA employer/union-only group waiver plans (EGWPs) for 2019. CMS proposes, as a condition of the waiver of the bidding requirements and the waivers otherwise provided to EGWPs, to establish payment amounts as described herein. In connection with the continuation of this waiver, for 2019 CMS is proposing to fully transition in 2019 to using only individual market plan bids to calculate the bid-to-benchmark (B2B) ratios to set EGWP payments, as initially discussed in the 2017 Advance Notice and Rate Announcement. The completion of this transition was initially contemplated for implementation in 2018, but was delayed for the reasons articulated in the 2018 Rate Announcement.

Recommendation #1:

BCBSA recommends that CMS freeze at the current blend (50 old methodology/50 new bid-to-benchmark methodology) and refrain from the phase-in to the new methodology in 2019 as proposed. However, we recommend that CMS apply their proposal to recognize HMO and PPO membership as this enhancement will allow for a better reflection of employer group offerings in MA. Twenty percent of all MA members are enrolled in an employer retiree plan and CMS needs to make sure that this segment of the market is again not hit with reductions in payments that lead to reduces benefits and/or higher premiums.

Rationale #1:

It is important to provide stability in the EGWP market to ensure that EGWP Plans are able to implement changes and satisfy the elements of their contracts with states, unions and other employers. Freezing the methodology also makes sense if CMS also accepts the recommendation to implement a new proposed step to its payment methodology as described below.

Issue #2: <u>Consideration of Adjustment for Proportion of HMOs vs. PPOs</u>

CMS is considering the inclusion of an additional enhancement in calculating the B2B ratios whereby an adjustment would be made to the calculation used to determine the B2B ratios to account for the difference in the proportion of beneficiaries enrolled in Health Maintenance Organization (HMO) vs Preferred Provider Organization (PPO) plan types between EGWPs and individual-market plans. Under this alternative proposal, for 2019, the 2018 individual market B2B ratios would be adjusted to account for the difference in the proportion of beneficiaries enrolled in HMO vs PPO between EGWPs and individual market plans. Specifically, to determine the weighted individual market B2B ratios, the individual market ratios would be calculated separately by plan type. HMO and HMO/POS plans would be combined into an "HMO plan type" and LPPO and RPPO plans would be combined into a "PPO plan type." Then, the plan type individual market B2B ratios by quartile would each be weighted by the total proportion of 2018 EGWP enrollment in the plan type across all quartiles. The calculations for the ratios would therefore be as follows:

- First: [(weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for 2018 individual market plan bids by February 2018 actual enrollment)/(weighted average of the county standardized benchmarks for 2018 individual market plan bids by February 2018 actual enrollment)] = 2018 individual market B2B ratios by quartile.
- Second: The 2018 individual market B2B ratios would be calculated separately for HMO plan types and PPO plan types by quartiles. The PPO B2Bs by quartile would be weighted by the total proportion of EGWP PPO plan type enrollment, and the HMO B2Bs by quartile would be weighted by the total proportion of EGWP HMO plan type enrollment to result in the final B2B ratios for 2019 by quartile.

Recommendation #2:

In addition to freezing the methodology at the current 50/50 blend, for CY 2019 BCBSA strongly recommends that CMS implement the additional step to the new methodology (as described above) to account for the proportion of PPO membership. This change will make the payment methodology more accurate to reflect MA employer plan offerings and will create additional stability in this growing area of MA. The current methodology does not accurately account for the PPO options most common in EGWPs.

Rationale #2:

EGWPs are a growing portion of MA as more states and employers turn to the MA program for its ability to control costs and provide quality, comprehensive coverage with care management. Since group retirees often reside and travel all over the country, the majority of EGWPs are PPO plans.

Issue #3: EGWP Payment Implementation

CMS is seeking comments on whether it should:

- Fully phase-in the current B2B methodology in 2019, as proposed;
- Fully phase-in to a B2B methodology in 2019, but include an additional step to adjust for the proportion of HMOs vs. PPOs (as described above); and
- Maintain the payment methodology that was applied in calculating the 2017 and 2018 MA EGWP payment rates for 2019. The B2B ratios used in 2017 and 2018 payment were calculated using a blend of all individual market plan bids and all EGWP bids from 2016, each weighted by 50% to determine the B2B ratios by quartile;

Plans would be pleased if CMS were to maintain the payment methodology that was applied in calculating the 2017 and 2018 MA EGWP payment rates (50/50 weight), but include the additional step to adjust for the proportion of HMOs vs. PPOs (as described above). Under this approach, the 2016 individual plan bid-to-benchmark ratios would be re-weighted, using February 2016 enrollment, based on the proportion of EGWP enrollment in PPOs vs. HMOs to determine the individual market portion of the blended bid-to-benchmark ratios.

Recommendation #3:

As stated above, BCBSA recommends that CMS freeze the payment methodology at the current 50/50 level and also include the additional step to adjust for the proportion of HMOs vs. PPOs membership in the new methodology portion of the blend (as described above).

Risk Adjustment Models

Issue #1: ESRD Risk Adjustment Model for CY 2019

For 2019, CMS proposes implementing an updated version of the ESRD risk adjustment model. The ESRD model currently used in payment was implemented in 2012 and has not been recalibrated since then. Therefore, for 2019, CMS proposes to update the ESRD model.

As you know, the 21st Century Cures Act allows all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021, in addition to those already enrolled in MA plans when they attain ESRD status or able to enroll in MA plans under 42 CFR § 422.50. Since many plans will experience an increase in their MA ESRD population in future years, CMS believes it would be preferable to update the ESRD model prior to that time and are proposing the implementation of an ESRD model calibrated on data that are more recent. While the HCCs used in the ESRD model are similar to those used in other MA risk adjustment models, CMS calibrated the ESRD model using the FFS ESRD population and, therefore, the resulting coefficients reflect cost and disease patterns for this subgroup of beneficiaries.

While the basic structure of the model and the HCCs will remain the same, CMS proposes the following two updates to the ESRD model for 2019:

- Update the data years underlying the model, and;

- Update the Medicaid factors to be concurrent with the payment year.

The ESRD risk adjustment model that CMS is proposing for 2019 is structurally the same ESRD model that is has used since 2005 in that it retains separate coefficients for dialysis, transplant, and post-graft beneficiaries. Further, it is the same clinical version of the ESRD model that is currently being used in payment (i.e., CMS has not made any changes to the HCCs from the 2012 model, which are being used to calibrate the new ESRD model).

Recommendation #1:

BCBSA thanks CMS for its recalibration of the ESRD model and encourages CMS to recalibrate the ESRD model on a more regular basis, as it does with the non-ESRD CMS-HCC model. We recommend that CMS consider phasing in the new, recalibrated model over time to smooth the impact of implementation. We request that CMS clarify in the final Rate Notice the impact of the new calibration on plans and the extent to which CMS will be providing further assessment of ESRD payment, required in the 21st Century Cures Act by December 31, 2018.

Rationale #1:

As discussed above, BCBSA continues to have concerns that ESRD payment is currently inadequate to properly manage these complex patients, such as steps necessary to halt the progression of the disease and invest in care innovations in order to improve outcomes and quality of life for these patients.

Issue #3: Frailty Adjustment for PACE organizations and FIDE SNPs

There is no change proposed to the frailty factors included in the frailty score calculation for PACE organizations in PY 2019.

Recommendation #3:

BCBSA has no comment.

Medicare Advantage Coding Pattern Adjustment

Issue #1: Coding Intensity Adjustment

For 2019, CMS proposes to apply the statutory minimum MA coding pattern adjustment of 5.90%.

Recommendation #1:

We support CMS's decision to implement the statutory minimum for coding intensity.

Rationale #1:

Stable risk adjustment is essential for stable MA payment, especially as other major changes are enacted, such as the addition of new codes, the phase-in of EDS, and possible implementation of a new model at some point that accounts for enrollees' condition counts.

Issue #2: <u>Alternative Methodologies</u>

CMS is considering multiple methodologies to inform its final decision regarding the Coding Intensity Adjustment for CY 2019. Three methodologies that have been publicly discussed include:

- The methodology discussed in the Payment Year 2010 Advance Notice and Rate Announcement, found here: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html;
- The methodology discussed in the Payment Year 2016 Advance Notice and Rate Announcement, also found at the same Web page; and
- The methodology discussed in MedPAC's March 2017 Report to Congress: Medicare Payment Policy. The report can be found here: http://medpac.gov/docs/default-source/reports/mar17_medpac_ch13.pdf?sfvrsn=0

CMS is considering these methodologies and seeking comments on these and alternative methodologies for finalizing the MA coding adjustment factor in the 2019 Final Rate Announcement

Recommendation #2:

BCBSA urges CMS not to change its methodology for determining the coding intensity adjustment factor in 2019. CMS should not change its methodology until at least 2020, after providing detailed advance notice of proposed changes in methodologies to plans and other stakeholders. The information provided in the 2019 Advance Notice for all three contemplated methodologies is outdated, insufficient, or both. Plans need significant details about any potential change to the coding intensity adjustment factor calculation in order to provide meaningful and accurate feedback to CMS.

As CMS considers updating this methodology, BCBSA urges CMS to keep the following questions/concerns in mind, and should provide opportunities for plans and other stakeholders to weigh on these issues as part of a formal comment process:

- What data should the adjustment be based on (including which cohorts of beneficiaries and which years)?
- To what extent do changing MA enrollee patterns make prior year trends irrelevant?
- How should the adjustment control for the disproportionate dispersion of MA vs FFS members?
- Should the coding intensity adjustment be recalibrated along with risk model recalibrations?
- How do the FFS normalization factors interact with the coding intensity adjustment?
- What is the impact of ICD-10 on so-called differences in coding intensity between MA and FFS?

- How should enrollment in different plan types – HMO and PPO options, SNPs, and Medicare-Medicaid Plans (MMPS) – be factored in to determining a potential adjustment?
- What other elements not reflected in historical FFS or MA data need to be adjusted? For example, to what extent does $0 cost sharing for Medicare Supplement plans and dual eligibles distort comparisons between MA and FFS members?
- How will CMS review medical records (both MA and FFS) to determine the adjustment?
- Should the adjustment continue to be the same across the industry, or specific to contracts or plans? How will CMS share that information with organizations?
- Should risk score growth rates be considered a proxy for coding disparity? How will CMS' analyses evaluate whether differences in MA and FFS risk score growth rates are driven by demographics or morbidity or not?

Rationale #2:

Changing the coding intensity adjustment in 2019 would create instability in payment and does not support the goal of a strong, growing MA program.

Normalization Factors

Issue #1: <u>Normalization Factor Methodology</u>

The Normalization Factor serves two main purposes in the MA risk adjustment models:

1) it keeps the average risk score at 1.0 for beneficiaries in FFS Medicare so that risk scores in the payment year align with the FFS rates used for payment. This helps account for shifting coding patterns or demographic changes, such as the aging-in of the baby-boomers; and

2) since the risk adjustment model isn't calibrated every year, updating the Normalization Factor annually stabilizes payments between risk model calibration years.

There is a separate Normalization Factor for each risk adjustment model in MA, including for each new "Payment Condition Count" model proposed in the Advance Notice (Part I). As part of this release, CMS also proposes to blend 75% of the risk score calculated with the CMS-HCC model used for payment in 2017 and 2018 with 25% of the risk score calculated with the proposed "Payment Condition Count" model. Consistent with that proposal, for payment year 2019, CMS proposes to calculate two normalization factors for MA, one for the CMS-HCC model used in payment year 2017 and 2018, and one for the proposed "Payment Condition Count" model, that would be blended with their respective risk scores in payment.

CMS proposes to maintain the linear slope methodology for all models in payment year 2019. In payment year 2018, CMS returned to using a linear slope method of projecting Normalization Factors that was used prior to payment year 2015, after using a quadratic functional form for several years. Using this method, CMS projected the slope of the observed trend over five years of historical risk scores, from the denominator year to the payment year. The trend includes 2013 through 2017 risk scores to calculate the normalization factor for the CMS-HCC

model, PACE model, ESRD Dialysis model, and ESRD post-Graft model. CMS proposes to use 2012 through 2016 risk scores to calculate the normalization factor for the RxHCC model.

Recommendation #1:

BCBSA encourages CMS to be more transparent in its calculation of Normalization Factors. A better understanding of the methodology, rationale, and underlying data trends would strengthen a plan's ability to incorporate these factors into their modeling and ensure a stable MA payment model.

Rationale #1:

Normalization is key to ensure an accurate risk adjustment model between calibrations, especially when large demographic shifts like the age-in of the "baby-boomer" generation is affecting the FFS and MA cohort. Over the past few years, the Normalization Factor methodology has become an area of confusion and uncertainty for MA organizations. Changing methodologies (from linear to quadratic and back again), issues with denominator years, interaction with ICD-9 and ICD-10 codes, and changing patterns in FFS risk score patterns cause concerns. These concerns are compounded while CMS is phasing in new risk adjustment models, all of which need different Normalization Factors. CMS should provide more data and transparency to ensure all stakeholders are informed about the decision process and methodology of updates to ensure confidence in the accuracy of CMS's normalization approach. Suggested data include: more information on the change from ICD-9 to ICD-10; a better understanding of the change in 2015-2016 FFS risk score changes; and other information and data related to the factor calculation and how it compares to previous years' methodologies.

Issue #2: <u>Normalization Factor Update for the CMS-HCC Model</u>

The proposed MA Normalization Factor for the CMS-HCC model used in payment years 2017 and 2018 is 1.041 and the proposed MA Normalization factor for the "Payment Condition Count" model is 1.038.

Recommendation #2:

BCBSA has no comment on the update.

Issue #3: <u>Normalization Factor for the PACE Model</u>

The proposed 2019 Normalization Factor for the CMS-HCC risk adjustment model used for the PACE program is 1.159. CMS is soliciting input on whether to apply a different approach to determine the Normalization Factor.

Recommendation #3:

BCBSA has no comment on the PACE Normalization Factor update or methodology.

Issue #4: <u>Normalization Factor for the ESRD – Dialysis and Post-Graft Models</u>

The proposed 2019 Normalization Factor for the ESRD dialysis model is 1.033 and the proposed 2019 Normalization Factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.048.

Recommendation #4:

BCBSA has no comment on the update.

Issue #5: Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The proposed 2019 Normalization Factor for the RxHCC model is 1.020.

Recommendation #5:

BCBSA has no comment on the update.

Medical Loss Ratio Credibility Adjustment

Issue #1: Medical Loss Ratio Credibility Adjustment

No policy change.

Recommendation #1:

BCBSA has no comment.

Encounter Data as a Diagnosis Source for 2019

Issue #1: Encounter Data System Implementation

BCBSA provided comments on this issue above with recommendations and insights from our Plans on operational impact issues.

Quality Payment Program

Issue #1: MACRA Implementation

As part of the implementation of the Other Payer Advanced APM part of MACRA starting in 2020, CMS will need to work with MA plans and clinicians to obtain information on payment arrangements in order to determine if they qualify as Other Payer Advanced APMs. CMS will do this using both a payer-initiated process and a clinician-initiated process. The payer initiated process will be voluntary and will be carried out in 2018 prior to the 2019 performance period. As part of the 2019 bid submission, Medicare Health Plans (including MA plans, cost plans, and MMPs) may submit applications to determine if their payment arrangements are Other Payer Advanced APMs. Payers may request Other Payer Advanced APM determinations from August 1 to December 1 of the same year as the relevant QP Performance Period.

CMS is implementing the payer-initiated process prior to 2019 so that they can publicly announce which payment arrangements are Other Payer Advanced APMs prior to the 2019 performance period. The clinician-initiated process will generally occur after the 2019 performance period, when APM Entities and eligible clinicians will be allowed to submit information on payment arrangements that they believe are Other Payer Advanced APMs, but were not identified through the payer-initiated process.

Recommendation #1:

BCBSA encourages CMS to review its Payer-Initiated Submission Form application timeline for future performance periods and allow a rolling application process rather than a time-limited submission deadline. We also call on CMS to allow payers or clinicians to submit determinations for 2020 as early as 2018 (rather than 2019).

Rationale #1:

An efficient and responsive process is key here to certifying physician payments under MACRA and certifying APMs in Medicare Advantage organizations' contractual arrangements with their network providers.

Attachment VI: Draft CY 2019 Call Letter

Star Ratings

Issue #1: <u>Enhancements to the 2019 Star Ratings and Future Measurement Concepts</u>

After the 2019 Call Letter is finalized, CMS' current Part C&D Star Ratings contractor (RAND Corporation) will establish a Technical Expert Panel (TEP) in 2018 comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures. CMS notes that the TEP may also provide suggestions regarding the data integrity review process and how the Star Ratings should relate to audits and enforcement actions.

Recommendation #1:

BCBSA is very supportive of the establishment of this Technical Expert Panel and had included such a recommendation in previous discussions with CMS. BCBSA would like to have representation on this panel and looks forward to the selection process. This Panel is a positive step in the right direction and BCBSA thanks CMS for this proposal.

We would also like to reiterate our request for CMS to return to the pre-determined 4-star threshold for Star Ratings. Without these thresholds, plans do not have the ability to appropriately focus on efforts and measures that most benefit their members.

Rationale #1:

Many other segments of Medicare have a technical panel for their measurement activity so establishment of this panel puts Star Ratings on a level playing field with other quality measurement systems in Medicare.

Issue #2: New Measures for 2019 Star Ratings

CMS proposes to add two new measures for 2019 Star Ratings:

- Statin Use in Persons with Diabetes (SUPD) (Part D): This measure is the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. CMS proposes to add this measure to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year. In subsequent years, CMS proposes a weight of 3 as an intermediate outcome measure.
- Statin Therapy for Patients with Cardiovascular Disease (Part C): This is currently included as a display measure. It focuses on the percentage of males 21 to 75 years old and females 40 to 75 years old who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin during the measurement year. CMS proposes to include this measure in the 2019 Star Ratings as a process measure with a weight of 1.

Recommendation #2:

BCBSA recommends that both of these measures retain "display" status until 2020.

Rationale #2:

BCSBA does not believe that either of these measures are ready to be formal Star measures.

In regard to the Statin measures, Plans also oppose CMS' proposal to eventually assign this measure a weight of 3. Compliance for these measures require only a single fill, which in and of itself does not represent an outcome measure. In order for a medication to truly contribute to an outcome, the medication requires adherences over a course of treatment, as it evidenced by the triple weighting of the medication adherence measures.

With respect to the Part C measure, this measure should remain as a display measure to better understand and review the performance until at least 2020. HEDIS measures in part rely on information included in medical records. Such data collection is expensive and burdensome. In addition, by relying on medical record data, rather than claims data, the measure is satisfied through a single fill of a statin. It is not clear that this HEDIS measure truly represents an outcome but rather recognizes that the physician properly prescribed the right drug relative to a diagnosis. As such, the measure is not an outcome measure, but rather a process measure. BCBSA encourages CMS to carefully analyze the definition of outcome measures.

Finally, Plans note that CMS should consider consolidating the measures of statin in use in persons with diabetes (SUPD), statin therapy for patients with cardiovascular disease (SPC), and the current statin adherence measure into a single statin measure. Managing around the technical variations of each metric may distract health plans from focusing on overall clinical quality improvement.

Issue #3: <u>Changes to Measures</u>

CMS outlines the measures proposed to calculate the 2019 improvement measures for Part C and D in 2019. CMS currently incorporates the improvement measures in determining a contract's overall Star Rating, and follows a specific methodology for calculating the improvement measures themselves, but does not address this methodology specifically in the Draft Call Letter.

Recommendation #3:

BCBSA would like to reiterate our concerns with CMS' approach, which we most recently provided to CMS in response to the MA and Part D proposed rule for CY 2019. We recommend that CMS adopt several changes to the improvement measures in order to ensure that the measures rewards plans that improve their quality, while not adversely impacting consistently high-performing plans.

CMS currently calculates the improvement measures in determining a contract's overall Star Rating using a methodology that calls for either inclusion of both Quality Improvement (QI) measures or exclusion of both QI measures. However, the current approach can potentially penalize plans who have consistent high performance in either the Part C or Part D group of measures, year over year.

For example, if Plan A had high performance for Part C measures in Year 1 and maintained that high performance in Year 2, the QI calculated for the Part C QI would be approximately zero change, thus earning Plan A a 3 Star for the QI measure rating. Given that the QI measures (C31 and D07) have a weighting value of 5, this 3 Star negatively effects Plan A's Overall Star Rating. To allow plans the ability to benefit from quality improvement without penalty in the other Part C or D group of measures, CMS should calculate plans' Star Ratings separately for Part C and Part D with and without the improvement measures to first determine if the corresponding QI measure should be included in the overall Star Rating calculation. Currently, the "hold harmless" methodology accounts for both QI measures together. A more appropriate approach would therefore be for CMS to calculate MA plans' Overall Star Ratings separately for Part C and Part D with and without the improvement measures to first determine if the corresponding QI measure should be included in the overall Star Rating calculation. We propose the following revision for MA-PD contracts:

1) Calculate the overall rating for MA-PD contracts with just the Part C improvement measure.
2) Calculate the overall rating for MA-PD contracts with just the Part D improvement measure.
3) Calculate the overall rating for MA-PD contracts *without* including either the Part C or the Part D improvement measures.
4) Calculate the overall rating for MA-PD contracts *with both* the Part C and Part D improvement measures.
5) If an MA-PD contract in any steps 1 through 4 has four (3.75) or more Stars, CMS should use that overall rating—otherwise, CMS should use the overall rating from step 4.

Example: Plan A

- Step 1: Overall rating with just Part C improvement measure = 3.783
- Step 2: Overall rating with just Part D improvement measure = 3.628
- Step 3: Overall rating without either improvement measure = 3.681
- Step 4: Overall rating with both improvement measures = 3.727
- Step 5: Use overall rating from Step 1 (include only the Part C improvement measure) = 3.783

CMS' methodology for how the QI measures are calculated (C31 and D07) should also be modified to include measures for which plans achieved and maintained at least 4 Stars in the "hold harmless" category. Though CMS compares year-over-year performance for all QI-eligible measures, the "hold harmless" provision only applies to those measures for which a plan scored 5 Stars for both years in the comparison (and are therefore deemed by CMS to be "not applicable" to the QI calculation). This deviates from the general rule CMS follows for "hold harmless," where plans earning 4 Stars or higher are deemed "high performing." Including measures with 4 Stars in both years would be a more appropriate approach. BCBSA recommends that CMS either adjust its methodology and assign "not applicable" when determining "Improvement, Decline, or No Change" (see Column U in the QI template) for measures that increased in Star Ratings for year two of the comparison, or add these measures to the "hold harmless" provision. Because the "hold harmless" provision is tied to raw rates, and does not take into account the actual Star Rating earned (except in cases when a plan earned a 5 Star Rating in the prior year)—combined with the fact that CMS' uses a clustering methodology for the cut points—a plan can improve its "earned" Star Rating while its raw rate declines year-over-year. This can lead to a "significant decline" in the QI calculation. For example: Plan A earned a 4 Star on the complaints measure (CTM) with a rate of 0.088 in 2017, and earned 5 Stars with a CTM rate of 0.142 in 2018. Because a lower score on this measure is preferable to a higher score, Plan A actually had a higher complaint rate in 2018, but earned a higher Star Rating. Since the QI calculation is based on raw rate performance, it results in a "significant decline." We urge CMS to implement our recommended modification to this component of the methodology.

Furthermore, all MA plans that are subject to the improvement measure should be allowed to benefit from it. BCBSA does not support any proposal that would limit the application of the improvement measure to only those plans with Star Ratings greater than 2.5 Stars (or any other minimum threshold). Limiting the measure to only plans with more than 2.5 Stars goes against the objective of the improvement measure in encouraging and rewarding improvements in performance, particularly among lower-rated plans. This is important because plans with 2.5 Stars may have a disproportionate share of members who are low income, have low health literacy, or who are otherwise vulnerable and are more difficult to reach. As a result, these plans may be struggling to make strides in the Star Ratings and should not be further disadvantaged by being excluded from the improvement measure.[6]

Finally, Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Health Outcomes Survey (HOS) measure should be removed from the improvement factor calculation

[6] ASPE. "Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs." December 21, 2016. Available at: https://aspe.hhs.gov/pdf-report/reportcongress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs. Accessed on February 20, 2017.

because survey data are based on respondents' perceptions of their health status and thus are not a true reflection of plan performance or patient outcomes. Plans should not be judged on perceptions, but rather on objective and clinically relevant outcomes. We also note that CMS has had challenges with its CAHPS vendor in recent years, particularly around sample selection, causing Plans to appeal their results as not statistically valid. If performed inconsistently, the improvement comparison will not be valid—further emphasizing the importance of excluding CAHPS and HOS measures from this calculation.

Rationale #3:

CMS did not address the methodology for the improvement measures in the Call Letter so BCBSA is taking this opportunity to again advance our recommendations in this area.

Issue #4: <u>Changes to Measures for 2019</u>

CMS also proposes the following changes to measures for 2019:

- <u>Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications (Part D):</u> For the 2017 measurement year, CMS proposes to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measure to include ICD-10-CM codes found in both Parts A & B Claims, Risk Adjustment Processing System (RAPS) RxHCCs along with the EDB ESRD indicator that is currently used.
- <u>Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications (Part D), and Medication Adherence for Cholesterol (Statins) (Part D):</u> CMS proposes to make an adjustment to the Proportion of Days Covered (PDC) calculation (which applies to inpatient stays and hospice for MA-PDs and PDPs and SNF stays for PDPs) in cases where a beneficiary has consecutive stays where the admission date of the second stay is one day after the discharge data. CMS proposes to concatenate consecutive stays to create a single admission and discharge date for the PDF adjustment.

CMS also proposes a number of measures to calculate the 2019 improvement measures for Parts C and D.

Recommendation/Rationale #4:

Overall BCBSA believes these are positive changes and supports CMS' proposal. We note that overall Plans support triple-weighting measures that relate to outcomes because they have an important effect on members and should therefore play a significant part of overall Star Ratings. However, it is important to be rigorous about the definition of an outcome measure: every time a new measure is upgraded to a 3-weight, it effectively dilutes the amount that the other 3-weight measures contribute to the overall Star Rating. We have concerns with the current and proposed designation of the measures: "Improving/Maintaining Physical Health & Improving/Maintaining Mental Health" as outcome-based. These measures are assessed via the Health Outcomes Survey (HOS), which is subjective by nature, given the fact that is based on members' perception of their health, rather than objective clinical data. Secondly, the

requirements of the survey allow for beneficiaries to complete the survey by proxy, and this proxy can differ between the baseline and follow-up survey. Such requirements add to the subjectivity of responses. Therefore, BCBSA recommends that CMS decrease these to a 1.5 weight (consistent with most other survey measures) for the time being until an alternative clinical data-based method of evaluation can be established.

Finally, we support the expansion of the adjustment to the Proportion of Days Covered (PDC) calculation, but request clarification on whether or not this will also include observation stays, which we recommend. Members would be similarly situated in terms of presumed access to medication and adherence regardless of the designation of their stay as "observational".

Issue #5: MPF Price Accuracy (Part D):

CMS proposes enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. These changes are largely the same as those that had been previously finalized in the 2018 Call Letter. In response to industry's request for information about the impact of these changes to future Star Ratings, CMS will first publish the modified measure as a display measure for 2020 and 2021 and intends to then consider adding this measure for the 2022 Star Ratings. Pending this change, CMS proposes to continue to include the current MPF measure in the Star Ratings using the same methodology from the 2018 Star Ratings until the modified measure is incorporated.

At a high-level, the changes include:

- Factoring both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores;
- Increasing the claims included in the measure; and
- Rounding a drug's MPF cost to 2 decimal places for comparison to its PDE cost.

Recommendation #5:

BCBSA recommends that the current MPF measure be moved to the display page while CMS considers alternatives or adjustments that take into consideration the volatility of the market for medications and create allowances for price swings that might be implemented with such speed that it is next to impossible for the plan to update the Plan Finder. Some of our Plans also suggest that the MPF display measure, "Plans Submitted Higher Prices for Display on MPF," should be considered in conjunction with the current price accuracy Star measure. CMS might want to consider focusing on outliers (organizations or medications) that are persistent outliers rather than those differences attributed to normal market changes in price, and should also assess retiring these measure altogether if accuracy across all MAPDs is already close to 100 percent.

Rationale #5:

The current metric carries inherent challenges created by CMS processes. For example, the reference NDCs used to calculate prices are sourced from the CMS Formulary Reference File and do not always reflect all product package sizes.

Issue #6: Members Choosing to Leave the Plan (Part C & D)

CMS proposes to expand the exclusions for this measure to include plan benefit package (PBP) service area reductions (SARs) that result in the unavailability of PBPs that the enrollee is eligible to move to within the contract.

Recommendation #6:

BCBSA appreciates the effort to explore new exclusions and respectfully requests CMS create an additional exclusion for the Members Choosing to Leave the Plan measures. BCBSA recommends adjusting the "Members Choosing to Leave the Plan" measures (Part C and Part D) to provide an exclusion for members who disenroll from a plan within one H-contract and enroll in another plan within a separate H-contract offered by the same parent organization.

Rationale #6:

Moving from one option sponsored by an organization to another sponsored by the same organization is not a negative activity**.**

When a member switches from one H-contract to another offered by the same parent organization, there is an adverse impact to the Star rating for the first H-contract. This assumes that a poor experience was the key driver behind the member's decision to leave his/her H-contract. However, this is not always the case. Health plans continue to drive innovation and improvement across their product offerings, and the needs and priorities of members change over time. Therefore, Plans are working to ensure they offer products that meet these evolving needs. Just as a beneficiary may choose to switch from one PBP to another within the same H-contract, he or she may also elect to move to another H-contract entirely. This is especially true in dynamic markets that feature continuous and transformational changes across health systems. As health plans innovate to meet these market demands, their Star ratings should not suffer when beneficiaries ultimately remain with the same parent organization. Therefore, BCBSA strongly recommends the development of an exclusion within the "Members Choosing to Leave the Plan" measure (Part C and Part D) that addresses this issue.

Issue #7: <u>Removal of Measures from Star Ratings</u>

For the 2019 Star Ratings, CMS proposes to retire the current Beneficiary Access and Performance Problems (BAPP) measure.

CMS proposes to modify the BAPP measure to only include Compliance Activity Module (CAM) data, and this revised BAPP measure would be on the display page for 2019 Star Ratings. CMS solicits stakeholders' input on the utility of this measure focused only on notices of non-compliance, warning letters, and ad-hoc corrective action plans and their severity.

Recommendation #7:

BCBSA would like this measure to be retired from the Star Rating Program so that audit and enforcement activities are delinked from the Star Program. We urge CMS to confirm that this will also be a display measure in 2020 and that it will continue to be a display measure in perpetuity. If the agency decides to keep this measure after two years of being on display, any revised measure should be subject to formal rule making with a defined comment period well in advance of replacement.

Rationale #7:

While BCBSA recognizes the importance of compliance and audit activity, these should be used for oversight, not Star Ratings. There can be inconsistency in how notices of non-compliance, warning letters, and ad-hoc corrective action plans are imposed on plans and also the degree to which they reflect current plan operations. In the past this measure has resulted in some plans being denied their quality bonus payments based on a handful of member related cases that pale when compared to the volume of appeals, coverage determinations and other administrative functions that can influence this measure.

Issue #8: Temporary Removal of Measure from Star Ratings

CMS proposes to temporarily remove the following measure**:**

- Reducing the Risk of Falling (Part C): NCQA has made two changes to this measure, including a change to the denominator and updating the list of example interventions. The second change required revising the underlying survey questions in HOS, and the revised questions will be first collected in 2018. As a result, there will be no data for the measure for the 2019 Star Ratings. CMS proposes to add it to the 2020 display page and intends to add it for the 2021 Star Ratings.

Recommendation #8:

BCBSA agrees with removal of this measure.

Rationale #8:

BCBSA accepts the methodology for the removal of this measure.

Issue #9: Data Integrity

In the past, contracts identified during an audit review to have systematic issues with the completeness of IRE data have had their appeals measures reduced to one star. In response to stakeholder concerns with this practice, CMS initiated the Timeliness Monitoring Project (TMP) in CY 2017, and all contracts submitted data during the first year of the project.

CMS is now proposing statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using TMP data or audits. This methodology would use scaled reductions (1-star, 2-star, 3-star, or 4-star reductions) based on the degree of missing IRE data.

CMS' proposed scaled reduction methodology would be a three-stage process using the TMP data or audit to determine:

1. Whether the contract may be subject to a potential reduction for the Part C or Part D appeals measures. CMS lays out the equations to calculate the error rate for Parts C and D and notes that given different lengths of TMP or audit data collected and evaluated (based on contract size), the number of non-forwarded cases in a three-month period per contract is projected by multiplying the number of cases found not to be forwarded by a constant determined by the associated time period and contract size.

CMS proposes that contracts would be subject to a possible reduction due to lack of data completeness if both of the following conditions are met:

   a. The calculated error rate is 20% or more; and
   b. The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

2. The basis for determination of the estimated error rate; and
3. Whether the estimated value is statistically greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars.

Once the scaled reduction for a contract is identified using the methodology, the reduction would be applied to the contract's associated appeals measure-level Star Rating.

Recommendation #9:

BCBSA appreciates CMS' proposal to scale reductions for the appeals measure and believes this approach is an improvement from current policy. However, we caution that because the TMP began in 2017 and CMS has not yet released individual plan data from that year, Plans currently have no way to validate that CMS' methodology is correct and meets the intent of this proposal. Therefore, we request that CMS delay this proposal until 2020 and release 2017 (and 2018 when available) TMP results to allow plans to measure their performance against the standards to determine risk and implement corrective action, if necessary. BCBSA supports CMS' proposal to scale reductions for the appeals measures when there are data integrity issues.

Rationale #9:

This new methodology is a more reasonable approach to reducing Stars based on data integrity issues. Distinguishing between plans that may have an occasional data error versus plans that have significant, material errors due to major systemic issues is critical when assessing and rating plans based on the integrity of their data. Further, existing CMS policy results in inequity because audited plans' Star Ratings are evaluated against the Star Ratings of plans that are not audited. Additional transparency is required so that plans can validate and respond to findings.

Issue #10: <u>2019 Star Ratings and the Categorical Adjustment Index</u>

The Categorical Adjustment Index (CAI) was first implemented in the 2017 Star Ratings program as CMS' interim response to address the within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and dual eligible (LIS/DE) and disability status.

For the 2019 Stars program, CMS is proposing to continue the use of the CAI with no changes to the overall methodology.

CMS also provided a 2019 Categorical Adjustment Index Measure Selection Supplement document, which provides details related to the selection of the adjusted measure set for 2019.In this document, CMS describes their methodology for measure selection and proposes the following measures for adjustment for 2019:

Part C (MA-PDs and MA-only)

- Annual Flu Vaccine
- Breast Cancer Screening
- Diabetes Care- Blood Sugar Controlled
- Medication Reconciliation Post-Discharge
- Osteoporosis Management in Women who had a Fracture
- Plan All-Cause Readmissions

Part D (MA-PDs and PDPs)

- Part D Medication Adherence for Hypertension
- Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR)

Recommendation #10:

BCBSA agrees that beneficiary-level characteristics have a meaningful impact on Star Ratings and that it is critical to allow plans that care for the program's most vulnerable beneficiaries to compete on an equal playing field. However, in our experience, the CAI is insufficient to address this important problem. CMS has also acknowledged that the CAI has a very small impact on plan ratings. We urge CMS to continue working with plans to identify a long-term solution to the impact of dual status and SES on Star Ratings. We appreciate CMS' ongoing attention to and focus on the impact of beneficiary-level characteristics—specifically, dual status and socio-economic factors—on plan performance. We understand that the CAI is a temporary solution, but we urge CMS to work quickly to evaluate the options recently proposed by the HHS Assistant Secretary for Planning and Evaluation and develop a longer-term, meaningful fix.

We are also interested in learning more about PQA's work on potential risk adjustment of the three medication adherence measures (Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol), as well as NCQA's ideas for stratified reporting of four Star Ratings measures (Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care – Eye Exam Performed, and Plan All-Cause Readmissions). While these changes represent potential improvements to accounting for the impact of SES on the Star Ratings, stakeholders require more insight into how CMS might incorporate them in order to provide more meaningful feedback. We urge CMS, in collaboration with these measure developers, to include plans and other relevant stakeholders in any discussions on these issues.

BCBSA also recommends adjusting the methodology to include a hold harmless provision for contracts that would have their overall rating decreased solely as a result of CAI application. This would be consistent with the hold harmless provision that is used for the Quality Improvement (QI) measures. BCBSA recommends that CMS examine all measures that are not currently case mix adjusted, rather than a subset, to assess appropriateness of inclusion in the CAI.

Rationale #10:

While BCBSA supports the concept of the CAI, BCBSA is concerned over the implementation of the CAI. First, these CAI values are adjusted retroactively, which effectively raises the bar for

plans with low LIS/DE/Disabled membership from achieving their Stars goals. This is problematic, because contracts rely on providers, vendors and other stakeholders to drive Stars outcomes. When thresholds are effectively raised retroactively, plans are unable to align measure-specific targets with their contracted partners to achieve these outcomes. BCBSA respectively requests CMS provide CAI adjustment values prior to the beginning of a measurement period.

Recognizing that the underlying rationale of the CAI is to place contracts with high proportions of LIS/DE/Disabled members on a level playing field with the other plans to which they are compared, a similar hold-harmless provision would prevent penalizing 4+ star contracts solely for not having 'enough' LIS/DE/Disabled members.

As noted in the 2019 Draft Call Letter, the application of the CAI resulted in one contract losing a half-star in Star Year 2018. The Overall Rating CAI value given to contracts in Final Adjustment Category A has doubled since then from -0.021 to -0.041, effectively making it the equivalent of a decrease of a Star on a 3-weighted measure. Without the protection afforded by a hold-harmless provision, it is likely that even more contracts could lose stars in 2019 solely due to the CAI.

Issue #11: <u>Additional Adjustment to Address Lack of an LIS Indicator for Enrollees in Puerto Rico</u>

Because beneficiaries in Puerto Rico are not eligible for LIS, in 2017, CMS made an additional adjustment for contracts with service areas entirely in Puerto Rico to make the application of the CAI equitable for Puerto Rico.

For the 2019 Star Ratings, CMS proposes to continue to employ the additional adjustment for contracts operating solely in Puerto Rico using the most recent data available at the time of development of the model. CMS notes that they continue to explore alternative data sources for Puerto Rico to provide both resource and income information for the determination of the additional adjustment.

Also for 2019, CMS proposes to continue to reduce the weights for the adherence measures to zero for the summary and overall ratings calculations and maintain the weight of three for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico.

Recommendation #11:

BCBSA recommends that CMS adopt their proposal to use the most recent data for development of this model and also retain the reduced weights for the adherence measures to zero for the summary and overall rating calculations in Puerto Rico.

Rationale #11:

BCBSA thanks CMS to continuing to speak to the differences in Puerto Rico that call for adjustments in the calculation of their Star Ratings, including those discussed below.

Issue #12: <u>Disaster Implications</u>

CMS proposes to adjust the 2019 and 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance period such as natural disasters (e.g. Hurricanes Harvey, Irma, and Maria and the California wildfires).

CMS proposes that affected contracts eligible for the adjustments would be:

1) Contracts operating solely in Puerto Rico; or
2) Contracts that meet all of these criteria:
    a. The service area is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act.
    b. The service area is within a county, parish, US territory, or tribal area designated in a major disaster declaration under the Stafford Act that served as a condition precedent for the Secretary's exercise of authority under Section 1135 of the Act.
    c. At least one enrollee under the contract resides in a FEMA-designated Individual Assistance area either at the time of the survey (for CAHPs and HOS adjustments to survey responses) or at the time of the disaster (for all other adjustments). For some adjustments, a certain percentage (25% or 60% of the enrollees under the contract must reside in a FEMA-designated Individual Assistance area.

CMS proposes adjustments to CAHPs, HOS, HEDIS and other Star ratings. In general, for contracts that operate solely in Puerto Rico, CMS proposes to make the survey optional, whereas for other affected contracts with more than 25% of beneficiaries living in affected areas at the time of the disaster, CMS would use the higher of the 2018 or 2019 Star Ratings.

Additionally, when deriving the cut points from the clustering algorithm for non-CAHPS measures, CMS proposes to exclude the numeric values for affected contracts with 60% or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the disaster.

Recommendation #12:

BCBSA appreciates CMS' acknowledgement that Hurricanes Harvey, Irma, and Maria, along with the wildfires in California, creates extreme and uncontrollable circumstances that negatively impacted the underlying operation and clinical systems plans (and CMS) rely on for accurate performance measurement in the Star Ratings program. We support CMS' proposal to adjust the 2019 and 2020 Star Ratings to take into account the effects of the disaster that occurred during the performance periods. With respect to CMS' proposed policy for identifying which contracts were impacted—and therefore eligible for CMS' proposed adjustments—BCBSA urges CMS to ensure timely alignment to and accurate updating of the FEMA website – if it will be used as the source of truth to determine eligibility.

We also note that the FEMA website (https://www.fema.gov/disaster/3396) has yet to be updated for the December California Wildfire Disaster Declaration (declared December 8, 2017 and referenced here: https://www.phe.gov/emergency/news/healthactions/section1135/Pages/cawildfires-11Dec17.aspx). Our Plans operating in California at one point had to refer to the Presidential Declaration to determine impacted counties, but note that as of February 13, 2018, that

Declaration was no longer accessible. Based on the current information available, some plans operating in California would not be eligible in the counties impacted by the wildfires because CMS' criteria "a" (The service area is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act) and "c" (At least one enrollee under the contract resides in a FEMA-designated Individual Assistance area either at the time of the survey [for CAHPS and HOS adjustments to survey responses] or at the time of the disaster [for all other adjustments]. For some adjustments, a certain percentage [25% or 60%] of the enrollees under the contract must reside in a FEMA-designated Individual Assistance area) do not align—but based upon previously provided information by the White House, certain Plan contracts should qualify.

We recognize that CMS itself does not have control over when or how these criteria are disseminated. However, because of their meaningful impact on Star Ratings, we urge CMS to work with the appropriate Federal Agencies to ensure necessary information is updated as quickly as possible. CMS should also notify contracts that meet its eligibility criteria. Otherwise BCBSA finds this proposal fair and reasonable for Plan contracts affected by these events.

Finally, while our Plans that were not affected by disasters appreciate the rationale for these adjustments and support their necessity, some are concerned that adjusting scores for just affected contracts or excluding them from measures could raise the cut points for all other measures. Therefore, we request CMS implement these adjustments in a way that holds harmless those contracts not impacted by extreme and uncontrollable circumstances. In general, we request that CMS provide more information on how the quality bonus payments will be calculated fairly and how excluding plans from the measurements would affect the cut-points.

Rationale #12:

BCBSA believes that Plans who were in these disaster areas should have accommodations for events that were out of their control and that the proposal crafted by CMS is reasonable and fair. However, we also urge CMS to discuss the implications of these adjustments on cuts points.

Issue #13: <u>2019 New Display Measures</u>

CMS proposes to add one new display measure for 2019:

- <u>Plan Makes Timely Decisions about Appeals (Part C):</u> This new appeals measure includes cases dismissed by the IRE because the plan has subsequently approved coverage/payment. CMS proposes to include the modified measure on the 2019 and 2020 display pages and intends to add it for the 2021 Star Ratings

Recommendation #13:

BCBSA questions the value of this measure and whether it will generate inconsistencies across Plans.

Rationale #13:

We question the value of this measure as there is no uniform way to assess whether these appeals were appropriate or not. Measurement focused on the fact that the appeal has been approved appears to be meaningless and of little value to a consumer.

Issue #14: Changes to Existing Display Measures

CMS proposes the following changes to existing display measures:

- Hospitalizations for Potentially Preventable Complications (Part C): NCQA is considering updating the specifications to include hospital stays that are considered observation stays. Therefore, CMS will retain this as a display measure for 2019, and intends to propose moving it to Star Ratings with a weight of 1 for the 2022 Star Ratings and increase it to a weight of 3 as an outcomes measure in subsequent years.
- High Risk Medication (Part D): CMS proposes to adopt a specification change made by the PQA to measure specifications for the numerator (beneficiaries with at least two fills of the same HRM drug on different dates of service) for the 2019 display measure.
- Drug-Drug Interactions (DDI) (Part D): CMS proposes to implement the revised drug list for the 2019 display measure using 2017 performance and PDE data.
- Antipsychotic Use in Persons with Dementia (APD) (Part D): For the 2017 measurement year, the APD measure includes an overall measurement rate and breakouts for community-only residents and long-term nursing home residents. CMS proposes to display the rates for the two population breakouts on the 2019 display page (in addition to the overall APD rate currently displayed) and will assess adding the APD measure to the Star Ratings in the future.
- Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D): CMS will add only the use of opioids at high dose and from multiple providers in persons without cancer (OHDMP) measure to the 2019 display page, but all three measures as specified by the PQA expert panel will continue to be reported to Part D plan sponsors through the Patient Safety reports.
- Transition Monitoring (Part D): CMS proposes to no longer display separate contract-level measures, one for drugs within the classes for clinical concern and one for all other drugs. Instead, the results would be consolidated into one failure rate and display measure, to align with the display measure for the Formulary Administration Analysis.
- Formulary Administration Analysis measure (Part D): Beginning with the 2019 display measure, the data will be displayed as a percentage with two decimal points.
- Timely Effectuation of Appeals (Part D): CMS proposes to modify this measure to be defined as all appeals received by the IRE in the defined timeframe. Additionally, CMS proposes to exclude the results of appeals that occur beyond Level 2 (e.g. ALF or Medicare Appeals Council) from the measure.

Recommendation #14:

BCBSA asks CMS to confirm whether any changes in policy proposed in the pending MA and Part D rule modifies the parameters of the "Transition Monitoring" Part D measure. Additionally, with respect to the Use of Opioids from Multiple Providers measure, BCBSA urges CMS to update the threshold and criteria to match that of the recent updates to the OMS. We also caution CMS to conduct careful evaluation of the upcoming Part D drug management program

to understand how it will impact that OHDMP measure (or other opioid-related measures) before determining to add it to the Star Ratings program. And finally we seek clarification as to whether the Opioid measure excludes those in hospice or palliative care programs.

Rationale #14:

Since beneficiaries will be subject to a new transition policy, if finalized in the MA and Part D proposed rule pending within the agency, we ask CMS to consider whether this measure should be redefined. We also ask for clarifications on the other point made above.

Issue #15: Measures Being Retired

CMS propose to retire the following measures:

- Enrollment Timeliness (Part C and D): CMS notes that overall contracts are receiving extremely high rates (96 percent on average) and proposes to discontinue display in 2019.
- Appropriate Monitoring of Patients Taking Long-term Medications and Asthma Medication Ratio (Part C): NCQA removed the Medicare population from these measures therefore CMS proposes to discontinue display in 2019.

Recommendation/Rationale #15:

BCBSA supports CMS' proposal to retire these measures.

Issue #16: Potential Changes for Star Ratings for 2020 or later

CMS reiterated that, as proposed in the Part C/D rule released in November 2017, new measures or measures with substantial changes would be proposed through the Federal Register rulemaking process for the 2021 Star Ratings and beyond, whereas the Advance Notice/Call Letter process would continue to be used for the 2019 and 2020 Star Ratings. We welcome that process and the opportunity for 30 or 60-day comment periods related to measures.

CMS describes potential changes to existing measures in 2020 and beyond.

Overall Recommendation #16:

In general, BCBSA declines to offer substantial comments on these measures at this time as, in keeping with the proposed Medicare Advantage and Part D rule, future measures should be subject to the federal rule making process with technical details for each measure in the notice for comment. This process will allow for more substantial comments compared to those that could be offered now. However, we offer limited specific feedback on several measures below.

Rationale #16:

To allow Plans to comment on these measures in a formal rule making process with additional technical details provided would allow for more thoughtful recommendations. Rulemaking should be timely so that Plans are not subject to measures after the measurement period has passed.

Recommendation #16a:

With respect to the following measure, BCBSA urges CMS to include out of office remote monitoring encounters in this measure calculation as this would demonstrate significant improvements in identifying patients with marked hypertension and ensuring adequate and needed blood pressure controls.

- Controlling High Blood Pressure (Part C): NCQA is evaluating potential updates due to the release of new treatment guidelines as well as modifications to the denominator to improve feasibility and reduce burden.

Recommendation #16b:

With respect to the following measure, BCBSA is supportive of CMS and NCQA evaluating the feasibility of and strategies for addressing telehealth services in various quality measures. However, given that many MA organizations are either in the early stages of exploring or do not offer a telehealth benefit, we caution CMS not to move prematurely to rely on data from telehealth encounters.

- Telehealth and Remote Access Technologies (Part C): CMS solicits feedback to share with NCAQ on the feasibility of and strategies for addressing telehealth services especially regarding the measures currently reported by Medicare contracts.

Recommendation #16c:

With respect to the following measure, BCBSA suggests that patients receiving palliative care, those with advanced illness, in hospice, or long term facilities, for whom screenings and tests may no longer be medically appropriate, be removed from this measure.

- Cross-Cutting Exclusions for Advanced Illness (Part C): NCQA is evaluating the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected HEDIS measures.

Recommendation #16d:

With respect to the following measures, BCBSA agrees with the update in methodology.

- Medication Adherence (ADH) for Cholesterol (Statins) (Part D): The PQA updated this measure for 2018 to exclude beneficiaries with ESRD. CMS proposes to apply this exclusion to the 2020 Star ratings (based on 2018 data).
- Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D): The PQA updated this measure for 2018 to include a new denominator exemption. CMS proposes to apply this denominator exception to the 2020 Star ratings.

Recommendation #16e:

With respect to the following measure, CMS agrees with the proposal given recently passed legislation that will expand VBID to all 50 states.

- Center for Medicare and Medicaid Innovation Model Tests: CMS is considering excluding Value Based Insurance Design (VBID) Model participants' data when calculating the cut points for relevant measures.

Recommendation #16f:

With respect to the following measure, BCBSA supports the proposal to revise the measure to include observation stays in both the numerator and denominator. Such a modification would more accurately reflect the experiences of beneficiaries and would permit a more equitable comparison among contracts with varying practices about admission reimbursement.

- Plan All-Cause Readmissions (Part C): NCQA is exploring several revisions based on feedback from the field and stakeholders that may impact the definition of the denominator, numerator and risk adjustment model. CMS is also proposing to combine the rates for ages 18-64 and ages 65+ for the revised PCR measure. The new revised measure would be part of the display page for 2019 and 2020 before moving to the 2021 Star Ratings with a weight of 1 the first year and 3 thereafter. The current Plan All-cause readmission measure would remain in Star Ratings through 2020.

Recommendation #16g:

BCSBA has no comment on the following measure:

- Initiation and Engagement in Alcohol or Drug Dependence (AOD) Treatment (Part C): NCQA modified this measure to include data on the use of MAT in the denominator and numerator components of the measure.

Issue #17: New measures for 2020 and beyond:

CMS is considering several new measures for 2020 and beyond. BCBSA reiterates our previous comment that future measures should be subject to formal federal rulemaking in the future with opportunity to comment on technical specifications, and offers the following specific recommendations on measures:

Recommendation #17a:

With respect to the following measure, BCBSA recommends that this complex area include interactions with primary care physicians as well as specialists as in a transition of care either type of provider might be involved. Also, some cases might involve all four of the elements above, some may not and therefore this measure needs to be carefully crafted so as to not "box in" appropriate transitions of care among settings. Finally, we are concerned that this measure could increase burdens on the provide community due to the need for medical record review. We encourage CMS to evaluate this impact prior to implementation of the measure.

- Transitions of Care (Part C): CMS solicits feedback about a new HEDIS Transitions of Care measure with four indicators**.** CMS plans to propose to include this measure with the four indicators on the 2020 display page for possible inclusion in the 2022 Star Ratings.

Recommendation #17b:

With respect to the following measure, BCBSA recommends that CMS consider multiple types of follow up care in designing this measure so that the most appropriate care is provided without hampering Plan innovations in this area because it is tied to a measurement.

- Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C): CMS is considering the use of a new HEDIS measure assessing follow-up care provided after an emergency department visit for patients with multiple chronic conditions. CMS plans to propose to include this measure on the 2020 display page for possible inclusion in the 2022 Star Ratings.

Recommendation #17c:

With respect to the following measure, BCBSA agrees with CMS that care coordination is central to the MA program's success, and that many highly rated MA contracts perform well on the Star Ratings measures because they effectively coordinate care for their members. We are eager to learn more about the care coordination measures CMS is testing. However, we remind CMS about our serious concerns with the use of survey-based measures in the Star Ratings, and particularly for measures assessing care coordination, which require beneficiary recall and rely on perception rather than data-driven evidence. Any care coordination measures contemplated by CMS for inclusion in the Star Ratings system must be based on objective clinical relevance. Ultimately, it will be important for CMS to adopt a gradual approach for how it measure care coordination with respect to Stars, which will require collaboration with plans and other stakeholders to develop the best measure and the most appropriate implementation process.

- Care Coordination Measure (Part C): CMS has identified potential new care coordination measures and is currently testing them for possible future implementation and will provide more detail at a later point.

Recommendation #17d:

With respect to the following measure, BCBSA supports work in this area given the large percentage of Medicare patients with one or more chronic conditions.

- Assessment of Care for people with Multiple High-Risk Chronic Conditions (Part C): NCQA is considering a new measure concept that would adapt the current Care for Older Adults measure by expanding the number of indicators and broadening the population covered by the set of measures.

Recommendation #17e:

With respect to the following measure, BCBSA recommends that the survey-based measure in HOS (improving or maintaining mental health) be phased out of the Star Ratings.

- Depression Screening and Follow-up for Adolescents and Adults (Part C): NCQA has developed a measure, which is part of the new effort to collect data using an Electronic Clinical Data System. Depending on the results during the first year of implementation, CMS may consider for the display page and Star ratings in the future.

Recommendation #17f:

With respect to the following measures, BCBSA recommends that CMS consider retiring the HRM measure, or clearly differentiating drugs that would fall under each measure. We request that CMS further evaluate this overlap and provide plans with the results of that evaluation before moving forward.

Polypharmacy Measures (Part D): PQA developed and endorsed two measures that identify potentially harmful concurrent drug use or polypharmacy.

- Use of multiple anticholinergic (ACH) medications in older adults (Poly-ACH): CMS proposes to begin reporting the Poly-ACH measure in the Patient Safety Reports for the 2018 measurement year and add to the display page for 20121 (2019 data) and 2022 (2020) data. CMS will consider this for the 2023 Star Ratings (2021 data) which would be proposed through rulemaking.

- Use of multiple central nervous system (CNS)- active medications in older adults (Poly-CNS): CMS proposes to begin reporting the Poly-CNS measure in the Patient Safety Reports for the 2018 measurement year and add to the display page for 2021 (2019 data) and 2022 (2020) data. CMS will consider this for the 2023 Star Ratings (2021 data) which would be proposed through rulemaking.

Recommendation #17f:

With respect to this measure, some Plans have concern that there is overlap between this measure and other measures of opioid use.

- Concurrent use of opioids and benzodiazepines: CMS proposes to begin reporting this measure in the Patient Safety Reports for the 2018 measurement year and add to the display page for 20121 (2019 data) and 2022 (2020) data. CMS will consider this for the 2023 Star Ratings (2021 data) which would be proposed through rulemaking. However, CMS seeks feedback if there are concerns with adding this measure given that the Overutilization Management System (OMS) already identifies potential opioid over utilizers who are also receiving a benzodiazepine and a proportion of the concurrent opioid/benzodiazepine users will already be identified within the Poly-CNS measure.

Recommendation #17g:

BCBSA has no comment on the following measures:

- Unhealthy Alcohol Use Screening and Follow-up (Part C): NCQA has developed a measure, which is part of the new effort to collect data using an Electronic Clinical Data System. Depending on the results during the first year of implementation, CMS may consider for the display page and Star ratings in the future.
- Readmissions from Post-Acute Care (Part C): NCQA is pursuing opportunities to measure acute facility readmissions during or following a skilled nursing facility stay by developing a new measure or a potential adaption of the Plan All-Cause Readmissions measure. CMS welcomes feedback on the feasibility, utility and burden of such a modification/stratification or new measure.

- Adult Immunization Measure (Part C): Building on the pneumococcal measure, NCQA is evaluating the relevance, scientific soundness, and feasibility of a composite measure for HEDIS that assesses the receipt of routine adult vaccinations.
- Anxiety (Part C): NCQA is exploring the feasibility and acceptability of developing quality measures assessing care for those with anxiety disorders for inclusion in HEDIS.
- Additional PQA Medication Adherence Measures (Part D): CMS may consider including these measures within the quarterly outlier reports to Part D contracts through the Patient Safety Analysis Website in the future.

Issue #18: Measurement and Methodological Enhancements

CMS notes that it and measure developers, such as NCQA and PQA, are exploring additional measurement concepts for future work, such as functional status, and use of non-pharmacological or non-opioid pain management interventions, which will require use of non-claims data**.** CMS is interested in stakeholder feedback about how these "upstream" concepts can inform measurement of quality of care and how measurement of these concepts might help CMS assess MA contracts' role in and capacity to affect quality of care. CMS is also interested in stakeholder feedback on how these concepts can be measured without adding undue burden on plans or providers and on new or enhanced measures of beneficiary access, including timeliness with effectuating appeals and provider outreach requirements.

Recommendation #18:

BCBSA would like CMS to clarify the above enhancements which at this point are not clearly understood. We would like to caution CMS against expanding measures that are not based on claims due to burden on plans and providers. With respect to new or enhanced measures of beneficiary access, we would also urge CMS to consider whether these measures facilitate appropriate comparisons and before moving forward, provide plans with greater insight into the standards that might be measured and what (if any) new reporting requirements might be imposed so that plans can provide meaningful feedback.

BCBSA also wishes to take this opportunity to remind CMS that, with respect to implementation of CARA provisions, we recommend that beneficiaries designated for lock-in be categorically excluded from the Consumer Assessment of Healthcare Providers and Systems and the House Outcomes Survey, voluntary disenrollment, and Compliant Tracking Module Star measures as their responses and actions may not appropriately reflect true satisfaction and access to the drug plan.

Finally, the new 2018 HEDIS specifications specifically exclude members enrolled in an I-SNP or institutionalized members from the following measures: breast cancer screening, colorectal cancer screening, osteoporosis management in women with a fracture, and controlling high blood pressure. Plans believe the intent of this exclusion is to remove both the institutionalized and institutional-eligible from the measure. The current specification does not do so, which we believe may have been an oversight, and therefore we ask consideration be given in time for HEDIS 2018 to allow all plan types to exclude the "institutional-eligible" from these measures. We also believe that exclusions should be expanded for osteoporosis management in women – concerns about the side effects of treatment drugs is a barrier to compliance as is concern of wasting resources, and therefore if a provider knows they will not act on the results of an OMW

screening due to other, more pressing medical concerns, the patient should be excluded from the measure.

Rationale #18:

Plans have questions as to what is meant by non-claims data in the above.

Incomplete and Inaccurate Bid Submissions

Issue #1: Incomplete Submissions

For CY 2019, the bid submission deadline is June 4, 2018 at 11:59 PM Pacific Daylight Time

Consistent with past years, CMS reminds organizations that all components of an organization's bid must be submitted by the deadline

Issue #2 Inaccurate Submissions

CMS reminds organizations that it will only approve a Part D bid if the organization offering the bid complies with all applicable Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

In addition, all Part C bids must be complete, timely, and accurate or CMS has the authority to impose sanctions or may choose not to renew the contract.

Recommendation #1:

BCBSA has no comments on these policies.

Plan Corrections

Issue #1:

CMS is not proposing changes to this process. As in past years, after bids are approved, CMS will not reopen the submission gates to correct errors identified by the organization or plan sponsor until the plan correction window in September.

Recommendation #1:

BCBSA asks for more flexibility for Plans in the bid process and that CMS understand that errors occur despite plan's best efforts to avoid them. Timelines are tights and there is a high volume of information which can change even after plans submit their bids. The intention of the plan corrections window should be to ensure that beneficiaries receive accurate and complete information, but CMS currently allows no room for inconsequential changes.

Rationale #1:

BCBSA asks CMS to recognize that the bid process moves quickly and that information can be constantly changing, which increases the chance for errors.

Validation Audits

Based on feedback from sponsors and independent auditing firms, CMS is considering several process improvements and enhancements to the program audit validation process that are intended to promote consistency and decrease burden on sponsors.

Issue #1: Threshold for Requiring an Independent Audit

CMS currently requires sponsoring organizations that have more than five program audit conditions in their final audit report to hire an independent auditing firm to conduct a validation audit. CMS is seeking comments on whether this threshold should be increased or decreased, or limited to conditions that may cause adverse impacts to beneficiaries.

In response to comments that there are challenges in hiring an independent auditing firm when only a limited number of conditions require validation, CMS proposes to exclude Compliance Program Effectiveness (CPE) conditions from the threshold calculation. As a result of this, CMS estimates that the number of sponsoring organizations that will be required to hire an independent auditing firm will decrease by approximately 3%.

Recommendation/Rationale #1:

BCBSA supports this proposal which will reduce administrative burden on plans and notes that CMS could further reduce burden by considering additional thresholds, such as more than ten program audit conditions, to justify the expense of an external auditor.

Issue #2: Conflict of Interest Limitations on Independent Auditing Firms

CMS clarifies that sponsoring organizations are not precluded from selecting the same independent auditing firm for their validation audit as their annual external CPE audit, as long as the firm has not provided consulting services or assistance with the correction of audit findings.

Recommendation/Rationale #2:

BCBSA supports this proposal which will reduce administrative burden on plans.

Issue #3: Required Use of CMS Validation Audit Work Plan Template

Based on CMS' experience in reviewing validation audit work plans and industry input, CMS intends to create a validation work plan template that sponsoring organizations undergoing independent validation audits in 2019 would be required to submit. CMS intends to include the draft template in an upcoming Federal Register proposed information collection in accordance with the Paperwork Reduction Act of 1995 (PRA).

Recommendation/Rationale #3:

BCBSA supports this proposal which will reduce administrative burden on plans.

Issue #4: Timeframe to Complete Validation Audits

Currently sponsoring organizations have 150 calendar days from the date that all of their program audit Corrective Action Plans (CAPs) are accepted by CMS to complete a validation audit and submit the independent audit report to CMS for review.

CMS proposes to extend this timeframe by 30 days, so sponsoring organizations will have 180 days from the date CMS accepts their program audit CAPs to undergo a validation audit and submit the independent audit report to CMS for review.

Recommendation #4:

BCBSA appreciates this extension, but believes it is still insufficient. CMS should revise the timeline to allow 180 days for initiation of the audit and for the plan to share with CMS, not only its audit approach (via the workplan), but also the timeline by which the audit will be completed, including the date by which the audit report will be available. If this information is transparent to CMS by day 180, it can be tracked and plans can be held accountable to their timelines.

Rationale #4:

While 180 days may be sufficient to begin a validation audit, it is not enough time to complete the audit and provide an audit report to CMS. A validation audit can take 6 weeks to complete. This means that with 180 days to complete an audit, a plan has less than 140 days to achieve compliance, which is required before the audit can begin. For very complicated or system issues, 140 days is not sufficient time.

Issue #5: Submitting Independent Audit Report to CMS

CMS clarifies that the sponsoring organization would continue to submit its independent auditing firm's validation report to CMS but would also be required to copy the independent auditor on the submission. The report should be submitted to CMS as received from the independent auditing firm (i.e. without modification by the sponsoring organization), but CMS encourages sponsoring organizations to submit additional documentation addressing any concerns with, or rebuttals to, the auditor's report.

Recommendation/Rationale #5:

BCBSA has no comments on this proposal.

Plan Finder Civil Monetary Penalty (CMP) Icon or Other Type of Notice

Issue #1:

Starting with the 2019 Annual Election Period (AEP), CMS intends to display an icon or other type of notice on Plan Finder for sponsoring organizations that have received a CMP. CMS expects that the icon or notice would provide current and prospective enrollees with general information about a CMP and may link to the CMP letter on the CMS website for that particular sponsoring organization.

Recommendation #1:

BCBSA recommends that CMS not adopt this proposal to display an icon or other type of display showing the fact that an organization received a CMP.

Rationale #1:

This proposal could generate significant confusion for beneficiaries. CMPs can be a part of contracting with the government and are not the same as a sanction or termination of an organization from a program. In addition, CMPs can vary from a very low amount to a very high amount, and this icon would not be able to distinguish among that variability. A plan could receive a CMP for failing to meet one member notification while otherwise performing at an excellent level. Such an icon, therefore, could lead to misinterpretations and further confusion for beneficiaries. As BCBSA has recommended in the past, the issue of oversight and enforcement should be separate from tools developed for a beneficiary to understand their plan options.

Enforcement Actions for Provider Directories

Issue #1:

CMS has received several inquiries as to when CMS would impose enforcement actions for provider director violations. CMS notes that as in all instances of non-compliance, CMPs and other enforcement actions may be imposed against MAOs that have received a compliance notice or notices for violations that have gone uncorrected.

Recommendation #1:

BCBSA would like to use this opportunity to share again with CMS the challenges Plans have with keeping their provider directories accurate and up to date. Plans are investing in costly and intensive resources to develop in good faith accurate provider directories and will continue to explore ways to have these directories as accurate and up to date as possible. Additionally, in the past CMS has said that they strive to let the industry see the audit tools and methodologies in advance, but this has not been the case. We request additional transparency in the future. We also recommend that future enforcement actions account for the rebuttal process.

Rationale #1:

Provider compliance is key in this area and Plans are aware that enforcement actions may be taken if they are not engaged in active updates of their directories.

Audit of the Sponsoring Organization's Compliance Program Effectiveness

Issue #1:

In response to stakeholders' requests, CMS is considering allowing sponsoring organizations that have undergone a program audit to treat that audit as meeting the annual compliance program audit for one year from the date of the CMS program audit. CMS believes that this will reduce burden on sponsoring organizations already undergoing a CMS program audit and will eliminate the duplication of effort, and is seeking comment on this.

Recommendation #1:

BCBSA favors this proposal and appreciates CMS accepting BCBSA's recommendation in this area. This is a step in the right direction for Plans and CMS as partners.

Rationale #1:

Adoption of this proposal will create a more reasonable approach to audit of compliance effectiveness**.**

Innovations in Health Plan Design

Issue #1:

CMS describes the Medicare Advantage Value-Based Insurance Design Model (MA-VID) and the Part D Enhanced Medication Therapy Management (MTM) model tests but does not make any specific proposals

Recommendation/Rationale #1:

BCBSA has no comments on this issue, but notes that following a recent legislative change that will allow VBID in all 50 states, analyses should be conducted to determine how inclusion or exclusion affects cuts points for Star Ratings.

New Medicare Card Program (Formerly the Social Security Number Removal Initiative, SSNRI)

Issue #1:

CMS reminds plans that beginning in April 2018, the current Social Security Number based HICN will be replaced with a new Medicare number, the Medicare Beneficiary Identifier (MBI). MBIs will be assigned to all Medicare recipients and new Medicare cards will be mailed to beneficiaries beginning in April 2018. During the transition period (April 1, 2018 to December 31, 2019), Medicare plans can use either the HICN or the MBI to exchange data with CMS.

Recommendation #1:

BCBSA thanks CMS for their ongoing communications on this initiative and would like CMS to communicate with Plans as to when these new cards are being mailed so that Plans can anticipate an uptake in questions on their customer service lines. BCBSA also recommends that CMS share their Call Center scripts on this issue with Plans so that this roll out among all stakeholders is smooth with consistent messaging to affected parties. We appreciate the "Readiness Check List" on this initiative that was recently shared with plans.

Rationale #1:

BCBSA understands this migration to new ID cards can be complex and offers to work with CMS for a smooth transition.

Special Needs Plan (SNP) Legislative Sunset Provision

Issue #1:

As of the publication of the advance notice/call letter, the SNP program has not been reauthorized for CY 2019. CMS will continue to accept applications for new and renewing SNPs based on a belief that Congress will likely act in 2018. However, CMS does not have the authority to allow SNP offerings in CY 2019 absent Congressional action to reauthorize, and if

Congress does not extend the SNP program, any contracts for CY 2019 SNPs would be void. CMS will provide updates to the industry as needed throughout the year.

Recommendation/Rationale #1:

Recent legislative action permanently reauthorized SNPs so this provision is no longer applicable.

Overview of CY 2019 Benefits and Bid Review

Issue #1:

Table 21 on page 169 outlines key MA bid review criteria and outlines the criteria that are used to review various plan types.

Recommendation/Rationale #1:

BCBSA has no comments on this issue

Plans with Low Enrollment

Issue #1:

CMS is not proposing any changes in current policy. At the end of March, CMS will send affected MAOs a list of non-SNP plans that have fewer than 500 enrollees or SNP plans that have fewer than 100 enrollees and that have been in existence for three or more years. The notification represents CMS' decision not to renew, and MAOs must either confirm the low enrollment plans will be eliminated or consolidated, or provide a justification for renewal.

Recommendation/Rationale #1:

BCBSA has no comments on this issue.

Meaningful Difference (Substantially Duplicative Plan Offerings)

Issue #1:

CMS proposes to eliminate the meaningful difference requirement beginning in CY 2019 as part of the Part C and D proposed rule in November 2017. CMS will provide instructions in the final rule and the final call letter or an HPMS memorandum.

Recommendation #1:

BCBSA supports this proposal and recommends that the Office of the Actuary provide additional direction to plans on this issue on their monthly calls related to the bid process.

Rationale #1:

While we appreciate the fact that additional instructions are forthcoming, we wish to convey a sense of urgency given the fact that the final rule and final call letter will be issues just a short time before final bids are required to be submitted. Plans welcome instructions and additional guidance as soon as possible.

Total Beneficiary Cost

Issue #1:

CMS' proposed methodology for developing the CY 2019 out-of-pocket costs (OOPC) model is consistent with last year's methodology.

In mid-April, CMS will provide plan specific CY 2019 TBC values and incorporate technical and payment adjustments in the TBC calculation to account for changes from one year to the next.

CMS is proposing to increase the TBC change threshold, for most plans, from $34.00 PMPM to $36.00 PMPM in CY 2019 to provide flexibility in addressing medical and pharmacy inflation and benefit design and formulary changes.

CMS notes that they are considering elimination of the current TBC evaluation in future years, subject to statutory and regulatory limitations or changes, and seeks comments on this matter and suggestions on other approaches to determine whether plan bids propose too significant an increase in cost sharing or decrease in benefits from one year to the next.

Recommendation #1:

BCBSA recommends that CMS show flexibility in this area as often there are external factors that can contribute to changes in cost sharing, benefit changes, etc. We appreciate this change in the threshold from $34 to $36 dollars.

However, we urge CMS to eliminate the TBC evaluation, and encourage CMS to collaborate closely with the plan community to ensure that any alternate approach for determining whether plan bids propose too significant an increase in cost sharing or decrease in benefits from one plan year to the next is sound and enables truly meaningful assessments by beneficiaries.

Rationale #1:

Plans can be subject to Congressionally-imposed initiatives that can lead to changes in benefit plans from one year to the next. Examples of such initiatives that impact Plans would be sequestration (just extended for two years by the Congress), changes in benchmarks as established in the Affordable Care Act, the Health Insurance Tax and developments in that area, changes in operational policies, etc.

Additionally, although the TBC test only compares a plan to itself year-over-year, there are benefit elements that are not captured by CMS' current out-of-pocket cost (OOPC) model. For example, a number of supplemental benefits that are important to beneficiaries, such as over-the-counter benefits, transportation, meals, etc., are not valued in the OOPC model but can significantly impact the benefit richness of the plan. In addition, tiering of benefits and provider network changes impact beneficiaries' enrollment decisions—but these factors are not reflected in the current OOPC model. We also note that Part D OOPC changes are valued on an old set of drug utilization and new drugs are not taken into account when conducting the TBC test.

Maximum Out of Pocket (MOOP) Limits

Issue #1:

Table 22 on page 174 of the proposed call letter displays the mandatory and voluntary MOOP amounts for local PPOs and regional PPOs.

Issue #2:

Per Member Per Month (PMPM) Actuarial equivalent Cost Sharing Limits

CMS will evaluate actuarial equivalent cost sharing limits separately in the following categories for CY 2019: inpatient, skilled nursing facility (SNF), durable medical equipment (DME), and Part B drugs.

Recommendation/Rationale #1 and 2:

BCBSA has no comments on these issues

Part C Cost Sharing Standards

Issue #1:

For CY 2019, CMS will continue the current policy of giving MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. Table 24 on page 178 summarizes the standards and cost sharing amounts by MOOP type for MA plans that CMS will not consider discriminatory or in violation of other applicable standards.

Recommendation #1:

BCBSA supports the CMS proposal to increase both voluntary and mandatory thresholds for the ER/Post Stabilization care limit for 2019.

Rationale #1:

Moving forward CMS should allow plans more flexibility in applying cost sharing to support the quality of care provided to beneficiaries while meeting actuarial equivalence standards necessary to align with traditional Medicare.

Employer Group Waiver Plans

Issue #1:

Beginning in CY 2017, CMS waived the requirement for MA employer plans to submit an MA or Part D Bid Pricing Tool (BPT), but employer plans must complete and submit the MA portion of the Plan Benefit Package (PBP) in accordance with CMS requirements. Organizations must make a good faith effort in projecting CY 2019 member months for each plan and plans the amount in Section A-2 of the PBP.

Recommendation/Rationale #1:

BCBSA has no comments on this issue.

Part C Optional Supplemental Benefits

Issue #1:

Consistent with previous years, CMS will continue to review non-employer bid submissions to verify that enrollees electing optional supplemental benefits are receiving reasonable value. CMS will continue to consider a plan to be non-discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meets the following threshold: a) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15%, and b) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses, as measured by percent of premium, is no greater than 30%.

Recommendation #1:

BCBSA is confused by this section and its interaction with the proposed Medicare Advantage and Part D rule on the issue of supplemental benefits as well as the recent legislative changes enacted in the Bipartisan Budget Act of 2018. We expected additional guidance from CMS on any new rules that related to supplemental benefits and are concerned with the statement optional supplemental benefits have "reasonable value."

Rationale #1:

CMS should issue additional guidance on the issue of supplemental benefits with so many agency and Congressional actions related to supplemental benefits in Medicare Advantage. BCBSA asks that there be a comment opportunity for any regulatory guidance so Plans have an opportunity to respond as needed.

Tiered Cost Sharing of Medical Benefits

Issue #1:

Plans may choose to tier cost sharing of medical benefits to encourage enrollees to seek care from providers the plan has identified based on efficiency and quality data. For CY 2019, CMS does not expect MAOs to submit a proposal summarizing their intent to tier cost sharing of medical benefits prior to bid submission, but MAOs are expected to indicate that they are tiering medical benefits and the applicable service categories in Section A-6 of the PBP and tiered cost sharing must satisfy standards laid out on page 181.

Recommendation #1:

BCBSA welcomes CMS encouragement of tiered networks.

Rationale #1:

Tiered networks can be a tool to allow beneficiaries to access high performing providers at lower costs which is beneficial to the plan, the MA programs, and the beneficiary.

Observation Services

Issue #1:

In an effort to make the cost sharing for observation services more transparent, CMS will distinguish the cost sharing for observation services from other outpatient services by modifying the PBP category B9a to include separate cost sharing data entries.

Recommendation #1:

BCBSA welcomes the opportunity to have a separate bid category for observation stays in an inpatient setting.

Rationale #1:

With more patients being subject to observation stays in a hospital, it is essential that beneficiaries know what their benefits and cost sharing amounts are for these stays and having a separate benefit category should help in this area. This policy will allow for the cost of observation stays to be more transparent which is positive for the beneficiary.

Coverage of Supervised Exercise Therapy (SET) For Symptomatic Peripheral Artery Disease (PAD)

Issue #1:

For CY 2019, MAOs should account for these items and services as a basic benefit and should not include these Medicare-covered items and services as supplemental benefits.

Recommendation #1:

It would be helpful in the final Call Letter to describe the expected services under this new benefit and offer common language should use in describing this new service so there is industry consistency.

Rationale #1:

Since this is a new basic benefit, more information should be communicated to plans on this national coverage determination.

Health Related Supplemental Benefits

Issue #1:

CMS currently defines a supplemental health care benefit as an item or service that is 1) not covered by original Medicare, 2) that is primarily health related, and 3) for which the MA plan must incur a non-zero direct medical cost. An item that meets all three conditions may be proposed as a supplemental benefit in a plan's bid and submitted plan benefit package.

CMS has not previously allowed an item or service to be eligible as a supplemental benefit if the primarily purpose is daily maintenance (vs to prevent, cure, or diminish an illness or injury).

For CY 2019, CMS intends to expand the scope of the primarily health related supplemental benefit standard. Under the new interpretation, for a service or item to be primarily health related, it must do one of four things:

1) diagnose, prevent, or treat an illness or injury;

2) compensate for physical impairments;

3) act to ameliorate the functional/psychological impact of injuries or health conditions; or

4) reduce avoidable emergency and healthcare utilization."

CMS states that the primary purpose of an item or service will be determined by national typical usages of most people using the item or service and by community patterns of care.

Prior to bid submission, CMS will issue detailed guidance for MAOs on this issue, which will be based on previous stakeholder feedback and comments in response to this draft Call letter.

Recommendation #1:

BCBSA would like to thank the agency for this expanded flexibility with supplemental benefits which will assist with patient needs in a more comprehensive manner and also be able to have plans address patient specific needs on a one on one basis. Given the overlap between the proposals here, those in the November 2017 proposed rule, and the provisions enacted in the Bipartisan Budget Act of 2018, we request that CMS provide additional guidance as soon as possible, especially since plans are already developing bids for CY 2019.

Rationale #1:

Supplemental benefits will be key to more efficient use of Plan resources for patient needs. We also need guidance on how this new flexibility can be communicated or marketed to members.

Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs)

Issue #1:

Beginning in CY 2019 D-SNPs and I-SNPs may offer the EDM supplemental benefit that is currently available to non-SNP MA plans. It will not be made available to C-SNPs because it is not necessary (C-SNPs must already have comprehensive targeted disease management elements beyond the EDM requirements in order to receive C-SNP designation).

Recommendation #1:

BCBSA supports this proposal.

Rationale #1:

This proposal will allow for more flexibility for D-SNPs and I-SNPs.

Medicare Advantage Uniformity Flexibility

Issue #1:

CMS reiterated their discussion in the November 2017 proposed rule that they have determined that they have authority to permit MA organizations the ability to reduce cost sharing for covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees

that meet specific medical criteria, provided that similarly situated enrollees are treated the same.

Following issuance of the Final Call Letter, CMS will establish a special mailbox for plan questions as to whether a specific targeted supplemental benefit is allowable.

Recommendation #1:

BCBSA recommends that CMS develop a question and answer guide for plans as to a specific benefit and that there be information sharing among all plan sponsors so that one Plan is not given an answer that is unknown to others. In keeping with the above, BCBSA also recommends that CMS address how this new flexibility should be disclosed to members, either in the Summary of Benefits and Coverage or the Evidence of Coverage.

Rationale #1:

This is a whole new area for plans and detailed guidance is needed as soon as possible for bid development.

Medicare Advantage Segmented Service Area Options

Issue #1:

CMS has determined that it has the authority to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of plan's service area.

Recommendation #1:

In keeping with the above BCBSA asks that CMS issue guidance on this new flexibility as soon as possible so that segmented service area options are clear as Plans approach their bids for 2019. We would appreciate the opportunity to comment on any such guidance or have an opportunity to ask for clarifications.

Rationale #1:

As with new rules for supplemental benefits, BCBSA supports the need for CMS to hold a user group call or issues guidance on this new flexibility so that the bid process is efficient and timely.

Medicare Diabetes Prevention Program (MDPP) Services Clarification

Issue #1:

CMS wants to ensure that plans are aware that while they must cover MDPP services in accordance with the MDPP regulations, they may also offer additional MDPP-like services as a supplemental benefit. For example, although MDPP services cannot be provided only remotely or in a 100% virtual format as a basic benefit under Part B, an MA plan may offer similar services in a virtual format as a supplemental benefit.

Recommendation #1:

BCBSA would again like to recommend that the agency allow the use of virtual format to deliver these services and provide plans with that flexibility that will allow for a greater uptake of these services. We would like to see CMS adopt virtual formats in delivering this new basic benefit, not have Plans have to provide it as a supplemental benefit because of unreasonable technical issues related to the delivery of this benefit.

Rationale #1:

Delivering this new service is a virtual format will provide for greater access and efficiencies than requiring a face-to-face encounter. In-person coaching is restrictive and less available to individuals with mobility limitations, and also means that Plans do not have an alternative solution available for their members when there are no in-person coaching services accessible in their services areas.

Special Needs Plan (SNP)-Specific Networks Research and Development

Issue #1:

CMS continues to examine the need for SNP-specific network adequacy evaluations and welcome continued stakeholder feedback**.**

Recommendation #1:

Any new standards related to the networks in Special Needs Plans should not be unduly inflexible as to time and distance metrics and must not have the unintended consequence of marking it more difficult for plans to serve these vulnerable members.

Rationale #1:

BCBSA questions the need for SNP-specific network evaluations on an ongoing basis. However, we encourage CMS to continue their ongoing work to develop SNF-specific evaluation criteria that permit SNPs to best tailor networks to meet the unique and complex needs of the targeted populations served by these plans.

Rewards and Incentives for Completion of a Health Risk Assessment (HRA)

Issue #1:

Beginning in CY 2019, MA plans may include the completion of an HRA as a permitted health-related activity in a rewards and incentives (RI) program.

Recommendation #1:

BCBSA thanks CMS for this enhancement for patient to complete an HRA.

Rationale #1:

Often patients respond to an incentive or rewards program and this policy will allow for a greater participation rate for completion of HRAs, which are important to establishing a baseline for a patient's medical status.

Cost Plans

Issue #1: **Cost Plan Transition to MA under MACRA**

CMS wants to remind cost plan entities that they must complete the transition to MA by contract year 2019 in order to deem their cost enrollees into an affiliated MA plan offered by the organization under MACRA cost transition requirements.

Any plan wishing to deem enrollees from its cost plan to one of its MA plans under the MACRA provisions must notify CMS via the HPMS crosswalk process. This may be completed as early as May of 2018 for enrollments in 2019. Additional guidance on the requirements of this transition is available on CMS' website.

Recommendation/Rationale #1:

BCBSA thanks CMS for these instructions for cost plans transitioning to MA plan status.

Issue #2: **Cost Plan Competition Requirements**

Cost plan competition requirements will first be effective in 2019. CMS will non-renew any portion of a cost plan's service area if there are at least two competing MA local or two MA regional coordinated care plans with a minimum of 5,000 enrollees (urban) or 1,500 enrollees (non-urban) for the entire year prior to the non-renewal.

Recommendation/Rationale #2:

BCBSA has no comments on this issue.

Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs

Issue #1:

Based on feedback from previous Call Letter cycles, CMS has identified priority areas for further integration for interested states and plans, as well as areas where administrative alignment for integrated D-SNPs is currently feasible within existing statutory, regulatory, and operational constraints. These include:

- Oversight
- Integrated model materials, including Summary of Benefits, Annual Notice of Change/Evidence of Coverage, and Provider and Pharmacy Directory
- D-SNP Non-Renewals
- Model of Care

CMS is interested in working with additional states to pursue similar efforts and welcomes comments about the opportunities identified as well as any others.

Recommendation/Rationale #1:

BCBSA believes that CMS should create opportunities for beneficiaries to better understand the value of Special Needs Plans and how they differ from HMOs and PPOs.

BCBSA commends CMS for its efforts to maximize the potential to align benefits and improve coordination for dually eligible beneficiaries. As CMS works with states, it should also incorporate feedback and lessons-learned from plans, which also have a vested interested in promoting integration. Below, BCBSA provides comments on the priority areas CMS identified for its work:

- Integrated Model Materials: CMMI, in coordination with MMCO, should explore models that allow states and participating FIDE-SNPs, D-SNPs, and Medicaid plans to test the delivery of services to dual eligibles under certain regulatory flexibilities. Similar to the structure and goals of the Medicare-Medicaid Plan (MMP) model, these Medicaid plans, D-SNPs and FIDE-SNPs serving duals could have the ability to test the positive impact that a single set of Medicare and Medicaid standards (i.e., unified appeals and grievances processes, unified beneficiaries materials, a single coverage identification card, benefit flexibility, and other integrated elements) could have on effective, efficient operation of programs covering dual eligibles. We understand that Congress addressed some of these issues (in particular unified appeals and grievances) as part of the recent Bipartisan Budget legislation. This may be an especially valuable model to test among those issuers serving the same dually-eligibles individuals in both of their Medicaid and Medicare products and are equipped to deploy tools and processes that offer an integrated experience. This type of model could promote a better experience for enrolled dual eligibles and network providers in these programs. It also promises higher levels of integration that could produce better outcomes and cost efficiencies. CMMI should enlist the input of stakeholders to identify those areas of needed integration and alignment as well as additional model elements in order to develop a demonstration inclusive of this concept.

- Non-renewals: As more states move towards integration, a streamlined process regarding pending non-renewals, service area reduction, and terminations will become increasingly critical, and a formal process that all states can follow as BCBSA believes that it may be helpful for CMS to outline a formal process that all states can follow for state notifications. Alternatively, CMS could consider developing a truly integrated termination notice in which plans would be able to include optional, customizable language outlining the steps a member should take if they receive Medicaid services from the non-renewing or terminating plan as well. Ultimately, while BCBSA supports a streamlined process, we continue to believe it would be most helpful for CMS to be less prescriptive and allow for plan flexibility when it comes to member materials and communication.

- Model of Care (MOC): CMS had previously noted its desire to explore allowing states to review MOCs against their requirements concurrent with NCQA's review of MOCs in HPMS to avoid duplicative reviews by each program. BCBSA notes that this is the process that occurs under the MMP demonstration—however, one challenge that Plans have experienced in this process is receiving consistent, timely feedback and approval from both the state and CMS. BCBSA supports CMS and states conducting a joint review and providing one set of comments instead of two. We note that this joint MOC review would need to allow for nuances such that MOC standards for LTSS at the state-level are appropriately factored into the requirements for D-SNP beneficiaries (keeping

in mind that not all D-SNP beneficiaries need or receive LTSS). Because of this, applying a one-size-fits-all approach to the D-SNP MOC review process (which could mean LTSS standards being applied to non-LTSS membership) could add unnecessary costs, and portions of it may not be meaningful to all models. Plans could be more exposed to these challenges as they move providers into risk-based contracts.

Rationale #1:

Much can be done to improve beneficiary communications around Special Needs Plans, and we urge CMS to work with stakeholders to improve the processes described above.

Parts A and B Cost-Sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program

Issue #1:

CMS does not propose any new policies

Recommendation #1:

BCBSA urges CMS leadership to ensure that all stakeholders (including plans, state Medicaid agencies, and providers [including pharmacists]) work together on this issue to assure cost sharing protections for the QMB population.

Rationale #1:

Not all providers know who these beneficiaries are so there needs to be more educational efforts to ensure that network providers do not discriminate against beneficiaries based on their payment status.

Encounter Data Listening Forums, Monitoring and Compliance Activities

Issue #1:

In the 2018 Call Letter, CMS presented a new approach to monitoring and compliance of encounter data. In November 2017, CMS issued an HPMS memo on this topic and requested feedback from stakeholders. CMS will review comments and finalize the monitoring metrics and thresholds in an HPMS memo to be distributed in early 2018.

Recommendation #1:

CMS is proposing to finalize two encounter data performance measures and thresholds, and has sought comments on an additional five measures and thresholds that would be utilized by the agency to evaluate whether an MA organization's encounter data submissions meet CMS' risk adjustment data submission standards. BCBSA strongly recommend that CMS should not move forward in this area until the agency and other stakeholders can determine that CMS's processing is reliable and accurate.

Rationale #1:

In the 2018 Call Letter, CMS noted that the agency intended to use these measures to guide oversight and enforcement efforts in this area, including implementation of compliance activity related to MA organization performance on the proposed measures. As indicated in previous comments, BCBSA recognizes CMS' responsibility to ensure collection of complete and accurate encounter data, and we have a strong commitment to and interest in submitting data that meet these standards. We believe encounter data-related monitoring measures could provide a useful tool to guide CMS and plans in our collective efforts to evaluate, understand and improve the overall encounter data process, and to assist the agency in identifying areas where additional technical assistance and/or guidance may be needed.

However, while CMS and plans have worked together to make progress in addressing the technical issues and challenges related to encounter data submission, we believe the proposal to begin compliance related activity, specifically for the "completeness performance" measures, should be delayed until the agency and plans can determine with confidence that plan performance is unhindered and not distorted by those issues.

We appreciate that CMS has developed and provided to plans Technical Notes that include details regarding the data used and calculations applied to produce the proposed encounter data performance metrics. However, similar details regarding the proposed thresholds are unclear. To assist plans in fully assessing the proposed thresholds and to facilitate meaningful feedback in response to the agency's proposal, we recommend that CMS revise and reissue the Technical Notes to include the underlying information detailing how the thresholds are determined for future monitoring.

BCBSA recommends that CMS not engage in setting metrics and compliance standards for encounter data submissions until the agency (and the Office of the Inspector General and the General Accounting Office) issues documentation to attest to the improvements in the encounter data submission process and the reliability of the data for risk adjustment. To date there has not been enough done on the part of CMS and its contractors to ensure the accuracy of encounter data.

Transparency and Timeliness with Prior Authorization Process

Issue #1:

CMS reminds MAOs that they should be transparent and provide adequate notice of any coverage restrictions, such as prior authorization requirements, to providers and enrollees.

Recommendation #1:

The stakeholder concerns about the burdens imposed by coverage restriction like PA reflect a complex issue. While a Plan's contracted provider network must follow the rules as established by the plan, even contracted provider and their staff have difficult managing all the PA requirements, not due to a lack of information provided by the plan, but due to the number of organizations they are contracted with and the different services that require PA by one or more plans. This can be challenging for many offices to navigate while also taking into consideration the type of plan a beneficiary may have and the benefits associated with those plans (PPO, HMO, HMO-POS, MMP, SNP, etc.) These challenges are further complicated by those

beneficiaries who have a Special Election Period (SEP) and can enroll in, change, or disenroll from coverage as frequently as monthly.

Plans appreciate the burden facing contracted providers; however, current CMS guidance hinders their ability to fully review appeals for appropriateness of services being requested and ensure services are covered and reimbursable under the Medicare program, essentially necessitating the application of a PA requirement. CMS should consider providing updates to MAO guidance to ensure plans can appropriately manage care while balancing provider burden and limiting beneficiary liability.

CY 2019 Formulary Submission Window

Issue #1:

The CY 2019 HPMS formulary submission window will open this year on May 14, 2018 and close at 11:59 PM PDT on June 4, 2018.

Recommendation/Rationale #1:

BCBSA thanks CMS for this information.

CY 2019 Formulary Reference File

Issue #1:

CMS is analyzing the Part D utilization of current FRF drugs and will be removing drugs from the FRF based on these results (this does not mean that a drug is not eligible for Part D coverage, only that there is very little Part D utilization due to the indication, dosage and administration, and usual administration setting).

CMS will release a draft FRF that reflects these changes in February 2018 and will provide plan sponsors and other stakeholders the opportunity to comment. A CY 2019 FRF will be published in March 2018 and will be updated in mid to late May prior to the June 4 formulary submission deadline.

CMS intends the move the summer formulary update window into later in the summer (it was held from July 27 to 31 last year) to allow the inclusion of newly approved brands and generics that occur in July into August. CMS seeks stakeholder comment regarding the optimal submission window that balances the opportunity for additional formulary substitution versus the need to finalize formulary documents for printing.

Recommendation #1:

Our Plans have raised some concerns with CMS' proposal to move the formulary update window into later in the summer. While CMS states that this change is to allow the inclusion of newly approved generics, a manufacturer could still add generics after this modified window, so the date change may be of limited value.

We recommend that the final update window dates should enable final CMS formulary approval no later than August 20th to ensure plans can meet mailing deadlines. Currently, mailings begin

mid-September to ensure documents are in members' hands by September 30th (per CMS' requirements). If the window dates will not allow plans to meet these timeframes, which are already tight, CMS should push out the mailing deadlines.

Rationale #1:

In setting the formulary update window, CMS must balance the desire to include newly approved drugs with the need to finalize formularies with sufficient time for document mailings.

Changes for CY 2019 Formulary Submissions

Issue #1: For CY 2019, CMS proposes changes to the following formulary-related files:

- Additional Demonstration Drug (ADD) file: CMS will make the ADD validation file available via HPMS in advance of the AD file submission deadline.
- Non-Extended Day Supply (NDS) file: Based on feedback from Part D sponsors, CMS has concluded that the burden of maintaining this supplemental file outweighs any benefits, and therefore is eliminating the file for CY 2019.
- Over-the-Counter (OTC) Validation file: In an effort to reduce burden on plan sponsors to create and submit these files and to streamline CMS review, CMS is proposing to provide plans with an OTC reference file for CY 2019 that uses a proxy code (e.g. RXCUI) to represent each unique drug ingredient, strength, route, and dosage form, but the file will not contain every possible branded OTC.

Recommendation #1:

BCBSA agrees with these proposed changes for formulary-related files.

Rationale #1:

These proposed changes will create new efficiencies for the program.

Expanding the Part D OTC Program

Issue #1:

CMS is considering allowing additional flexibilities for Part D plan sponsors to offer access to OTC, such as including additional OTC products, such as dietary supplements and cough medicines without the requirement that the OTC product offset the use of a Part D drug. CMS is soliciting feedback from stakeholders on Part D OTC enhancements that could be considered, including information on how well the current program is working, the deficiencies of the current program, what additional flexibilities would be helpful, and what the impact would be on spending (particularly premiums) as a result.

Recommendation #1:

BCBSA recommends that the concept of offering OTC medications as a benefit needs further analysis. There are many over the counter medications that might be in the best interest of a patient to take, but without coverage from the plan and credit for the spending in the RX benefit, enrollees may be reluctant to purchase these medications. The reasons for this failure to

secure a recommended OTC medication could be varied, e.g. cost, fear of the side effects of the medication, lack of understanding of a provider's recommendation, etc. Expanding coverage at this time needs more analysis.

Rationale #1:

While the concept of offering OTC medications as a benefit is interesting, such a policy could be inconsistent in administration and also have impact on MLR reporting as well as the enrollee's progress throughout the Part D benefit.

Medication Therapy Management

Issue #1:

The 2019 MTM program annual cost threshold will be the 2018 annual cost threshold ($3,967) adjusted based on the API and will be finalized in the 2019 Call Letter.

Recommendation/Rationale #1:

BCBSA thanks CMS for this update to the annual cost threshold

Part D Benefit Parameters for Non-Defined Standard Plans

Issue #1: The benefit parameters for CY 2019 are laid out in Table 25 on page 199 of the Call letter.

CMS notes that they have included a proposal in the November 2017 proposed rule to eliminate the PDP enhanced alternative (EA) to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor.

For CY 2019, CMS proposes a minimum monthly cost-sharing out-of-pocket –cost (OOPC) difference between basic to enhanced PDP offerings of $22.

Recommendation/Rationale #1:

Similar to comments on meaningful difference policies in Part C, BCBSA recommends that CMS consider eliminating this policy in Part C and also the dollar amounts associated with the policy.

Issue #1: Benefit Review

CMS does not propose policy changes and will continue to scrutinize the expected cost-sharing amounts incurred by beneficiaries under coinsurance tiers in order to more consistency compare copay and coinsurance cost-sharing impacts.

Recommendation/Rationale #1:

BCBSA has no comments on this issue.

Issue #1: **Tier Composition**

Based on an analysis of CY 2018 formulary and benefits data, CMS proposes a maximum threshold of 25% generic composition for the non-preferred brand tier for CY 2019.

Recommendation #1:

BCBSA disagrees with this percentage of 25% as it appears to be unreasonable. Overall, BCBSA finds no value in assigning a percentage as to a maximum threshold of generic composition for the non-preferred brand tier. We recommend that CMS be more specific as to the objective of this proposed policy and clearly state the agency's thought process in offering this percentage.

Rationale #1:

The issue with assigning a percentage is that such a proposal does not take into account the methodology that might force a plan sponsor to place a drug on that tier. BCBSA asks for more information as to the objective of this proposal.

Issue #1: **Improving Access to Part D Vaccines**

CMS does not propose policy changes but encourages Part D sponsors to offer a $0 vaccine tier or to place vaccines on a formulary tier with low cost-sharing to encourage access.

Recommendation #1: BCBSA recommends that CMS define the vaccines that should be offered for $0 copayment or placed on a formulary with low cost sharing. Some vaccines may be recommended for personal travel reasons and some for clinical reasons. BCBSA welcomes CMS to expand this discussion in the Final Call Letter and also retain flexibility for plans as to how vaccines are placed on their formularies.

Rationale #1:

While some vaccines are essential to good health, such as the shingles vaccine, others may be elective, such as vaccines for foreign travel. CMS should not advocate that all vaccines be available for a $0 copayment.

Issue #1: Specialty Tiers

CMS will maintain the $670 threshold for a Part D drug to be placed on the specialty tier for CY 2019

Recommendation/Rationale #1:

BCBSA thanks CMS for this update for CY 2019.

Issue #1: Low Enrollment Plans (Stand-alone PDPs only)

CMS proposes that if a plan is identified as a low enrollment plan for two consecutive years using the existing criteria, CMS can exercise its authority to non-renew the plan. By April 2018, CMS will notify affected low enrollment plans with less than 1,000 enrollees of available options for consolidation/withdrawal options.

Recommendation/Rationale #1:

BCBSA has no comments on this issue.

Part D Opioid Utilization Policy

Issue #1: <u>New Strategies to Address Opioid Epidemic</u>

CMS proposes new strategies to more effectively address the national opioid epidemic within Part D. These proposals include (and are described in more detail in the sections below):

- Enhancing the OMS by adding additional flags for high risk beneficiaries who use "potentiator" drugs (such as gabapentin and pregabalin) in combination with prescription opioids. OMS already flags concurrent benzodiazepine use;
- Implementing revisions to the PQA opioid quality measures used by CMS, and consideration of a new PQA measure, Concurrent Use of Opioids and Benzodiazepines (discussed in Star ratings section);
- Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) in the pharmacy (which can only be overridden by the sponsor) at a dosage level of 90 MME per day, with a 7 day supply allowance;
- Implementing a days supply limit for initial fills of prescription opioids (e.g. 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g. 50 MME per day); and
- Expecting all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and request feedback on concurrent prescription opioid and benzodiazepine soft edits.

CMS welcomes feedback on these proposals and notes that all Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis.

Recommendation #1:

In general, BCBSA believes that quality metrics related to opioid overutilization should consider or build upon currently existing CMS initiatives such as OMS, Level 3, and MED Limit.

Rationale #1:

BCBSA is committed to working with CMS on ways to address the national opioid crisis, while also ensuring that the quality metrics are accurate and reduce unnecessary burden on providers and plans to the extent possible.

Issue #2: <u>Retrospective DUR: OMS Metrics and Opioid Potentiator Drugs</u>

Beginning with the 2018 OMS reports, CMS proposes to change the Opioid Daily Dose measurement period from 12 months to 6 months to align with the revised OMS criteria measurement period. CMS also proposes to report a second Opioid Daily Dose rate with a 90 MME threshold to further align with the 2018 OMS criteria.

Therefore, in the April 2018 OMS reports, CMS will report:

- 90 MME Opioid Daily Dose rate: # opioid days > 90 MME/1000 Opioid utilization days during last 6 months
- 120 MME Opioid Daily Dose rate: #opioid days > 120 MME/1000 Opioid utilization days during last 6 months

CMS proposes to discontinue reporting the 120 MME opioid daily dose rate in the 2019 OMS reports

CMS is also concerned about the increase in gabapentin use and higher doses in opioid users which may place beneficiaries at higher risk for adverse events. These concerns also extend to pregabalin, which is also a gapapentinoid. Therefore, CMS proposes to add a concurrent opioid-gabapentin/pregabalin flag to OMS, and solicits comments from stakeholders about their experience with the potential overuse of gabapentin and pregabalin and whether this additional flag would be useful for Part D plan sponsors. CMS also seeks comment on other potentiator drugs that should be added to the OMS and the utility of adding such drugs that may increase the risk for overdose when used with opioids.

Recommendation #2:

Regarding Opioid Potentiator Drugs, given the widespread impact of the opioid epidemic, BCBSA supports CMS' efforts to monitor use of drugs that are used to increase the effects of a substance (potentiator drugs), increasing both the substance and the potentiator's abuse potential. While adding a concurrent opioid-gabapentin/pregabalin flag to OMS is an important step, we ask CMS to consider including a flag for carisoprodol, as combining opioids with benzodiazepines and skeletal muscle relaxants like carisoprodol has a known potentiating effect. In addition, we ask CMS to clarify whether it will allow sponsors to apply a restriction at the point-of-sale for potentiator drugs, including benzodiazepines. Regarding benzodiazepines, BCBSA recommends that CMS refine its definition of this class to include zolpidem, zaleplon, and eszopiclone and to, in turn, apply OMS flags for these potentiator drugs.

Rationale #2:

While not technically benzodiazepines, zolpidem, zaleplon, and eszopiclone are also known to potentiate the effects of substances like opioids and thus should be flagged in OMS.

Issue #3: <u>Concurrent DUR</u>

CMS proposes policies to strengthen the concurrent DUR requirements, specifically:

- <u>Cumulative morphine milligram equivalent daily dose (MME) safety edits for high, chronic prescription opioid users</u>.
    - Currently, sponsors are expected to implement either soft and/or hard formulary-level safety edits for opioids based on a cumulative MME at POS. Plans may set any soft cumulative opioid claim edit MME threshold at or above 90 mg per day and any hard cumulative opioid claim edit at or above 200 mg per day. CMS' analysis shows that most contracts have implemented soft and hard edits at the "floor" of CMS' guidance.

- For 2019, CMS proposes that all sponsors should implement a hard edit that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90mg, which aligns with CDC guidance.
- Sponsors should not include multiple prescriber or multiple pharmacy criteria, and should continue to apply specifications to account for known exceptions (e.g. hospice care, cancer diagnoses, reasonable overlapping dispensing dates for prescription refills, etc.)
- To balance beneficiary access to medically necessary drug regimens and reduce the potential for unintended consequences for patients already on higher doses of opioids such as withdrawal symptoms, CMS proposes that sponsors should implement these edits in 2019 to allow beneficiaries to receive a 7 day supply of the prescription that triggered the hard edit as written to provide a short-term supply for patients to allow time to pursue coverage through the exceptions process.

Recommendation #3:

Provider education on a national and local level is key here and we believe that all stakeholders need to engage in extensive provider education on the serious risks of concurrent use of certain medications.

Rationale #3:

Providers are key to successful implementation of much of this monitoring.

Issue #4: <u>Day Supply Limits for Opioid Naïve Patients</u>

CDC guidelines state that opioids prescribed for acute pain should be limited to three days or fewer, and that seven days are rarely necessary. CMS intends to establish in the final call letter an expectation that all Part D sponsors will implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain.

CMS requests feedback from stakeholders, especially plan sponsors, providers and PBMs, on the implementation of a days supply limitation at 7 days or if an alternative day supply limit would be more appropriate (e.g. 3 days or 5 days). CMS also solicits comment on whether a days supply limit with or without a daily dose maximum (e.g. 50 MME per day) would be more effective. CMS also request information on both inclusions and exceptions for specific clinical situations and other parameters and safeguards that should be in place to protect appropriate beneficiary access.

Recommendation #4:

In 2019, CMS will expect all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. BCBSA is in support of this proposal given the magnitude of the opioid use crisis and its alignment with current CDC guidelines.

In implementing these changes, BCBSA notes for CMS that current submission quantity limits are based on 30 days. HPMS submission must be updated to allow for 7 or 10 day limit on

opioids. The HPMS factor needs to be updated to allow treatment similar to antibiotics, which normally allows a 7 to 14 day supply per fill and may get more than 1 course of therapy.

Rationale #4:

BCBSA urges the above recommendation to assure a successful implementation of these new policies. We also recommend that first fills of short acting opioids not be subject to immediate coverage determinations which could undermine the intent of the adoption of these limitations.

Issue #5: <u>Opioid Duplicative Therapy Safety Edits</u>

CMS expects all Part D plan sponsors to implement a soft POS edit for duplicative long-acting (LA) opioid therapy beginning in 2019.

CMS requests feedback from stakeholders on the proposed expectation that sponsors implement a soft duplicative LA opioid therapy POS edit and recommendations on the most effective edit specifications.

Recommendation #5:

BCBSA appreciates CMS' proposal regarding soft edits for duplicative long-acting opioid therapy, but notes that soft edits only notify the dispensing pharmacist of duplicate or concurrent use and can be passed easily, dampening the effect CMS is hoping to achieve. Therefore, we are supportive of the more effective hard edit.

Rationale #5:

CMS's strategy to improve the notification and awareness of opioid prescribing and use will work to decrease both the rate of prescribing and the use of opioids by Medicare beneficiaries.

Issue #6: <u>Concurrent Use of Opioids and Benzodiazepines</u>

CMS proposes that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit.

CMS requests feedback from stakeholders on their experience with concurrent or duplicative soft POS edits including an opioid and benzodiazepine and other drug combinations

Recommendation #6:

As discussed above, while BCBSA appreciates CMS' proposal regarding a soft edit for concurrent opioid and benzodiazepine use, we believe a hard edit would be more effective.

Rationale #6:

While soft edits are a good start, our Plans' experience suggests that hard edits are more effective in addressing opioid overutilization.

Issue #7: <u>Access to Medication-Assisted Treatment</u>

As noted in previous Call letter guidance, CMS will closely scrutinize formulary and benefit submissions with respect to formulary inclusion, utilization management criteria, and cost-sharing of Part D drugs indicated for medication-assisted therapy (MAT).

Consistent with recent FDA guidance, CMS will not approve prior authorization criteria that require a beneficiary to need an authorization any more frequently than once during a plan year. Further, when a sponsor has authorized MAT for a beneficiary in the prior plan year, they expect that the sponsor would carry that authorization through to the next plan year.

Recommendation/Rationale #7:

BCBSA has no comments on this issue.

Issue #1: **Coordination of Benefits (COB) User Fee**

CMS reviews and updates the user fee annually to reflect the costs associated with COB activities for a specific year. The 2019 COB user fee rates will be announced in the Final Call Letter.

Recommendation/Rationale #1:

Subsequent to the publication of the draft Call Letter, CMS released the user fee information via an HPMS memo release on February 8. We thank CMS for disclosing this user fee in a separate communication as it was requested by the industry prior to the final Call Letter.

Issue #1: **LIS Enrollee Cost-Sharing for Out-of-Network Part D Drugs**

CMS reiterates current policies prohibiting plans from billing LIS enrollees for the difference between a plan's negotiated price and the pharmacy's U&C cost, and reminds plans of their obligation to process direct member reimbursements from all enrollees timely.

Recommendation/Rationale #1:

BCBSA has no comments on this issue.

Issue #1: **Timely Updates to LIS Status Based on Best Available Evidence**

CMS proposes no policy changes.

Recommendation/Rationale #1:

BCBSA has no comments on this issue.

Issue #1: **Using the Best Available Information When Making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs**

CMS is proposing new guidance on how Part D sponsors should determine whether a drug is a Part B drug and when to revise its findings if the information from CMS changes.

CMS also clarifies how Part D plans can determine that a beneficiary is residing in a long-term care facility for the purposes of determining coverage of inhalation drugs (which can be covered under Part D when the long-term care stay is not covered by Part A).

Recommendation/Rationale #1:

BCBSA has no comments on this new guidance

Issue: **Part D Mail-Order Refill Consent Policy- Solicitation for Comments**

In the 2014 Call Letter, CMS stated that Part D sponsors should require their network retail and mail-order pharmacies to obtain patient consent to deliver a new or refill prescription prior to each delivery to decrease waste and unnecessary cost associated with unneeded or unwanted prescriptions.

Despite modifications, CMS has received requests to further modify or eliminate this policy.

CMS is interested in any information and data associated with mail-order auto-ship programs that indicate actual adherence by patients resulting from automatic (not patient-initiated) refills. CMS is also interested in any information or data that rebuts concerns that such programs increase waste.

CMS is specifically interested in receiving feedback on possible modifications to the current policy, such as replacing affirmative prior consent for refills with a refill shipping reminder that provides a beneficiary sufficient time to cancel, or modifying the current condition of annual beneficiary confirmation to continue automatic refills to be more frequent or contain an opt-in on a per-drug basis.

Recommendation #1:

BCBSA believes the current policies on mail order need modification. BCBSA believes there should not be a one-size-fits-all approach to mail order for a variety of reasons: patients might be on different drugs; some medications are favorable to an automatic refill mechanism and some are not. Our Plans know that auto-fills in a mail order system do not guarantee medication adherence and also can produce waste. BCBSA recommends that Plans be allowed to design the systems they think would work best for their members, e.g. an opt-in per drug feature for an auto-refill; no auto-refills; an annual opt in for all medications; a call in-system per medication. Some plans have a call-in system and some have efficient electronic refill systems and allow beneficiaries to order refills as they see fit. CMS should establish beneficiary protections as a floor and allow plans to vary their approach to mail order, subject to the broad parameters set out by CMS.

Rationale #1:

BCBSA believes that Plans should be able to work with their beneficiaries and their pharmacy benefit managers to come up with systems that are member responsive as well as cost effective and timely in delivery of refills. We do not feel a one size fits all policy is needed in Part D and advocate for Plans to be able to set up their mail order programs with a sense of responsiveness to the member, cost effective mechanisms to avoid unnecessary expenses to

the member, the plan and the government, and systems in place to present fraud, and waste. Convening a panel to talk through best practices at a CMS conference would be most welcomed.

Issue #1: <u>Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2019</u>

CMS has no proposed changes. CMS provides information about the Medicare requirements and timeframes for renewal of the MMP contracts. CMS will also provide guidance shortly after the issuance of the CY 2019 Final Call letter about the applicability of other sections of the Call Letter to MMPs.

Recommendation/ Rationale #1:

BCBSA has no comments on this issue.

March 5, 2018

TRIPLE-S ADVANTAGE

March 1, 2018

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Principal Deputy Administrator and Director
Centers for Medicare and Medicaid Services

Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
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Subject: Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies

Dear Mr. Kouzoukas and Ms. Lazio:

Triple-S Advantage, Inc. thanks you for this opportunity to comment on the 2019 Advance Notice and Draft Call Letter (ANCL). Triple-S Advantage is part of Grupo Triple-S (GTS), an independent licensee of the Blue Cross Blue Shield Association and a publicly traded company since 2007. Through its different lines if business, Triple-S is the leading insurance company in Puerto Rico, chosen by two out of three people to meet their insurance needs. Our experience in providing high quality health insurance to the people of Puerto Rico extends back for more than 55 years. At present, Triple-S Advantage serves one of every five members of the island's Medicare Advantage (MA) program, including those dually eligible to the Medicare and Medicaid program.

The MA program in Puerto Rico serves more than 70 percent of Medicare beneficiaries residing on the island– with 580,000 individuals benefitting from the comprehensive services provided through the program. Our MA penetration rate stands at 74.6%, the highest in the US, when compared to a national average of 33 percent. Although US citizens residing in Puerto Rico are subject to the same Medicare tax and Part B premium payments as those residing in the US mainland, the annual per capita Medicare expenditure in Puerto Rico is estimated at $5,230 compared to a national average of $9,501. Medicare Advantage benchmarks in Puerto Rico remain 26% below the US Virgin Islands, even though both are US territories that share certain communalities, and 38% below the benchmark for Hawaii, the state with the lowest average MA rates.

In addition to the disadvantages the island faces in terms of benchmark calculations for Medicare Advantage, Puerto Rico continues to struggle amidst of a significant wave of migration that has been exacerbated by the recent hurricanes. In addition to the impact this reduction in population will have on already troubled economic and social conditions, it will have a direct impact on federal and state expenditures. For example, Medicare beneficiaries relocating to Florida, as so many have in the aftermath of the storms, represent an increase of approximately 65 percent more to the federal government directed towards the enrollment of the relocating beneficiary.

Triple-S appreciates the Centers for Medicare and Medicaid Services (CMS) staff who have met repeatedly with representatives of the local health care community to discuss Puerto Rico specific challenges including those that have developed since last September's hurricanes. We are extremely proud of the collaborative efforts CMS, HHS and the local health plans employed during the emergency to ensure beneficiaries' most urgent needs were met. As we shift into the recovery phase after this unprecedented catastrophe, we are faced with a long term challenge of rebuilding the healthcare market for Puerto Rico and CMS' continued engagement

and collaboration will be key in identifying opportunities to counteract adverse impacts to the Medicare Advantage program until a more permanent solution is identified. CMS's commitment to improving the program is enormously important to the more than half a million Puerto Ricans who rely on Medicare Advantage coverage.

From a broader perspective, it is important to note that Congress recently passed legislation that includes tremendously important emergency supplemental relief for Puerto Rico's recovery efforts and also specific funding to address the looming Medicaid funding cliff. The Medicaid changes include a 100 percent matching rate for two years paired with lifting the Puerto Rico specific Medicaid cap. This package is welcome and necessary and will make a meaningful difference in stabilizing Puerto Rico's Medicaid challenges for the next two years.

Given that Congress has acted to address the Medicaid cliff over the short term, we now encourage CMS to take similar steps to support the recovery efforts by enacting the necessary policy adjustments that will ensure that Medicare Advantage can continue to serve as the critical backbone of the Puerto Rico's healthcare system. We believe CMS has the administrative authority to establish a benchmark proxy as the right step in terms of addressing our fundamental challenges with disproportionate MA rates.

As discussed in detail in our attachment related to the 2019 Advance Notice, we have significant concerns with the Puerto Rico-specific provisions. We are grateful that the Advance Notice acknowledges a number of the unique challenges facing the MA program in Puerto Rico, in particular the hold harmless provisions enacted for areas affected by natural disasters. We also appreciate that CMS has maintained the STARS double bonus policy adopted in the 2018 Call Letter as well as the Star rating adjustments to medication adherence measure and the CAI calculation with an LIS proxy to address anomalies in the Puerto Rico program. Finally, we strongly support the CMS proposal to review and ideally sustain the zero claims adjustment applied since 2017.

Unfortunately, the Advance Notice did not provide additional specific measures that would ensure meaningful adjustments to address the significant discrepancies in the Puerto Rico payment rates for 2019 and we are concerned that without concentrated efforts by CMS the Puerto Rico recovery efforts may not avert the tide of professional providers' migration, resulting in significant damage to Puerto Rico's healthcare infrastructure. Therefore, our main priority for 2019 is described below and additional details related to other important aspects of the Advance Notice are attached.

- *Average Geographic Adjustment (AGA) Floor.* We strongly encourage CMS to consider an AGA floor to provide temporary relief for Puerto Rico plans as a longer solution to the identified discrepancies in the fee for service data and other documented inconsistencies in the Puerto Rico specific factors. The AGA floor would also protect other US counties from significant negative impacts to Medicare Advantage program as market penetration contuse to grow and fee for service data becomes less reliable as an estimate of actual cost. The AGA floor should also be applied to the ESRD benchmark rates which are also disproportionally lower than all other States and Territories.

In addition to this critical adjustment, we also provide feedback to additional considerations discussed by CMS on the Advance Notice.

- *Zero Claims.* CMS has applied an adjustment since 2017 to reflect the higher proportion of zero-claimants in Puerto Rican fee for service (FFS) program. We were grateful that HHS came to understand that using fee for service as a benchmark is not representative of utilization as accurately in Puerto Rico as it is in the mainland. We firmly believe that such an adjustment is appropriate, and

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is of vital importance to programmatic stability; eliminating last year's adjustment would result in a loss of over $150 million for Puerto Rico.

- *Use of Encounter Data Diagnosis for Risk Adjustment*. CMS is proposing to increase the proportion of encounter data used for risk adjustment from 15% to 25% effective in CY2019. Although Triple-S encourages the use of encounter data for purposes of determining appropriate risk adjustment, EDS continues to be subject to error codes when processed in the system that would place MAO's in a disadvantaged position should CMS move forward with this proposal. More transparency in the root cause of errors would warrant postponing implementation of this proposal for a later date.

- *STARs Puerto Rico Adjustments*. The Advance Notice maintains the Puerto Rico specific adjustments to the STARs medication adherence measure as well as the CAI calculation with an LIS proxy. We are grateful to CMS for including these adjustments, particularly since Medicare beneficiaries living in Puerto Rico remain ineligible for the Part D Low Income Subsidy.

- *STARs Disaster Implications Adjustments*. The Advance Notice establishes a policy to adjust the 2019 and 2020 STAR rating scores on contracts impacted by extreme and uncontrollable circumstances, and specifically dictates that contracts operating solely in Puerto Rico automatically qualify for the adjustments. We strongly support this recommendation and appreciate the acknowledgement of the challenges we face in the post-hurricane environment. Nonetheless, we would appreciate additional guidance from CMS is needed to better understand specific detailed technical proposals laid out by CMS.

We thank you for your consideration of our priorities and we would welcome any opportunity to serve as a resource for you as you work to finalize the policy initiatives for the Medicare Advantage program for 2019. If you have any questions, or would like additional information, please contact Carlos L. Rodriguez-Ramos, Vice President of Legal Affairs and General Counsel at Triple-S. He can be reached at crodrig@ssspr.com or 787-281-2315.

Sincerely,

Madeline Hernández Urquiza
President