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Demetrios Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-2017-0163 -- Comments on the 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 Call Letter

Dear Mr. Kouzoukas:

Health Care Service Corporation (HCSC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the “Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model” and the “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 Call Letter,” which were issued by the agency on December 27, 2017 and February 1, 2018, respectively.

Background

HCSC is the largest customer-owned health insurance company in the United States. The company offers a wide variety of health and life insurance products and related services, through its operating divisions and subsidiaries including Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of New Mexico, Blue Cross and Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas. HCSC serves more than 15 million members, and has established Medicare Advantage Prescription Drug (MAPD) plans and Part D Prescription Drug (Part D) stand-alone plans in all five of the HCSC states. In addition, HCSC operates a Medicare-Medicaid Plan (MMP) contract in the State of Illinois. Our comments appear below.

Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of New Mexico, Blue Cross and Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas

Divisions of Health Care Service Corporation, a Mutual Legal Reserve Company, an Independent Licensee of the Blue Cross and Blue Shield Association

COMMENTS

CY 2019 ADVANCE NOTICE (Parts I & II)

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

Section A. MA Benchmark, Quality Bonus Payments and Rebate

- **Cap on Benchmarks** (pg. 13). CMS indicates that while the agency appreciates the concerns stakeholders have raised in connection with the cap on MA benchmarks, CMS continues to believe that the Secretary does not have the discretion under the statute to eliminate the application of the pre-ACA rate cap or to exclude the Quality Bonus Payment (QBP) from the cap calculation when determining the benchmarks. As a result, the benchmark cap will continue to apply for 2019.

HCSC remains concerned that the cap is inconsistent with the agency's longstanding goals of encouraging plans to continuously improve the quality of care provided to enrollees, and rewarding the delivery of high quality care. As a result, we continue to encourage CMS to explore options under which the agency can exercise existing regulatory authority to eliminate the benchmark cap, or at a minimum, exclude quality bonus payments from the application of the pre-ACA benchmark cap, as this arbitrarily reduces payment rates for high-performing MA plans and ultimately limits and impacts the benefits available to enrollees. For example, we encourage CMS to reconsider the legal brief the Blue Cross Blue Shield Association (BCBSA) has submitted to the agency in prior years outlining an administrative pathway CMS could consider to address this issue.

Section B. Calculation of Fee for Service Cost

- **Calculation of MA Payment Rates** (pg. 15). To be eligible to join an MA plan, beneficiaries must be enrolled in both Medicare Parts A and B; however, benchmarks used to calculate MA payment rates are based on spending for Medicare fee-for-service (FFS) beneficiaries enrolled in either Medicare Part A and/or B. The Medicare Payment Advisory Commission (MedPAC) has indicated that this approach systematically understates the benchmarks because approximately 12% of FFS beneficiaries are Part A-only, and spending for these beneficiaries is lower than for those with both Medicare Part A and B¹. To address this issue and to ensure the beneficiary population used to calculate FFS spending is representative of the expected spending for MA beneficiaries, MedPAC has recommended that CMS calculate MA county benchmarks using FFS spending data only for beneficiaries with both Medicare Part A and B. We note that a recent Health Affairs Blog reiterates MedPAC's findings and recommendation.²

In addition, CMS currently adjusts the FFS rate calculation in Puerto Rico used to determine MA rates so that it is based on beneficiaries enrolled in both Medicare Part

¹ See Medicare Payment Advisory Commission, Report to Congress: Medicare Payment Policy, March 2017

² See Health Affairs Blog, January 25, 2018: <https://www.healthaffairs.org/doi/10.1377/hblog20180119.528795/full/>

A and B “in order to produce a more accurate projection of FFS costs per capita in Puerto Rico.” We note that while CMS indicated in the 2018 Rate Announcement that the agency would “continue to analyze this issue and consider whether any adjustments to the methodology on this point may be warranted in future years,”³ CMS has not included discussion of the issue (beyond the Puerto Rico-specific adjustment) or the results of any underlying analysis in the 2019 Advance Notice. HCSC supports the MedPAC recommendation and strongly encourages CMS to calculate the 2019 benchmarks using FFS spending data only for beneficiaries with both Medicare Part A and B (i.e., excluding spending for Part A-only enrollees), which is consistent with the agency’s goal of ensuring MA payment accuracy.

Section G. MA Employer Group Waiver Plans

- **Proposed MA EGWP Payment Methodology** (pg. 25). CMS is proposing to continue to waive the Bid Pricing Tool (BPT) bidding requirements for all MA employer/union-only group waiver plans (EGWPs) for 2019. In addition, the agency is seeking comment on whether to fully transition in 2019 to the policy of using the weighted average bid-to-benchmark ratios for individual market plan bids (including RPPOs) from the prior payment year (2018) to calculate the 2019 Part C base payment amounts for EGWPs (by quartile), or whether to maintain the payment methodology applied in calculating the 2017 and 2018 MA EGWP payment rates. Under this approach, the bid-to-benchmark ratios reflected a blend of individual market plan bids and EGWP bids from 2016, with individual market plan bids weighted by 50 percent and EGWP bids weighted by 50 percent. CMS also is considering the inclusion of an additional step in calculating the bid-to-benchmark ratios, whereby an adjustment would be made to the calculation used to determine the ratios to account for differences in the proportion of beneficiaries enrolled in Health Maintenance Organization (HMO) vs Preferred Provider Organization (PPO) plan types between EGWPs and individual-market plans.

As indicated in our previous comments on this topic, HCSC has concerns with CMS’ proposal to continue to utilize a revised payment methodology for MA EGWPs based on average bids in the individual market. Such an approach does not sufficiently reflect key factors such as geographic service patterns, benefits, historical claims experience, or plan type all of which are critical to ensuring underlying payment rates are appropriate. For example, individuals receiving coverage in MA EGWPs are more likely to be geographically dispersed given their retiree status, and therefore may place a very high value on out-of-network coverage options available through local and regional PPOs. As a result, even with the proposed adjustment to better account for plan types, we are concerned that determining MA EGWP payments as proposed will not be sufficiently representative of the products in which EGWP beneficiaries are enrolled. It is important that organizations and employers are able to offer benefits that are consistent with those received by individuals as active workers, and to satisfy other priorities identified by employers to serve their group health plan members.

³ See <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>

Accordingly, we recommend that CMS reinstate the bid-based payment methodology for determining MA EGWP payments that was in effect prior to 2017. We recognize that CMS has raised transparency-related concerns about utilizing this approach (i.e., allowing organizations to submit composite bids and benefit packages, rather than unique bids and benefit information for each plan) as well as concerns about the administrative complexities inherent in an approach that would rely on the submission, review and approval of individual bids and benefit packages for each EGWP; however, we firmly believe ensuring the payment methodology is designed in a manner that results in the most accurate and appropriate payments to plans far outweighs the administrative benefit associated with continuing to waive the BPT requirements.

If additional time is needed for CMS to work with the industry to address the agency's operational concerns related to a bid-based payment approach before reinstating the methodology, as an interim step for 2019, HCSC would recommend that CMS base the individual plan bid-to-benchmark ratios on PPO plans only. An interim approach along these lines would likely provide a more accurate comparison to utilization that occurs in MA EGWPs as noted above.

Section H. CMS-HCC Risk Adjustment Model for CY 2019

- **MA Risk Adjustment Model Changes** (pg. 30). For 2019, CMS is proposing significant modifications to the current MA risk adjustment model, including to reflect changes required by the 21st Century Cures Act that direct the agency to evaluate the addition of mental health, substance use disorder, and chronic kidney disease conditions in the model, and to make adjustments to take into account the number of conditions an individual beneficiary may have. Specifically, CMS is proposing to:
 - Implement a new “Payment Condition Count Model” that would add new variables that take into account the number of diseases or conditions an individual has, among the conditions included in the payment model. As an alternative, CMS presents a second option, the “All Condition Count Model” that would take into account all conditions a beneficiary has, including both those in the payment model and those not included in the model;
 - Add new Hierarchical Condition Categories (HCCs) to the model related to mental health conditions and substance use disorders, and reinstate the HCC for “Chronic Kidney Disease, Moderate (stage 3)” that was previously removed from the model;
 - Recalibrate the model with more recent data (i.e., 2014 diagnoses data to predict 2015 spending); and
 - Utilize only encounter data in the new model and apply the encounter data filtering logic to calibrate the new model.

In addition, CMS indicates that the 21st Century Cures Act directs the agency to phase-in any changes to the MA risk adjustment model over a 3-year period, “beginning with 2019, with such changes being fully implemented for 2022 and subsequent years.” However, CMS notes that this language could be interpreted to permit the agency to begin implementation of the new model in either 2019 or 2020. CMS states that this interpretation may allow the agency to use the 2019 Advance Notice and comment

process to obtain feedback to inform options for the phase-in of the new model starting in 2020.

HCSC agrees with CMS' interpretation and strongly recommends that the agency exercise discretion to begin the phase-in starting in 2020, rather than move forward with implementation of the proposed MA risk adjustment model changes in 2019. This approach will provide additional time for MA organizations to continue to evaluate the proposed changes, which are complex and require significant actuarial and other resources to conduct a comprehensive and thorough analysis. In addition, it is of critical importance that any potential changes to the risk adjustment model do not result in unintentional consequences for our members and the MA program, or impede our ability to perform in a manner that best serves program goals. Permitting an opportunity for further review helps safeguard against these type of inadvertent outcomes.

We also believe the additional time provides an opportunity for CMS to work with stakeholders to ensure development of a new model appropriately adjusts payment in a manner that is consistent with the intention of the 21st Century Cures Act, and avoids adverse impacts on payment. Specifically, CMS should convene regular and ongoing dialogue with plans and industry experts to discuss key model considerations, other potential alternative approaches, and to provide a general forum for the agency to respond to technical questions as evaluation of the changes continues.

Section I. ESRD Risk Adjustment Model for CY 2019

- **ESRD Risk Adjustment Model Changes** (pg. 30). CMS is proposing to implement an updated version of the ESRD risk adjustment model in 2019, although the basic structure of the model and the HCCs would remain the same. Specifically, the agency is proposing to: (1) recalibrate the model based on updated data years, using 2014 diagnoses to predict 2015 costs; and (2) update the Medicaid factors to be concurrent with the payment year (i.e., Medicaid designation would be based on payment year status). CMS notes that the ESRD risk adjustment model currently used in payment was implemented in 2012 and has not been recalibrated since.

In addition, CMS indicates that plans may experience an increase in the MA ESRD population in future years due to implementation of the provision in the 21st Century Cures Act that will allow all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021, and believes it would be preferable to update the model before that time. The agency notes that the updated model “will result in payment that is more accurate and provides MAOs time to adjust to payments based on this new model prior to experiencing potential increases in enrollment.” We have identified the following issues and related recommendations for CMS' consideration.

- **Implementation Timing.** To help mitigate any potential adverse impacts of recalibrating the ESRD risk adjustment model since it has not been recalibrated in over 5 years (i.e., significant swings in the model coefficients, etc.), we recommend that CMS consider a phased implementation of the new model over a period of time (e.g., two years).

- **Additional 21st Century Cures Act Requirements.** The 21st Century Cures Act requires CMS to evaluate the ESRD risk adjustment model, and mandates that the agency issue an initial report by December 31, 2018. In the Advance Notice Part I, CMS indicates that the evaluation will include a discussion of the criteria utilized by the agency to develop the model and to determine incremental changes. CMS notes that, as part of this effort, the agency “will produce a wide range of predictive ratios, for various subgroups, including very high and very low cost enrollees, groups defined by the number of chronic conditions for enrollees, and for each conditions category.” To support transparency, we request that CMS specify in the final 2019 Rate Announcement, the expected timing for release of the additional information required by the statute, or if possible, release the additional information if it is available at that time.

Section K. Medicare Coding Pattern Adjustment

- **Coding Intensity** (pg. 35). Each year, as required by law, CMS applies an adjustment to MA risk scores to reflect differences in diagnosis coding between MA organizations and fee-for-service (FFS) providers. For 2019, CMS proposes to apply the statutory minimum MA coding pattern adjustment factor of 5.90 percent. HCSC supports the agency’s decision to not exceed the statutory minimum adjustment amount. In addition, CMS indicates that the agency is considering multiple methodologies to inform final decision-making regarding the adjustment factor for 2019. CMS does not include in the Advance Notice specific details on the additional methodologies, but notes that the methodologies “have been publicly discussed” (i.e., in a previous CMS Advance Notice, Rate Announcement, or MedPAC report), and references the websites where these documents are posted.

We are concerned that CMS has not provided sufficient details to support our analysis of the additional methodologies, and as a result, our ability to fully assess the approaches and the potential impacts, as well as to provide informed and meaningful feedback for the agency’s consideration is significantly impacted. Accordingly, we strongly recommend that CMS move forward with implementing the statutory minimum adjustment for 2019 and refrain from considering any additional adjustments beyond that level. If CMS intends to consider alternative methodologies in future years, we encourage the agency to do so in a manner that is consistent with CMS’ stated commitment to ensuring transparency, by providing sufficient information and time to support stakeholder analysis and feedback.

Section L. Normalization Factors

- **FFS Normalization** (pg. 36). For PY 2019, CMS is proposing a Part C normalization factor of 1.041 for the current version of the MA risk adjustment model (i.e., the version of the model used in 2017 and 2018), and a factor of 1.038 for the proposed Payment Condition Count (PCC) model, which CMS predicts will result in a 2.3 percent reduction in MA plan payments in 2019. CMS indicates that the agency applies a normalization factor to each year’s risk scores to account for coding and population changes that are expected to occur in FFS, with the goal of keeping the average FFS risk score across

all beneficiaries at 1.0 in the payment year. The agency calculates normalization factors using historical risk score data that are updated annually with more current data. For example, CMS used FFS risk scores from 2013 to 2017 to calculate the estimated 2019 normalization factor.

We note that, for 2016 and 2017, CMS observed large increases in the average FFS risk scores that were not consistent with prior year's observations. The agency has not yet provided an explanation for the increases, but acknowledged on an industry call that the issue was under evaluation. HCSC is very concerned about the preliminary factor and the underlying abnormally large increase in the FFS risk scores calculated for these years. We understand that a potential explanation for the increases may be related to the transition from ICD-9 codes to ICD-10 codes, which began October 1, 2015. That is, the increases could potentially result from differences in coding and HCC mappings between the ICD-9 and ICD-10 code sets, and may not be a true reflection of higher risk scores in FFS for 2016 and 2017. In addition, CMS indicated that both the current MA risk adjustment model and the proposed PCC model were estimated based on ICD-9 data; however, due to the transition to ICD-10, both the 2016 and 2017 FFS risk scores utilize ICD-10 data. This difference between how the models were estimated and the risk scores used to determine payments may further explain the observed increases.

We urge CMS to evaluate whether the transition to ICD-10 is the likely cause of the significant increases in the 2016 and 2017 FFS risk scores, or provide insight into the rationale for the increases as quickly as possible if it is determined that the transition is not the underlying cause. We also recommend that the agency implement an approach to mitigate the impact of the outlier 2016 and 2017 FFS risk scores on the normalization factor for 2019 to ensure payment accuracy and stability. For example, include 2011 and 2012 data (in addition to 2013-2017 data) in the calculation of the factor to reduce the risk of placing too much weight on ICD-10 codes if the transition to the code set is the underlying cause.

Section N. Encounter Data as a Diagnosis Source for 2019

- **MA Encounter Data** (pg. 42). For payment year (PY) 2019, CMS is proposing to continue to calculate MA and Part D risk scores by blending and weighting two separate risk scores, one calculated using diagnoses from the Risk Adjustment Processing System (RAPS), and another calculated using diagnoses from the Encounter Data System (EDS). Specifically, the agency is proposing to increase the proportion of risk scores based on encounter data, from 15 percent for 2018 payment to 25 percent for 2019 payment. In addition, CMS proposes to supplement the diagnoses from encounter data with inpatient diagnoses from RAPS submissions in an effort to "improve the completeness of the data for payment in 2019." Lastly, as noted above, CMS is proposing that the encounter data-based risk scores would be calculated only with the proposed "Payment Condition Count" model.

HCSC continues to be firmly committed to the submission of accurate and complete MA encounter data and we have consistently worked toward achieving that goal. We have appreciated CMS' increased efforts, particularly over the past 12 months, to

engage with plans regarding technical and operational issues related to encounter data, and to make improvements based on feedback received. However, we continue to have significant concerns regarding the increased use of encounter data for risk score calculation and payment purposes in light of the ongoing operational and technical issues and challenges that have impacted submission, acceptance and processing of encounter data, and remain a barrier to successful implementation. Our specific concerns and related recommendations follow below.

- **Impact of Encounter Data on Risk Scores and Payment.** We note that a number of recently updated studies have reported that the use of encounter data in the calculation of risk scores negatively impacts those scores as well as the resulting plan payments. This includes an updated white paper issued by Milliman⁴ in February 2018, which describes the findings from the firm's analysis of data from 10 MA organizations representing 313,000 beneficiaries. Based on the analysis, Milliman determined that the median percentage difference between 2016 risk scores based on RAPS data and EDS data was 3.1 percent. In addition, the study found that this variance in risk scores persisted in payment year 2017, noting a median difference of 2.5 percent. The white paper also notes that Special Needs Plans (SNPs), which serve vulnerable members with very unique and complex health care needs, had a median difference in risk scores for payment year 2017 of 5.2 percent, even higher than the variance for MA plans overall. Similarly, Avalere Health released an updated study toward the end of 2017⁵, which evaluated the impact of shifting the determination of plan risk scores from RAPS to EDS. The study analyzed data from 30 unique MA plans, representing 760,000 beneficiaries and found that average risk scores resulting from EDS were 3 percent lower in payment year 2016 compared to risk scores under RAPS.

In addition, we note that CMS explicitly indicates in the Fact Sheet that accompanied the 2019 Advance Notice (Part II) that the transition to encounter data as a diagnoses source for risk adjustment results in an estimated reduction in MA payment. Specifically, CMS estimates that increasing the proportion of risk scores based on encounter data from 15 percent in 2018 to 25 percent in 2019, will result in a payment reduction of 0.04 percent. Further, the proposed transition to increased reliance on encounter data for risk score calculation and payment is highlighted in the President's fiscal year (FY) 2019 Budget proposal as a budget offset, estimating that the proposed transition will reduce MA spending by \$11.1 billion over 10 years. We believe that the estimated negative payment impact of the increased reliance on encounter data, is inconsistent with CMS' stated expectation that "since the same diagnoses that are submitted into the Risk Adjustment Processing System (RAPS) can be submitted into the encounter data system...the scores should be similar."⁶

⁴ Milliman; Impact of the transition from RAPS to EDS on Medicare Advantage risk scores. February 2018. See <http://us.milliman.com/uploadedFiles/insight/2018/Medicare-RAPS-to-EDS-2017.pdf>

⁵ See Avalere Health, October 2017: <http://avalere.com/expertise/managed-care/insights/impact-evaluation-medicare-advantage-transition-from-raps-to-eds>

⁶ See CY 2016 Final Rate Announcement: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf> ; p. 35, April 6, 2015.

- **Evaluation of MAO-004 Reports.** MA organizations rely on the CMS MAO-004 Risk Filtering Reports to determine which diagnoses submitted to and accepted by EDS are eligible for risk adjustment, and will be used by the agency to calculate risk scores after CMS' filtering logic is applied. These reports also play a critical role in our efforts to track and reconcile acceptable diagnoses with their submitted encounters, and impact our ability to evaluate the agency's filtering logic to determine whether the approach to filtering diagnoses from encounter data results in risk scores that are consistent with those calculated under RAPS.

The initial versions of these reports were issued starting in late December 2015, but our ability to utilize the reports was significantly hindered by structural issues and other technical and operational challenges. In addition, CMS has had to implement continued changes to the reports and reissue the reports after each round of modifications. HCSC has seen improvements in the reports over time and very much appreciates CMS' willingness and efforts to work with the industry toward resolving these issues and implementing updates, including based on plan feedback and input. However, CMS does not expect to issue the most recent iteration of the report (a fifth edition), until April 2018. These updated reports will be issued for all encounter data records submitted since January 2014 and will be critical to our efforts to further analyze the impact of CMS' filtering logic and to track and reconcile acceptable diagnosis with our submitted encounters. Due to the anticipated April 2018 release of the enhanced version of these reports, we will not be able to consider any analysis or findings from the updated reports to inform feedback to CMS during this comment opportunity given the March 5, 2018 comment submission deadline.

- **GAO Report & Recommendation.** As we have noted in our previous comments on this issue, the Government Accountability Office (GAO) issued a report in July 2014⁷ that evaluated CMS' collection of MA encounter data. The report concluded that "CMS should establish specific plans for using MA encounter data and thoroughly assess data completeness and accuracy before using the data to risk adjust payments or for other purposes." The GAO issued an updated version of the report in January 2017⁸ that updated the 2014 study, focusing on steps the agency has taken to validate encounter data as well as plans and timeframes for using the data. As recommended in the July 2014 report, the updated report again concluded that CMS should complete all the steps necessary to validate the data before using them to risk adjust payments or for other intended purposes. The report also noted, "to the extent that CMS is making payments based on data that have not been fully validated for completeness and accuracy, the soundness of billions of dollars in Medicare expenditures remains unsubstantiated."

Given the range of issues and concerns described above, HCSC continues to believe it would be inappropriate to further increase reliance on encounter data for risk score

⁷ GAO Report. Medicare Advantage: Limited Progress Made to Validate Encounter Data used to Ensure Proper Payments; <http://www.gao.gov/assets/670/665142.pdf> ; July 2014.

⁸ GAO, Report. Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments; <http://www.gao.gov/products/GAO-17-223>; January 2017.

calculation and payment purposes until CMS and plans can determine with confidence that the issues have been fully resolved and no longer present a barrier to establishing a data stream on which payments could be reliably based. We note that in the CY 2019 MA and Part D proposed rule, CMS stated that the agency “expects that MA encounter data will be more accurate and complete in the future” which acknowledges that this important milestone has not yet been fully achieved. Accordingly, we strongly urge CMS to not move forward with adoption of this proposal and to maintain and not exceed the current 85 percent RAPS/15 percent EDS blend that is applicable for payment year 2018. CMS should not consider increasing the percentage of plan risk scores determined by encounter data until the issues highlighted above have been fully addressed. We believe an approach along these lines will better preserve the integrity and accuracy of the payment process and ensure payments are no less from the use of EDS data than they otherwise would be from the use of RAPS data.

In addition, CMS indicated in the CY 2016 Final Rate Announcement that the agency would monitor the impact of using encounter data-based diagnoses on risk scores and risk score trends. We have encouraged CMS to make available the agency’s underlying methodology and aggregate results of the monitoring and evaluation in this area to ensure transparency and to support plan internal evaluation efforts; however, CMS has not yet publicly released the requested information. We continue to believe the methodology and results of the agency’s monitoring in this area would be valuable and strongly recommend that CMS release this information as quickly as possible.

Section O. Quality Payment Program

- **Payer-Initiated Submission Process** (pg. 43). Beginning in 2019, CMS will be implementing the All-Payer Combination Option under the agency’s Quality Payment Program (QPP), which was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The All-Payer Combination Option takes into account eligible clinician participation in both Advanced Alternative Payment Models (Advanced APMs) as well as in “Other Payer Advanced APMs,” which are non-Medicare FFS payment arrangements such as MA, Medicaid, and commercial payers that meet criteria similar to Advanced APMs.

CMS indicates that, as part of the 2019 bid submission process, Medicare Health plans (including MA plans, MMPs and cost plans) may submit applications to determine whether their payment arrangements are considered “Other Payer Advanced APMs” under the QPP. CMS notes that guidance and submission forms will be part of a QPP module of the bid submission package that will be released in April 2018. HCSC encourages CMS to release draft versions of the anticipated QPP module and related instructions for review and comment before they are finalized. We believe an approach along these lines will permit end-users to identify and raise with CMS any potential operational barriers, questions or concerns as early as possible and may avoid the need for the agency to make adjustments to the module or instructions subsequent to implementation.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2019

Section E. Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap

- **Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap** (pg. 55). The Bipartisan Budget Act (BBA) of 2018, which was signed into law subsequent to the publication of the 2019 Advance Notice, changes the beneficiary, Part D sponsor and manufacturer liability for applicable (brand) drugs in the coverage gap phase of the Part D benefit. As a result, the Part D benefit parameters that were included in the 2019 Advance Notice must be adjusted, and CMS also may need to update the Part D risk adjustment model and make other potential changes (e.g., update the Out-of-Pocket Cost model, etc.) to reflect the adjustments accordingly, including to support Part D bid development and to ensure bids are appropriately standardized.

Section G. Part D Calendar Year Employer Group Waiver Plans

- **Reinsurance Payments** (pg. 56). For Payment Year (PY) 2017, CMS began making prospective reinsurance payments to all Calendar Year EGWP Part D sponsors based on the average per member, per month (PMPM) actual reinsurance amounts paid to Calendar Year EGWP Part D sponsors for 2014. For 2019, CMS is proposing to make prospective reinsurance payments to all Calendar Year EGWP Part D sponsors based on the average PMPM actual reinsurance amounts paid to Calendar Year EGWPs for 2016, as the 2016 reconciliation data are the most current actual total reinsurance amounts available for publication in the 2019 Advance Notice/Rate Announcement. HCSC continues to support this proposed approach.

DRAFT CY 2019 CALL LETTER

Section I – Parts C and D

Annual Calendar

- **Timeline for Issuance of Sub-Regulatory Guidance** (pgs. 100-105). CMS states that the combined annual calendar included in Section I of the draft Call Letter lists key dates and timelines for operational activities pertaining to MA organizations, Part D plan sponsors, MMPs and cost plans. As indicated in our comments on CMS' CY 2019 MA and Part D proposed rule, it will be of critical importance for the agency to provide operational guidance and requirements related to program changes that are finalized for 2019 as quickly as possible following release of the final rule to support successful implementation and timely compliance with the agency's requirements. Toward that goal, we encourage CMS to consider adjusting timelines (i.e., moving up) for issuance of relevant guidance and reflecting the adjusted dates in the final Call Letter as appropriate (e.g., related to the Marketing Guidelines, etc.).

Enhancements to the 2019 Star Ratings and Future Measurement Concepts

- Technical Expert Panel** (pg. 106). CMS indicates that in 2018 (after the final 2019 Call Letter is issued), the agency's Part C & D Star Ratings contractor, RAND Corporation, will establish a Technical Expert Panel (TEP) comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, operational measures and other potential issues (e.g., data integrity review process, how the Star Ratings should relate to audits and enforcement actions, etc.). Suggestions resulting from the TEP will be provided to CMS to inform potential future enhancements. HCSC supports establishment of the TEP, which is consistent with longstanding HCSC and industry recommendations for CMS to establish a framework to facilitate ongoing, transparent and collaborative efforts related to Star Ratings issues that would include CMS, plans and other key stakeholders. We strongly encourage CMS to ensure the TEP prioritizes evaluation and discussion of pre-determined measure cut-points, improvements to the interim Categorical Adjustment Index (CAI), and a robust and meaningful longer-term solution to account for the disparity in performance associated with a contract's percentage of beneficiaries with low income subsidy and/or dual eligible and disability status.
- Measure Cut Points** (pg. 106). CMS indicates that the "cut points to determine star assignments for all measures and case-mix coefficients for the CAHPS survey and Health Outcomes Survey (HOS) will be updated for 2019 Star Ratings using the most current data available." Consistent with our previous comments related to measure cut-points, HCSC continues to strongly encourage CMS to reinstate the previous policy of providing pre-determined 4-star thresholds under the Star Ratings system, which allows us to set goals, both internally and for our contracted providers, and to work efficiently toward well-defined standards that reflect key CMS priorities. Further, pre-determined cut points provide greater transparency in the Star Ratings system and facilitate our ongoing assessment of the effectiveness of our efforts to achieve or maintain the highest level of ratings.

We appreciated CMS' willingness in the recent CY 2019 MA and Part D proposed rule, to consider methodologies to minimize year-to-year changes in the cut-points, which make it challenging for plans and our contracted providers to set goals and make progress toward achieving them. To address this concern, we reiterate our recommendation for CMS to evaluate whether establishing measure cut-points based on industry performance over a period of time, rather than a specific point in time, results in improved stability by minimizing year-to-year fluctuations. In addition, to ensure that measure cut-points result in ratings that reflect meaningful differences in performance across contracts, we recommend that CMS evaluate whether establishing cut-points based on quadrants between whole stars (e.g., 3, 3.25, 3.5, 3.75) results in ratings that more accurately reflect distinctions in quality and performance. We also recommend that CMS make available to plans, the results of the agency's evaluation/analysis (and the underlying methodology applied), and provide a subsequent opportunity for further review of and feedback on proposed approaches. In addition, as noted in our comments above, we strongly encourage CMS to ensure the

Star Ratings TEP prioritizes evaluation and discussion of this issue once the panel is established.

- **New Measures for 2019 Star Ratings**
 - **Statin Use in Persons with Diabetes (SUPD) (Part D) & Statin Therapy for Patients with Cardiovascular Disease (Part C)** (pg. 107). As previously signaled, CMS is proposing to add the “Statin Use in Persons with Diabetes (SUPD)” Part D measure and the “Statin Therapy for Patients with Cardiovascular Disease” Part C measure to the Star Ratings for 2019. The agency also proposes to classify the Part C statin measure as a process measure with a weight of 1 in 2019 (and subsequent years as process measures are assigned a weight of 1), and to classify the Part D statin measure as an intermediate outcome measure with a weight of 1 in 2019 (the initial year) and a weight of 3 in subsequent years. While we support CMS’ proposal to apply a weight of 1 to both measures in 2019, we recommend that CMS continue to apply a weight of 1 for both measures in subsequent years to ensure consistent treatment across both measures. In addition, to refine the measures, we recommend that CMS work with the Pharmacy Quality Alliance (PQA) and the National Committee for Quality Assurance (NCQA), the applicable measure developers, to continue to evaluate and apply additional exclusions due to intolerance to statins and/or contraindications, as appropriate.
- **Changes to Measures for 2019**
 - **Improvement Measures (Part C & D)** (pg. 108). We recommend that CMS revise the chart on page 108 of the draft Call Letter to explicitly identify adjustments to the measure list (i.e., additions and deletions, inclusion/exclusion in the improvement measure calculation) to ensure ease of use and to facilitate a uniform understanding of year-to-year changes. In addition, we recommend that CMS include a similar version of the revised chart in the Call Letter in future years.
- **Proposed Scaled Reductions for Appeals IRE Data Completeness Issues** (pg. 114). As previously signaled in CMS’ CY 2019 MA and Part D proposed rule, the agency is proposing a new rule to authorize scaled reductions in Star Ratings for the Part C and Part D appeal-related measures. Specifically, the proposed methodology would employ scaled reductions to account for the degree to which Independent Review Entity (IRE) data are missing, ranging from a 1-star reduction to a 4-star reduction, with a 4-star reduction being the most severe and resulting in a measure-level Star Rating of 1 star for the associated appeal measures. CMS plans to utilize findings from the agency’s industry-wide appeals Timeliness Monitoring Project (TMP) or audit data to inform the data integrity reviews and ultimately the scaled reductions, when applicable.

We believe the proposal to implement scaled reductions for the appeal measures is a reasonable approach that will permit CMS to consider the degree and severity of the issues identified, rather than a one-size fits all approach. In addition, we note that the

TMP, which was first initiated in 2017, is still in the initial years of implementation. We continue to encourage CMS to ensure the agency and plans have had sufficient time to gain experience with the monitoring effort, to refine the approach and underlying processes as needed, and to ensure the data and approach are stable and appropriately reliable for data integrity purposes. In addition, we recommend that CMS ensure impacted plans have access to the underlying data the agency utilizes to determine the reductions to assist plan efforts to compare and reconcile CMS data with plan internal data and to better understand associated findings.

- **2019 Star Ratings Program and the Categorical Adjustment Index** (pg. 122). For the 2019 Star Ratings and beyond, CMS is proposing to continue the use of the interim analytical adjustment, the “Categorical Adjustment Index (CAI),” to account for the average within-contract disparity in performance associated with a contract’s percentage of beneficiaries with low income subsidy and/or dual eligible (LIS/DE) and disability status. HCSC continues to believe that serving and enrolling a population comprised disproportionately of individuals with complex needs (including beneficiaries with LIS/DE and disability status), presents unique challenges that have not been accounted for in the Star Ratings System and are only minimally addressed by the CAI. While HCSC supports CMS’ proposal to continue to apply the CAI to the Star Ratings, we look forward to working with the agency to develop a meaningful long-term approach and solution to these issues. As noted in our comments above, we urge CMS to ensure the forthcoming Technical Expert Panel prioritizes action related to improvements to the interim Categorical Adjustment Index (CAI), and a robust and meaningful longer-term solution to account for the disparity in performance associated with a contract’s percentage of beneficiaries with low income subsidy and/or dual eligible and disability status.
- **Additional Response to Address Lack of an LIS Indicator for Enrollees in Puerto Rico** (pg. 133). For the 2019 Star Ratings, CMS is proposing to continue to employ the methodology developed for the 2017 Star Ratings to apply an additional adjustment for contracts that solely serve beneficiaries in Puerto to make the application of the CAI equitable, as those beneficiaries are not eligible for LIS. CMS also proposes to continue to reduce the weights for the adherence measures to zero for the summary and overall rating calculations and maintain the weight of 3 for the adherence measures for the improvement measure calculations for these contracts. HCSC continues to support CMS’ ongoing recognition of these issues and the proposed continuation of these adjustments accordingly.
- **Disaster Implications** (pg. 133). To address Star Ratings issues related to contracts impacted by natural and other disasters, CMS is proposing to adjust the 2019 and 2020 ratings of affected contracts to take into account the effects of these events, including hurricanes and wildfires, that occurred during the 2017 performance period. Specifically, CMS is proposing a policy to identify contracts that were affected by extreme and uncontrollable circumstances that may impact their performance on Star Ratings measures and/or their ability to collect the necessary measure-level data; rules for adjusting the applicable measures for impacted contracts (i.e., for CAHPS, HOS, HEDIS and other measures); and adjustments to cut point calculations to mitigate impacts. HCSC appreciates and supports CMS’ proposed approach to address Star

Ratings issues related to contracts impacted by extreme and uncontrollable circumstances and we recommend that the agency finalize the proposal in the forthcoming final Call Letter.

- **Forecasting to 2020 and Beyond**

Potential Changes to Existing Measures

- ***Telehealth and Remote Access Technologies*** (pg. 146). In the CY 2018 draft Call Letter, CMS solicited feedback on the appropriateness of including telehealth and/or remote technology encounters, as allowed under the current statutory definition of Medicare covered telehealth services and/or as provided by an organization as a supplemental benefit, as eligible encounters in various Part C quality measures. In the current draft Call Letter, the agency welcomes feedback to share with NCQA on feasibility of and strategies for addressing telehealth services especially regarding the following measures that are reported by Medicare contracts: Use of Spirometry Testing in the Assessment and Diagnosis of COPD; Adults' Access to Preventive/Ambulatory Health Services; Controlling High Blood Pressure; and Comprehensive Diabetes Care.

HCSC continues to appreciate CMS' efforts to consider and solicit feedback on these issues. Given that many MA organizations are either in the early stages of exploring or do not offer a telehealth benefit, we believe it would be premature for the agency to include and rely on data from telehealth encounters for star rating purposes at this time. We encourage CMS to continue to examine and reevaluate this issue in the future, as availability of this type of benefit increases particularly in light of the recent statutory changes that expand telehealth services under MA.

- ***Cross-Cutting Exclusions for Advanced Illness (Part C)*** (pg. 146). CMS indicates that NCQA is evaluating the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected HEDIS measures, particularly in instances where providing certain treatments and services may not be appropriate. Specifically, NCQA is exploring which specific illnesses and healthcare utilization may warrant an exclusion, and to which measures the exclusion should be applied. The agency notes that if approved, updates to HEDIS measures for any additional exclusions would be incorporated in HEDIS 2019. HCSC supports NCQA's evaluation and looks forward to additional details regarding the resulting findings.
- ***Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D)*** (pg. 146). CMS proposes to update this measure to apply a new denominator exception to the 2020 Star Ratings (based on 2018 data). The exception is applicable to patients eligible for a comprehensive medication review (CMR) with fewer than 61 days of continuous enrollment in the MTM program who would be excluded from the denominator if they did not receive a CMR within this timeframe. HCSC supports the proposed application of this exception.

Potential New Measures for 2020 and Beyond

- **Transitions of Care (Part C)** (pg. 148). As signaled in the 2018 Call Letter, CMS plans to propose to include a new HEDIS Transitions of Care measure (with four indicators), on the display page in 2020 and consider the measure for possible inclusion in the 2022 Star Ratings. While we understand and value the importance of ensuring the quality of care transitions from an inpatient setting to the home, we are concerned that the four indicators for this new measure are predicated on certain assumptions about care and the structure of health care delivery systems more broadly, that may not be consistent across all MA organizations or for all MA enrollees. For example, the indicators generally are dependent on the enrollee having a primary care provider (PCP), which may vary based on the type of plan in which the beneficiary is enrolled (i.e., HMO vs. PPO). In addition, it is unclear from an administrative and systems perspective how CMS envisions the exchange of information between involved entities (e.g., the PCP and hospital after discharge) would occur, be documented and subsequently considered for this measure. Further, inclusion of additional HEDIS measures in the Star Ratings increases burden on the provider community due to the need for related medical record review. Given these administrative and operational concerns as well as the general lack of clarity, we continue to strongly recommend that CMS not move forward with collection of this measure or inclusion of resulting data in the Star Ratings at this time, and encourage the agency to work with plans to identify more appropriate alternative options.

Measurement and Methodological Enhancements

- **Treatment of “Topped Out” Measures** (pg. 156). CMS indicates that the agency will continue to analyze existing Star Ratings measures to determine if measure scores are “topped out” or showing high performance across all contracts. HCSC has consistently advocated that any policy or technical changes impacting Star Ratings should be implemented prospectively (i.e., after the applicable measurement year) and with sufficient advance notice to ensure the integrity and effectiveness of the system. We believe it will be of critical importance for CMS to apply this key concept when evaluating whether measures should be transitioned due to consistently high performance across all contracts.

Validation Audits

- **Proposed Changes to CMS Independent Validation Audits** (pg. 159). CMS is proposing several process improvements and enhancements to the program audit validation process based on feedback from the industry. The agency indicates that the changes are “intended to promote consistency and decrease burden on Sponsors.” HCSC appreciates and supports CMS’ efforts to implement improvements. We have identified the following issues and related recommendations for CMS to consider as the agency works toward refining this phase of the audit process.

- **Threshold for Requiring an Independent Validation Audit** (pg. 160). We support CMS' proposal to modify the threshold used to determine when a sponsoring organization must hire an independent auditing firm by excluding Compliance Program Effectiveness (CPE) conditions from the threshold calculation as these conditions "do not directly and adversely impact beneficiaries."
- **Required use of CMS Validation Audit Work Plan Template** (pg. 162). HCSC supports CMS' proposal to create a standardized validation work plan template that organizations undergoing an independent validation audit in 2019 would be required to submit. We agree with the agency's belief that the template will facilitate consistency across all validation audits and may help standardize the cost of an independent audit. In addition, we believe the template will assist the independent audit organization in developing the audit work plan, and also assist plan efforts to provide input on the development process. CMS notes that the draft template will be issued for comment under the Paperwork Reduction Act (PRA) process in an upcoming Federal Register proposed information collection. We look forward to an opportunity to review the draft template and to provide comments to CMS to inform potential refinements, as applicable.
- **Timeframe to Complete Validation Audits** (pg. 163). HCSC supports CMS' proposal to extend by 30 days (i.e., from 150 to 180 calendar days), the timeframe organizations are afforded from the date that all of the program audit Corrective Action Plans (CAPs) are accepted by CMS, to complete a validation audit and submit the independent audit report to the agency for review. We believe the extended window ensures sufficient time is allotted to successfully complete the required actions and steps, and better aligns with the agency's goal of ensuring all originally reported audit conditions are substantially corrected.

New Medicare Card Project (formerly the Social Security Number Removal Initiative, SSNRI) (p. 167). In the draft Call Letter, CMS reminds plans that beginning in April 2018, the current Social Security Number based Health Insurance Claim Number (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 accordingly. HCSC is committed to working with CMS and other partners to ensure a successful implementation. Toward that goal, we have identified the following issues and related recommendations for the agency's consideration.

- **Call Center Scripts.** We recommend that CMS share with MA organizations and Part D plan sponsors the call center scripts that will be utilized by 1-800-MEDICARE customer service representatives when responding to issues and inquiries related to the New Medicare Card initiative. While we appreciate the information and materials the agency has provided to-date to support beneficiary education and outreach efforts, we believe having access to this additional resource will further ensure consistency in the information our members receive regarding this effort.

- ***CMS Mailing Strategy.*** Starting in April 2018, CMS will begin mailing new Medicare cards to beneficiaries on a flow basis by geographic location. The agency has issued a high-level mailing strategy that outlines the general sequence in which the new Medicare cards will be distributed for various geographies (e.g., “after June 2018”) and has indicated that additional details on timing will be available as the mailings progress. HCSC strongly encourages CMS to provide specific timing details to plans, as quickly as possible, indicating the specific month (rather than a range of months) during which plan members in a specific state will receive their new cards. This step will allow plans to allocate appropriate administrative resources (e.g., call center or other staff) to support and ensure a seamless transition for enrollees.
- ***Timeline of Outstanding Technical Milestones.*** To support ongoing planning and implementation efforts, we recommend that CMS develop and provide to plans a detailed timeline highlighting the remaining technical milestones anticipated for the initiative (e.g., software release, reporting or other deadlines, etc.). We note that CMS previously provided a timeline outlining new Medicare card-related project milestones, and a similar timeline focused on technical milestones would be useful.

Section II – Part C

Meaningful Difference (Substantially Duplicative Plan Offerings) (pg. 170). As signaled in the CY 2019 MA and Part D proposed rule, CMS is proposing to eliminate the “meaningful difference” requirement, under which approval of an MA organization’s bid is conditioned upon whether the plan is substantially different from those of other plans offered by the organization in the same service area with respect to certain characteristics (i.e., benefits, cost sharing, etc.). CMS is proposing to implement this change beginning with MA bid submissions for CY 2019. As noted in our comments in response to the proposed rule, HCSC strongly supports the proposed change, which will provide MA organizations with greater flexibility to develop and offer innovative benefit designs that best meet the needs of our enrollees.

Total Beneficiary Cost (TBC) (pg. 171). The draft Call Letter indicates that for CY 2019 the agency intends to continue to exercise its statutory authority to deny MA bids, on a case-by-case basis, if it determines the bid proposes too significant an increase in cost sharing or decrease in benefits from one plan year to the next through the use of the total beneficiary cost (TBC) standard. CMS further states that, by “limiting excessive increases in the TBC from one year to the next, CMS is able to make sure enrollees who continue enrollment in the same plan are not exposed to significant cost increases.” However, CMS also indicates that the agency is considering elimination of the current TBC evaluation in future years.

HCSC is firmly committed to ensuring our enrollees have access to quality care and benefits at an affordable cost, and we support CMS’ goal of ensuring beneficiaries have access to viable and sustainable MA plan offerings. While CMS’ policy is intended to protect beneficiaries who continue enrollment in the same plan, it does not protect a beneficiary’s access to that plan when a plan is not permitted to address changes in the

market by balancing revenues and costs, but instead is forced to exit the market. Rather, use of this standard diminishes the ability of beneficiaries to exercise their choice of plan enrollment (e.g., to remain enrolled in their plan), despite the detailed information they are provided and have access to, including via their Annual Notice of Changes (ANOC). The Medicare Advantage market is highly competitive and we believe the TBC policy is inconsistent with these marketplace dynamics and impedes the ability of plans to effectively respond to factors, such as increased consolidation. We recommend that rather than relying on an arbitrary TBC standard, CMS rely on existing controls to limit increases in cost and decreases in benefits, such as competitive market factors, establishment of maximum copay amounts, and Medical Loss Ratio (MLR) requirements. A revised approach would preserve beneficiary choice and the ability of plans to respond effectively to changing dynamics in an increasingly competitive environment.

Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs) (pg. 183). Beginning with CY 2019, CMS is proposing to permit Dual Eligible SNPs and Institutional SNPs to offer the enhanced disease management (EDM) supplemental benefit that is currently available to non-SNP MA plans. The benefit, which may be proposed as a supplemental benefit in a plan's bid and submitted plan benefit package, includes qualified case managers with specialized knowledge about the target diseases/conditions, education activities focused on the target diseases/conditions, and routine monitoring applicable to the target diseases/conditions. HCSC supports this proposed change and recommends that CMS finalize the proposal in the final Call Letter accordingly.

Medicare Advantage Uniformity Flexibility (pg. 184). As indicated in the CY 2019 MA and Part D proposed rule, CMS has proposed to adopt a new interpretation of the statutory and regulatory MA uniformity requirements to permit MA plans to reduce enrollee cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, "provided that similarly situated enrollees (that is all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits." CMS notes that as MA plans consider implementation of flexibility in the uniformity requirement, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations. The draft Call Letter indicates that if a MA plan wants to propose a targeted supplemental benefit offering, but has questions as to whether or not it is allowable, CMS will establish a special mailbox following issuance of the final Call Letter.

Consistent with our comments on the proposed rule, HCSC commends CMS for proposing to provide these new tools, and agrees with the agency's stated expectation that this flexibility will permit MA plans to better manage health care services, and improve care and outcomes for our most vulnerable enrollees. While we support adoption of these proposed changes, we have identified below several issues and related recommendations that we believe will further ensure the changes are implemented in a manner that best meets the needs of MA enrollees.

- ***Beneficiary Communications.*** In an effort to ensure that individuals are provided with comprehensive information to make the most informed decisions about their health care coverage, we strongly recommend that the marketing and

communication requirements and guidelines do not inappropriately restrict the ability of plans to provide key details, including to prospective enrollees, about benefits offered consistent with this new flexibility. We believe providing comprehensive information to support informed decision making is consistent with CMS' stated priority to maintain and ensure beneficiary choice, and will play a critical role in how effectively this new benefit flexibility can positively impact the health care and outcomes of MA enrollees.

- **Operational Guidance.** HCSC continues to believe it will be important for MA plans to review and comment on the operational details and guidance regarding implementation of this new flexibility before they are finalized, as these steps will allow plans to provide the agency with feedback informed by practical experience and permit CMS to consider potential operational challenges before processes and guidance become final. In addition, timely issuance of final bid-related guidance will be important to coordinate with and inform MA plan bid development processes, and we encourage the agency to issue all necessary guidance no later than release of the final Call Letter accordingly.

Special Needs Plan (SNP)-Specific Networks Research and Development (pg. 185).

In the CY 2018 Final Call Letter, CMS indicated that the agency intended to move forward with developing SNP-specific network adequacy evaluations, which HCSC supports. However, in the 2019 draft Call Letter, CMS notes that the agency “believes that the current network adequacy criteria and exception request process account for the unique healthcare needs and delivery patterns for beneficiaries enrolled in SNPs,” and that CMS will continue to examine the need for SNP-specific network adequacy evaluations and welcomes continued stakeholder feedback.

HCSC strongly encourages CMS to continue to work toward establishing SNP-specific network adequacy criteria, particularly given the different, unique and complex needs of the populations enrolled in and served by these plans. We continue to believe in the value of and need for SNP-specific network adequacy criteria, and urge CMS to move forward with developing criteria that are meaningful, not more restrictive than current MA requirements and permit SNPs the flexibility to ensure adequate access for the vulnerable enrollees served by these plans.

Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs (pg. 187). CMS indicates in the draft Call Letter, that the agency “continues to seek opportunities to maximize the potential for D-SNPs to align benefits and improve coordination for Medicare-Medicaid enrollees.” In addition, CMS expresses interest in hearing from states that would like to work with the agency “to develop comprehensive administrative alignment work plans” toward that goal.

HCSC appreciates and shares CMS' continued commitment to better integrate care and improve experiences for Medicare-Medicaid dual eligible enrollees, and we commend the agency for working to expand pathways for increased and enhanced integration for D-SNPs. To further increase opportunities for integration, we encourage CMS to actively promote these arrangements with states, particularly those states that may be deterred by

concerns regarding potential operational or other challenges associated with such changes.

Encounter Data Listening Forums, Monitoring and Compliance Activities (pg. 191).

The draft Call Letter indicates that CMS has initiated a series of listening forums with MA organizations and expects to continue to hold similar forums in 2018 in an effort to highlight areas where both the agency and plans can implement improvements to the encounter data submission process. In addition, the draft Call Letter reiterates CMS' framework for monitoring and compliance activity related to encounter data submissions. We have identified the following issues and recommendations.

- **Listening forums.** We appreciate and support CMS' efforts to conduct listening forums with MA organizations toward the goal of continuing to improve the encounter data process. To further improve the utility and transparency of these forums, we recommend that the agency ensure that lessons learned and best practices identified during the sessions, as well as "frequently asked questions" and the related CMS responses, are made available to all MA organizations (as appropriate). In addition, we encourage CMS to target a diverse group of MA organizations so that discussions are representative of the full range of MA plans and the varying levels of experience and resources.
- **Monitoring & Compliance Activities.** HCSC 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. As we stated in our comments in response to the agency's November 1, 2017 HPMS memorandum seeking feedback on proposed encounter data performance metrics and thresholds, HCSC believes 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 CMS' 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.

In addition, while we appreciate that CMS developed and provided to plans Technical Notes that included details regarding the data used and calculations applied to produce the proposed encounter data performance metrics outlined in the November 1, 2017 memorandum; similar details regarding the proposed thresholds remain unclear. Accordingly, we reiterate our request for CMS to revise and reissue the Technical Notes to include the underlying information detailing how the thresholds are determined. This additional insight about the agency's approach will assist plan efforts to fully assess and provide meaningful and informed feedback on the proposed thresholds. We strongly recommend that CMS make these additional details available as quickly as possible and provide a further opportunity for comment before the proposed metrics and thresholds are finalized.

Section III– Part D

Changes for CY 2019 Formulary Submissions

- **Expanding the Part D Over-the-Counter (OTC) Program** (pg. 196). CMS is considering allowing additional flexibilities for Part D plan sponsors to offer access to OTC products. As an example, CMS notes that the agency could consider allowing sponsors to include additional OTC products such as dietary supplements and cough medicines, without the current requirement that the OTC product offset the use of a Part D drug. CMS is seeking feedback on Part D OTC enhancements that could be considered for future policy, 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.

HCSC appreciates that CMS is seeking input from stakeholders in advance of proposing potential future policy changes related to coverage of OTC products. To facilitate informed and meaningful feedback, we recommend that CMS consider providing additional examples of the type of flexibilities the agency may consider along with a general overview of how those potential flexibilities could be operationalized under the Part D benefit.

Part D Benefit Parameters for Non-Defined Standard Plans

- **Part D Meaningful Difference Requirement** (pg. 197). As signaled in the CY 2019 MA and Part D proposed rule, for CY 2019, CMS is proposing to eliminate the stand-alone Prescription Drug Plan (PDP) Enhanced Alternative to Enhanced Alternative (EA to EA) meaningful difference requirement, under which two EA plans offered by the same parent organization in the same region must provide different and distinct coverage options determined by specific threshold differentials that are established by the agency on an annual basis. The agency is proposing to maintain the requirement that EA plans must be meaningfully different from the basic plan offered by a sponsor in a service area and is proposing that the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be \$22 (from \$20 in 2018). However, CMS intends to reexamine in the future, how the agency defines the meaningful difference requirement between basic and EA plans, including investigating whether the current Out-of-Pocket-Cost (OOPC) model or an alternative methodology should be used to evaluate differences. CMS plans to seek stakeholder input on this topic as part of that process.

HCSC strongly supports the proposal to eliminate the PDP EA to EA meaningful difference requirement, and we agree with CMS' assessment that the proposed revisions will strike an appropriate balance between encouraging competition and plan flexibilities, while still providing PDP choices to beneficiaries that represent meaningful choices in benefit packages. In addition, we appreciate that CMS intends to reexamine how this requirement is defined between basic and EA plans in the future and whether the OOPC model or another alternative should be used in the evaluation. We look forward to the opportunity to provide input on these topics and potential future improvements.

- **Tier Composition** (pg. 198). For CY 2019, CMS proposes to continue to provide Part D sponsors the option of selecting a non-preferred brand tier or non-preferred drug tier (but not both), and will continue to evaluate the brand/generic composition of the non-preferred brand tier as part of the bid review process. Based on analysis of CY 2018 formulary and benefits data, CMS is proposing a maximum threshold of 25 percent generic composition for the non-preferred brand tier for CY 2019. The agency notes that this threshold is based on the mean generic composition, submitted at the plan level, of the non-preferred brand tier for CY 2018. We recommend that CMS defer further consideration of the proposed maximum threshold amount until the agency engages in discussions with Part D plan sponsors to ensure CMS' is aware of the key considerations that inform plan decisions. We believe this approach will permit the agency to better evaluate whether the proposed threshold level is appropriate, while also ensuring CMS does not inadvertently restrict sponsors' ability to establish and implement formulary designs best suited for enrollees.
- **Specialty Tiers** (pg. 201). Currently, Part D sponsors may choose to designate one formulary tier as their Specialty Tier, on which Part D drugs with sponsor negotiated prices that exceed the dollar per month threshold established annually by CMS may be placed. However, in an effort to address changes in the prescription drug landscape, including the considerable impact of high-cost drugs on the Part D program, as well as maintain an affordable and accessible Part D program for beneficiaries, HCSC continues to believe that CMS should permit sponsors to designate two separate specialty tiers, a preferred specialty tier with lower cost sharing and a non-preferred specialty tier.

As we have indicated previously, an approach along these lines could provide sponsors with greater leverage in negotiations with manufacturers for certain high-cost drugs, as well as encourage and increase competition among existing specialty drugs. In addition, as more biosimilar products are approved by the Food and Drug Administration (FDA), this two-specialty tier structure could encourage Part D enrollees to substitute lower-cost biosimilar products for the corresponding reference product. This could result in more affordable care for Part D enrollees and lower costs for the Part D program more broadly. As you know, in their June 2016 Report to Congress⁹, the Medicare Payment Advisory Commission (MedPAC) recommended that CMS revise their Part D guidance to allow for two specialty tiers, and indicated that if used appropriately, this tier structure could reduce the need for non-formulary exceptions as less cost-effective options could be placed on the non-preferred tier rather than excluded from the plan's formulary. HCSC continues to strongly recommend that CMS revise the Part D formulary tier model options to include an additional 6-tier structure that would allow for a preferred and non-preferred specialty tier as described above. We note that in conjunction with this recommendation, we also previously recommended that if this specialty tier option is permitted, CMS revise the tiering exception guidance to permit enrollees to obtain a 6th tier non-preferred drug at the 5th tier preferred drug cost sharing level when the 6th tier drug is medically necessary.

⁹ See MedPAC June 2016 Report to the Congress: Medicare and the Health Care Delivery System at <http://www.medpac.gov/-documents/-reports>

Improving Drug Utilization Review Controls in Medicare Part D

- **Part D Opioid Overutilization Policy** (pg. 204). CMS indicates that all “Part D sponsors are expected to have a documented, written strategy for addressing opioid overutilization of prescription drugs given the public health crisis.” As part of the recent opportunity under the Paperwork Reduction Act (PRA) process to comment on the 2019 Formulary Submission requirements, CMS proposed to collect an upload of responses from Part D plan sponsors, via a new “Opioid Strategy Layout” document, that will detail the comprehensive strategies an organization is using to combat the opioid crisis. CMS indicated that the agency was proposing this data collection “to assist in the modification of existing Part D policy and/or development of new policy” in this area. In addition, CMS noted that the agency may potentially synthesize the data collected and use the data to publish “best practices,” although any information publicly disclosed will not be attributed to a specific organization. Given the relevance of this topic, we are reiterating below the key comments we submitted to CMS in response to the proposed information collection.
 - **Final upload requirements and layout.** If CMS moves forward with the proposed Part D opioid strategy upload as part of the CY 2019 formulary submission process, we strongly recommend that the agency release the final version of the “Opioid Strategy Layout” as quickly as possible and well in advance of the upload deadline to ensure sponsors are afforded sufficient time to prepare submissions that are responsive to the full range of topics and questions on which CMS is seeking feedback.
 - **Commercial efforts to combat the opioid crisis.** As part of the “Opioid Strategy Upload,” CMS is proposing to require Part D sponsors to describe “any programs, initiatives, or other efforts” organizations have in place for commercial lines of business, whether these efforts have been successful, and if there are policy barriers that prevent implementation of these initiatives in Part D. Our understanding is that CMS is not requesting that sponsors submit a full summary of the comprehensive strategy to combat the opioid crisis in commercial plans offered by the same entity, but rather is specifically interested in more streamlined reporting of initiatives employed to combat the opioid crisis that have been *successful* in commercial plans, but cannot be replicated under the Part D program due to current policy and operational limitations. To support consistency in submissions, we recommend that CMS confirm whether our understanding is accurate, and revise the relevant section of the “Opioid Strategy Upload” as applicable to ensure clarity.
 - **Future Part D policy development.** As noted above, CMS intends to utilize information received from the proposed opioid strategy uploads to help inform potential future policy changes and/or development of new policy related to combatting the opioid crisis under the Part D program. We believe it will be important for Part D plan sponsors to have an opportunity to review and comment on any proposed policy changes before they are finalized, as these steps will allow plans to provide CMS with feedback informed by practical experience and will permit the agency to consider potential operational

challenges before processes and guidance become final. As a result, we recommend that CMS provide a meaningful opportunity for comment on any future program changes related to combatting the opioid crisis under Part D, before any such changes are finalized.

- **OMS Metrics** (pg. 205). Beginning with the 2018 Overutilization Monitoring System (OMS) reports, CMS is proposing to change the “Opioid Daily Dose” measurement period from 12 months to 6 months, and to add a second “Opioid Daily Dose” rate with a 90 MME threshold. These proposed changes are intended to align the report with the revised OMS measurement period and criteria, respectively. The agency also proposes to eliminate the 120 MME “Opioid Daily Dose” rate in the 2019 OMS reports. HCSC appreciates CMS’ efforts to align the OMS reports with the corresponding OMS criteria and measurement period.
- **Days Supply Limits for Opioid Naïve Patients** (pg. 212). For CY 2019, CMS intends to establish a days supply limitation policy for opioid naïve patients, that would require sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days when prescribed for acute pain. To inform development of the policy, CMS is requesting feedback on the potential addition of a daily dose maximum of 50 MME, and potential operational challenges and issues.

While we recognize the potential value of implementing a policy that would limit initial opioid prescription fills to 7 days coupled with a 50 MME daily dose maximum, we are concerned that appropriately defining an “initial” opioid fill may be challenging, particularly in instances where sponsors may not have access to a beneficiary’s complete history (e.g., for new enrollees, etc.). To avoid confusion and to ensure a uniform understanding across all plans, HCSC recommends that CMS engage in discussions with sponsors to determine an appropriate definition of and method for identifying an opioid naïve patient or a first-time prescription for an opioid, prior to moving forward with finalizing this proposal and any related requirements. Discussions also should include further consideration of potential exceptions for specific clinical situations (e.g., cancer treatment), and steps to ensure appropriate pain treatment of access is unhindered.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2019

- **Formulary and Supplemental Drug Files** (pg. 224). Each year, MMPs must submit and be approved to offer a demonstration-specific, integrated formulary that meets both Medicare Part D and Medicaid requirements. As part of the required submissions for the integrated formulary, MMPs must submit an updated Additional Demonstration Drug (ADD) file containing non-Part D drugs, including drugs in Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. For CY 2019 CMS is proposing to make the ADD validation file available via HPMS in advance of the ADD File submission deadline, and

is also continuing to evaluate whether additional efficiencies are possible with respect to timing of the file's completion.

HCSC participates as a MMP under the Illinois Medicare-Medicaid Alignment Initiative (MMAI) and we appreciate CMS' efforts to streamline the ADD file submission process and support the proposal to provide earlier access to the ADD validation file accordingly. In addition, we note that the draft Call Letter indicates that the ADD file is due on June 4, 2018 and that CMS will work with states to provide the applicable ADD file guidance to MMPs by May 2018. If possible, we recommend that CMS and states work to provide the guidance to plans on an earlier timeline to further ensure sufficient time is available for plans to comply with the early June submission deadline.

We appreciate the continued partnership we have with CMS in serving beneficiaries under the MA, Part D and MMP programs. If you would like additional information or have questions about these comments and recommendations, please contact me at 202-249-7214 or Dana.Mott-Bronson@hcsc.net.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Dana Mott-Bronson', with a stylized, cursive script.

Dana Mott-Bronson
Divisional Vice President, Health Policy – Government Programs