March 5, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Verma:

Thank you for the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule *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.*

Established in 2003, Commonwealth Care Alliance (CCA) is a community-based, not-for-profit healthcare organization dedicated to improving care for people with complex chronic conditions, including multiple disabilities. For individuals who are dually eligible for MassHealth, the Medicaid program in Massachusetts, and Medicare, our unique, nationally recognized health plans provide and coordinate the full spectrum of care – medical, behavioral health, dental, durable medical equipment and social services – to eliminate gaps in care and reduce costs. Disability-competent direct primary care is provided by our wholly owned clinical affiliate, Commonwealth Community Care, an organization with more than 30 years of experience supporting adults with complex physical, developmental, intellectual and mental health disabilities, as well as through over 27,000 providers in our contracted provider network.

CCA serves more than 25,000 beneficiaries statewide in Massachusetts through our dual eligible special needs plan (D-SNP) and our Medicare-Medicaid Financial Alignment Initiative plan. Our D-SNP plan provides services to over 9,000 beneficiaries, the vast majority of whom are dually eligible for both Medicare and Medicaid age 65 and above. We have consistently achieved four stars or above in the Medicare Advantage Star Ratings program, including achieving five stars on 18 measures and four stars on another 12 measures for 2018.

CCA supports a number of provisions in this proposed rule that would promote greater alignment of medical and non-medical coverage and encourage enrollment in aligned plans. We believe these proposed changes will help special needs plans and MMPs achieve better coordination of medical and non-medical services and supports.

Commonwealth Care Alliance's comments and suggestions 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 draft Call Letter* include the following.

CY 2019 Medicare Advantage Risk Model - Adjustment for Number of Conditions

CMS presents two options to account for the number of conditions or diseases of an individual, as required by the 21st Century Cures Act. Under one option, called the Payment Condition Count (PCC) model, CMS would only include payment HCCs to determine the count of diseases or conditions. Under the second option, called the All Condition Count model, CMS would include all HCCs, including those not used for payment, to determine the count of diseases or conditions. CMS is not proposing to take into further account the total number of diseases or conditions of an individual in 2019. Rather, it is proposing to phase in a new model between 2020 and 2022. CMS's preference is to implement the "payment condition" model but have the "all conditions" model as an alternative. CMS is looking for comments on what organizations think is better and why.

CCA supports efforts by CMS to take into account the total number of diseases or conditions of an individual in the CMS-HCC payment methodology but cannot at this time fully account for the effects that the two proposed models may have on payment rates for our population. Since CMS is not planning to implement this model until 2020, we will use this interim period to conduct a more thorough analysis of these two options and provide a more definitive recommendation at a later date, but in time for implementation in 2020.

New Measures for 2019 Star Ratings *(pg. 107)*

CMS is proposing to add two new measures for the 2019 Star Ratings: Statin Use in Persons with Diabetes (SUPD) and Statin Therapy for Patients with Cardiovascular Disease.

CCA urges CMS to establish pre-determined 5 STAR threshold rates and publish them well in advance of the measurement period. This approach enables plans and their network providers to set markers for quality improvement activities and goals. While clinically appropriate, these measures would need prescriber and provider engagement to improve the measure and plans will need time and resources well in advance of publication of threshold rates.

Proposed Scaled Reductions for Appeals IRE Data Completeness Issues *(pgs. 114-122)*

CMS is proposing statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using TMP data or audit. The reduction would be applied to the measure-level Star Rating for the applicable appeals measures.

CCA requests that CMS clarify the first measurement year of the Timeliness Monitoring Project (TMP) data results that will impact Star Ratings and the Star Rating year that will first be impacted by the TMP data. CCA appreciates and values CMS' transparency and requests that CMS make accessible, via HPMS or other secure mechanisms, the detailed case-level results that impacted the missing IRE data score. We also request that CMS limit the universe collection of TMP to only measures with a direct impact on missing IRE data score.

Threshold for Requiring an Independent Validation Audit *(pgs. 160-161)*

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 conducts the validation audits of sponsoring organizations that fall below this threshold. We are seeking comments on whether this threshold should be increased or decreased, or limited to conditions that may cause adverse impacts to beneficiaries.

CCA supports the removal of CPE conditions from the threshold. As the independent auditor process requires a great deal of resources from sponsors, we encourage CMS to take additional action so that the threshold is "limited to conditions that may cause adverse impacts to beneficiaries" as considered in this section. This would reserve the independent auditor resource to focus on the most impactful results and allow sponsors to resolve less severe results with reduced effect on resources.

Required use of CMS Validation Audit Work Plan Template *(pgs. 162-163)*

Based on CMS's 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.

CCA believes that this validation work plan template would be a helpful tool and supports CMS' plan to release the work plan template so that sponsors may use it when considering different potential audit vendors.

Timeframe to Complete Validation Audits *(pgs. 163-164)*

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. Based on 2016 validation audit experience, CMS intends to extend the timeframe by 30 days. Sponsoring organizations would have 180 days from the date that CMS accepts their program audit CAPs to undergo a validation audit and submit the independent audit report to CMS for review.

CCA thanks CMS for considering sponsors' experience and we support the increase to 180 days; and further suggest that CMS allow for negotiation of longer time periods when needed, as the additional 30 days may not be sufficient extension for all validations.

Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice *(pgs. 164-165)*

CMS proposes to begin displaying the CMP icon (or other type of notice) on Plan Finder for the 2019 AEP for any sponsoring organization that receives a CMP in 2018 (or receives a CMP for a 2017 Program Audit). Beginning in 2019, CMS proposes that regular updates would occur throughout the year.

CCA requests reconsideration of CMS' proposal to put a CMP icon on Plan Finder because this is potentially misleading to prospective members. Only a minority of plans undergo audit, therefore prospective members are not viewing a level field. If Sponsor X is audited and receives a CMP and Sponsor Y is not audited, the CMP icon will cause the prospective member to think that Sponsor Y's performance is superior when in fact it has not been evaluated. Also, CMPs vary significantly in their causes, nature of impact, number and percentage of enrollees affected, but CMP letters do not contain this level of detail, making it difficult for the prospective member to understand the extent of the audit issue. Finally, issues requiring enrollment suspension or other intermediate sanction are typically much more severe than those involving CMPs, so we do not believe that the sanction icon is a fair comparison.

Audit of the Sponsoring Organization's Compliance Program Effectiveness *(pgs. 165-166)*

CMS is considering allowing sponsoring organizations that have undergone a program audit to treat the program audit as meeting the annual compliance program audit requirement in 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F) for one year from the date of the CMS program audit. CMS is seeking comment on this.

CCA believes that the frequency of the external Compliance Program Effectiveness audits impairs the ability of Sponsors to take full advantage of the recommendations and enhancements made during these audits and suggests that CMS consider a less frequent requirement than an annual audit. This will allow for plans to execute meaningful enhancements of their Compliance Program between audits. Under the current requirement for a Sponsor to perform an annual audit, the time to engage with an external audit firm or Sponsor's Internal Audit function (if one exists) and provide the materials, interviews, and discussions of results is minimally 6-9 months. This leaves minimal time to take meaningful action to enhance the Compliance Program based on the audit results before the next annual audit, thus the subsequent annual audit does not add as much value as it could in reevaluating the progress made based on prior results. The practical result has been that the Compliance staff are spending time preparing for the next audit when more valuable resources could be brought to bear on executing and validating enhancements recommended in the previous audit. CCA highly values the opportunity the Compliance Program Effectiveness audits afford and would like to maximize their value by allowing for a less frequent schedule than the current annual schedule. We encourage CMS to look to the discipline of Internal Audit itself for a parallel guideline of frequency of evaluation of a program for quality assurance and improvement. The Institute of Internal Auditors' International Professional Practices Framework Standard 1300 specifies that an Internal Audit function undergo an external review of the Internal Audit department every five years. This external review allows for two approaches, which brings flexibility for Sponsors of varying sizes and resources. The first approach allows the Sponsor to hire an independent assessor or assessment team from outside the organization to perform a full external assessment of the program. The second option allows for the Sponsor to hire an independent assessor or assessment team from outside the organization to validate the program's self-assessment and assure the comprehensiveness of the self-assessment. We urge CMS to consider ways that will make the required Compliance Program Effectiveness audit most meaningful in order to maximize the opportunities for Sponsor improvements.

CY 2019 Formulary Submission Window *(pgs. 193-196)*

In 2017, for the 2018 plan year, the update window was held from July 27 to July 31. Since the summer update window is the final opportunity for plan sponsors to remove drugs from their formularies prior to the start of the plan year, CMS intends to move this window later into the summer, with the goal being the inclusion of newly approved brands and generics that occur in July and into August. We recognize, however, that Part D sponsors must finalize their formulary submissions for CY 2019 with enough time to meet printing deadlines. We thus seek stakeholder comment regarding the optimal submission window that balances the opportunity for additional formulary substitution versus the need to finalize formulary documents for printing.

CCA fully supports lengthening the update window later into the summer by as many as 30 days.

Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs *(pgs. 218-219)*

In order to streamline the coverage determination process and establish CMS as the single source for transplant information, 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.

CCA fully supports this streamlining approach as health plans often struggle in the area of Part B as opposed to Part D determinations..

Part D Mail-Order Refill Consent Policy– Solicitation for Comments *(pgs. 220-221)*

Replacing affirmative prior consent for refills with a refill shipping reminder, prior to shipping, which provides sufficient time for a beneficiary to cancel an order.

CCA supports this proposal as it would help members who would like auto-ship.

Eliminating affirmative prior consent for refills but expecting plans to implement a full refund policy for any refills auto shipped that a beneficiary reports or returns as unneeded or otherwise unwanted. We welcome feedback on possible approaches to confirm medications reported as unwanted were partially or fully unused.

CCA is concerned that this proposal increases administrative burden on Sponsors and requests that in any such proposal CMS consider narrowing the reasons for refunds on returns.

Modifying the current condition of annual beneficiary confirmation to continue automatic deliveries but with an opt-in on a per drug basis.

CCA supports this proposal as it would allow members the freedom to opt-in to automated refills that benefit them.

CCA welcomes the opportunity to comment on the above policy recommendations and solicitations for comment. We remain committed to providing access to the highest quality healthcare for our Members. We look forward to partnering with CMS moving forward as these and other changes are finalized. For further information on our comments above, please contact Ken Preede, Vice President, Government Relations at 202-579-8446 or via email at kpreede@commonwealthcare.org.

Yours sincerely,

Ken Preede
Vice President, Government Relations