



January 16, 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 Service's proposed rule *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.*

Established in 2003, Commonwealth Care Alliance 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 and elders 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.

Commonwealth Care Alliance 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 *Contract Year 2019 Policy*

and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program include:

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (Preamble p. 56340)

CMS proposes to codify current policies, with some modifications, for retrospective Drug Utilization Reviews (DUR) and the Opioid Monitoring System (OMS). CMS also proposes detailed rules that implement the option under CARA for Part D plans to limit coverage of frequently abused drugs for those determined to be at risk of misuse or abuse to selected prescribers, pharmacies, or both.

Commonwealth Care Alliance commends CMS for producing a thoughtful and thorough approach to implementing the CARA provisions. As a member of AHIP, we support the approach. However, we have several recommendations to ensure that the finalized policy protects Medicare beneficiaries from misuse or abuse of opioids while retaining access to pain medications, reduces the burden placed on sponsors in administering such programs, and ensures the integrity of the Part D program.

- **Frequently Abused Drug.** The Proposed Rule limits the 2019 designation of frequently abused drugs to opioids, except for buprenorphine when used as a medication-assisted treatment for opioid addiction. In light of the overwhelming evidence that beneficiaries taking opioids in addition to other high-risk medications, such as hypnotic-sedatives and muscle relaxants, are at a higher risk of harm, we recommend that CMS continue to review evidence around the use of such high-risk medications in conjunction with opioids and update the drugs designated as frequently abused drugs when appropriate.
- **Exempted Beneficiaries.** The Proposed Rule exempts certain beneficiaries – those electing to receive hospice care, residents of certain facilities, and patients with a cancer diagnosis – from being designated as at-risk beneficiaries. Commonwealth Care Alliance recommends that CMS provide further clarifications around when and how to apply these exemptions. For example, it is unclear whether long term care (LTC) exemptions apply to DUR processes or are applicable only to coverage limits (i.e., point-of-sale edits, lock-ins). CCA suggests that CMS clarify how the cancer diagnosis exemption is to be applied, for example, whether a cancer diagnosis is an active diagnosis or whether a cancer diagnosis must be coupled with a pain diagnosis. Additionally, we urge CMS to provide clearer guidance on appropriately exempting beneficiaries well before sponsor bid applications are due to ensure successful implementation by the beginning of the Plan Year 2019.
- **Case Management, Clinical Contact, & Prescriber Verification.** The Proposed Rule requires clinical staff to contact prescribers to verify that a potentially at-risk beneficiary is in fact at-risk. We believe that the expectation of three prescriber outreach attempts by phone after a written attempt is burdensome and unnecessary. We ask that CMS consider a

allow the sponsor, prior to the expiration of the 12-month period, to determine if a continuation is warranted, and if so, to allow for extension of the designation for another 12-month period. We believe this flexibility to continue limits without interruption is necessary to best protect against misuse and abuse of opioids. Beneficiaries could then be allowed to seek a redetermination of the extension.

2. Flexibility in the Medicare Advantage Uniformity Requirements (Preamble p. 56360)

CMS indicates they have developed a new interpretation of statutory provisions (Sections 1852(d) and 1854(c)) of the Social Security Act and regulation (§422.100(d)) to permit Medicare Advantage (MA) organizations starting in CY 2019 to lower cost sharing for benefits, offer tailored supplemental benefits, and offer lower deductibles for beneficiaries who meet certain objective clinical criteria. The benefit design would remain subject to a CMS determination that it is not discriminatory.

We strongly support and commend CMS for adopting an interpretation of the MA statute and regulation that allows plans to structure enrollee cost sharing and other services to encourage enrollees with particular clinical conditions to consume high-value clinical services under the MA program. We believe that plans should have flexibility to implement patient-centered innovative benefit designs that would promote better health and outcomes by focusing on prevention, early detection, and care management; reducing beneficiary costs; addressing the needs of low-income beneficiaries and individuals with disabilities; and applying clinical best practices to increase patient safety and to limit unnecessary utilization of services.

In the Preamble, CMS indicates that for CY 2019, the agency is considering issuing guidance to clarify the flexibility that MA plans would have to offer targeted supplemental benefits. We support CMS's plans to provide this guidance. We recommend that CMS also provide guidance about other permissible flexibilities, including the offering of enhanced benefits and reduced cost sharing and deductibles based on objective criteria. Additionally, we recommend that CMS provide guidance about the marketing rules for these new benefit designs. Commonwealth Care Alliance supports ensuring that plans have the flexibility they need to communicate with and educate beneficiaries about the availability of new, innovative benefit plans that are tailored to meet their unique health care needs and financial situations.

To avoid potential future uncertainties, we also urge CMS to include regulatory text in the Final Rule that supports the flexibility that will be allowed in the MA uniformity requirements. Further, we strongly recommend that this new interpretation be extended to Part D benefits. We are not aware of any statutory or regulatory restrictions to extending this flexibility to Part D benefits. This extension would maximize health outcomes through improved care coordination and medication use. Enabling plans to offer comprehensive care that covers both medical services and drug benefits would provide beneficiaries with access to high quality care tailored to meet their individual holistic care and needs.

4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101; Preamble p. 56361) & 5. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100; Preamble p. 56362)

CMS proposes to amend regulations to clarify CMS's authority to use Medicare Fee-for-Service (FFS) data to establish annual maximum out of pocket (MOOP) and cost sharing limits. CMS also indicates the agency's intention to use MA encounter data to help identify MA plan cost sharing standards and thresholds and requests comments about whether to use MA encounter data to inform the setting of MOOP limits.

While we support CMS's proposals to use FFS data to establish MOOP and cost sharing limits, we have concerns with the use of plan encounter data to establish these limits due to the challenges associated with the Encounter Data System (EDS), including the unresolved operational, technical and other issues in the collection, processing, and validation of these data. Given the current challenges and concerns, we believe it is premature for CMS to use encounter data to inform the setting of MOOP or cost sharing limits. We therefore recommend that CMS defer use of MA encounter data to establish appropriate MOOP or cost sharing limits until the EDS and related data issues are resolved and, per recommendations made by the Government Accountability Office,¹ CMS has shown the encounter data to be complete, accurate, and reliable.

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

Dual eligibles have a high rate of voluntary disenrollment from the One Care program. Even with the 60-day and 30-day notices that CMS requires for duals who will be passively enrolled into a plan, many either do not receive these notices, do not read them, or do not understand them. This is particularly true for the CCA population as often our members are transient, have no fixed address or are even homeless. As such, their first realization of being enrolled into a managed care plan is when they visit the physician, visit the emergency room or fill a prescription at the pharmacy. Unfortunately, plans are not allowed to provide sufficient information to these providers to assist them in educating beneficiaries when they do present as new members. Due to their confusion and lack of information beneficiaries often opt out of the program before they even understand or can benefit from the care model described above.

Current rules provide that dually eligible beneficiaries can change Part D plans outside of the annual enrollment period for any reason without any limit to the number of changes per coverage year. CMS proposes to limit the SEP rules for dually eligible beneficiaries to one annual opportunity to change plans. Under the proposal, beneficiaries would have additional opportunities to change plans upon auto-enrollment into a plan and a change in Medicaid or Low-Income Subsidy (LIS) status.

¹ Government Accountability Office. Medicare Advantage: Limited progress made to validate encounter data used to ensure proper payments [GAO-17-223]. January 2017.

While Commonwealth Care Alliance generally supports the proposed change to the SEP policy as it would allow for improved continuity of care for the dually eligible population and thereby improve the care they receive, we request that CMS develop clarifying guidance in the final rule outlining all aspects of the proposal.

11. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§422.160, 422.162, 422.164, 422.166, 423.180, 423.182, 423.184, 423.186; Preamble p. 56375)

CMS proposes to codify the MA and Part D Star Ratings System, with several program changes beginning with the CY 2019 measurement period. Along with AHIP, Commonwealth Care Alliance strongly supports this new regulatory structure. Such an approach would greatly improve transparency and predictability in the Star Ratings System. However, we have specific comments and recommendations on the proposed changes and on current program requirements that CMS has not specifically proposed to change in the Proposed Rule.

- **Set of Guiding Principles.** The Preamble includes a set of principles that CMS indicates have been used in making changes to the Star Ratings System and that CMS plans to use to make future changes to the program. CMS requests comments on the principles and welcomes feedback on additions to the set.

We agree with the agency that it is important to have a set of principles for the Star Ratings System and work towards them when considering changes to the measures and methodology for the program. We support the set of guiding principles set forth in the Preamble. In addition, we recommend that CMS revise the sixth principle, “Data are complete, accurate, and reliable” to include the term, “timely.” The lag time between the time the clinician’s service is rendered and the issuance of the beneficiary survey impacts beneficiary experience responses used for Star Ratings purposes. We believe that timeliness of data is a critical data quality factor that affects performance results and should therefore be acknowledged. Further, we recommend that CMS add a principle to the set indicating that Star Ratings measure cut points must reflect meaningful differences. Under the current program, the cut point thresholds are not clearly delineated, such as the upper and lower thresholds for the 4- and 5-star cut points for the MPF Price Accuracy measure. Plans face challenges establishing their own performance metrics and thresholds when the assigned Star Ratings measure cut points are not distinguishable. Finally, given their importance, we recommend that CMS formalize and maintain the set of guiding principles for the Star Ratings System and ensure their accessibility to the public.

- **Contract Consolidations.** Included in the proposed regulation is a new set of rules regarding the calculation of Star Ratings for consolidated contracts. Regarding the effective date for changes to the Star Ratings System, the regulatory text under §422.160(c) states that “[t]he regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year and used to assign QBP ratings for the 2022 payment year.”

We recommend that CMS confirm in the Final Rule that consistent with the aforementioned regulatory text, proposed changes to the Star Ratings System including calculation of Star Ratings for consolidated contracts will take effect with the 2019 measurement period.

- **Adding, Updating, and Removing Measures.** CMS proposes new rules to govern adding, updating, and removing Star Ratings measures. New measures and substantive updates to existing measures would be added to the Star Ratings System via rulemaking and in advance of the measurement period. Additionally, CMS indicates that new measures and updated measures (with substantive changes) would be on the display page for a minimum of two years prior to becoming a Star Ratings measure. CMS also proposes to remove measures due to changes in clinical guidelines or that show low statistical reliability and would announce these changes in advance of the measurement period.

Commonwealth Care Alliance supports these proposals, which would enable plans and their network providers to implement and gain experience with new measures and substantive changes to existing measures prior to the measurement period. This approach fosters stability and transparency in the Star Ratings System and supports plan and provider value-based arrangements that include quality and performance metrics that would need to be assessed and/or modified with the addition of new measures or changes to existing measures. We further believe that new measures should be fully defined, tested, and validated by measure stewards (e.g., National Committee for Quality Assurance, Pharmacy Quality Alliance) prior to being considered for Star Ratings. We therefore recommend that CMS include regulatory text that indicates that new measures must be fully defined, tested and validated by measure stewards prior to inclusion on the display page.

- **Non-substantive Updates to Measures.** CMS proposes to codify a list of non-substantive updates to measures. Non-substantive updates would be announced during or in advance of the measurement period.

We have concerns with the potential for non-substantive changes to occur during a measurement period. Even non-substantive updates to Star Ratings measures, including changes to the Part C and Part D reporting requirements, require advance evaluation, planning and implementation by plans and their partners. We recommend that any changes to Star Ratings measures be announced in advance of the measurement period to provide sufficient time for plans, providers, and other affected parties to modify their administrative, operational, and clinical processes to meet the new measure specifications.

- **Physicians' Experiences Measures.** CMS solicits comments on inclusion of survey measures of physicians' experiences in the Star Ratings System.

We acknowledge that physician experience surveys can provide helpful information and data on which to build quality improvement efforts. Plans value their partnerships with providers to improve beneficiary access to high quality care and beneficiary care experiences. Plans work closely with their network providers to develop and implement innovative ways to deliver better health care through streamlining administrative processes and use of better technology. However, we are very concerned about the burden impact on physicians if they

are required to complete a survey for every health plan with which they contract. This high burden level is likely to lead to unreliable results. Additionally, we are concerned about potential bias in survey responses given that it may be difficult for physicians to distinguish plan types and contracting entities. We therefore recommend that CMS not include survey measures of physicians' experiences in the Star Ratings System.

- **Measure Cut Points.** CMS proposes to codify existing policy to determine cut points by applying either a relative distribution and significance testing methodology to Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures or the clustering methodology to non-CAHPS measures. CMS solicits comments on determination of cut points, including publishing of pre-determined cut points. Our specific comments and related recommendations on cut points follow below.
 - + **Pre-determined Cut Points.** We urge CMS to re-establish pre-determined cut points 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. For value-based arrangements to work best, plans and providers need to assess and modify performance goals. Pre-determined cut points will enhance the ability of plans and their providers to set their own performance benchmarks and evaluate the effectiveness of their efforts to improve the quality of care and reduce costs while maintaining high rating levels. The setting of pre-determined 4-star thresholds also aligns with CMS's set of guiding principles that calls for stability and transparency in the rating system.
 - + **Greater Transparency through Access to Data.** The clustering methodology that CMS would continue to apply to all Star Ratings measures except for the CAHPS measures is complex, and cannot be replicated through publicly available data. In line with CMS's set of principles that calls for transparency in the rating system, we recommend that CMS provide greater transparency about their methodology – whether the methodology uses clustering or another approach to set pre-determined cut points – and public access to more granular data that would allow plans to replicate and validate the published cut points.
 - + **Shifts and Meaningful Differences in Cut Points.** CMS's set of guiding principles calls for ratings to be stable over time. However, certain measure cut points in the Star Ratings System have experienced significant year-to-year shifts (up or down), which make it very challenging for plans and their providers to know what the standards are in advance and work towards them. For example, the 2017 and 2018 Star Ratings 4- and 5- star cut points for the Part C Breast Cancer Screening and SNP Care for Older Adults - Medication Review measures significantly shifted.² We recommend that CMS limit year-to-year cut point changes to a range based on industry performance trends to minimize

² Breast cancer screening measure 4 and 5 star cut points from 2017 to 2018 Star Ratings went from 69 percent to ≥ 78 percent (4 star), and 76 percent to ≥ 84 percent (5 star), and SNP Care for Older Adults - Medication Review measure 4 and 5 star cut points from 2017 to 2018 Star Ratings went from 75 percent to ≥ 88 percent (4 star), and 87 percent to ≥ 93 percent (5 star).

wide fluctuations. Also, as previously indicated, we recommend that CMS ensure that Star Ratings measure cut points reflect meaningful differences so that goal lines for 4- and 5- Star thresholds are clearly delineated.

- **Data Integrity Policy.** CMS proposes to codify their data integrity policy, with a proposed change that would apply scaled reductions for appeal measures.

We continue to strongly recommend that CMS not use program audit findings and enforcement activities to deduct from a contract's Star Ratings. The goals and analytic approaches associated with program audits differ significantly from the Star Ratings program. As we have indicated in other comment letters, linking agency audit and enforcement activities to the Star Ratings System is not methodologically sound, causes duplicative penalties, raises serious fairness and equity questions, and does not provide a true measure of clinical care and customer service.

Commonwealth Care Alliance request that CMS clarify the first measurement year of the Timeliness Monitoring Project (TMP) data results that will impact Star Ratings. We request that CMS clarify the Star Rating year that will first be impacted by the TMP data.

Commonwealth Care Alliance appreciates and values CMS' transparency and request that as part of TMP notification, CMS makes 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.

We do support CMS's proposal to use scaled reductions for the appeals measures to account for the degree to which the Independent Review Entity (IRE) data are missing. However, we remain concerned that CMS plans to continue to apply their current policy to automatically downgrade scores to 1 star for Healthcare Effectiveness Data and Information Set (HEDIS) measures and measures based on Parts C and D data reporting requirements. We recommend that CMS engage with industry groups, plans, and other relevant stakeholders to consider alternative approaches to their current policy for non-appeals measures that would not impose such severe penalties in cases where the data submission error is identified early on, is not egregious or systemic, and is curable during the plan preview period.

- **Measure Weights.** CMS proposes to codify their current weighting of measures in the Part C and D Star Ratings program by assigning: a weight of 5 to improvement measures, a weight of 3 to outcome and intermediate outcome measures, a weight of 1.5 to patient experience/complaints and access measures, and a weight of 1 for process measures. In the Preamble, CMS indicates that it is considering increasing the weight of the patient experience/complaints and access measures and solicits comments on this possible change.

We do not support increasing the weight of measures that are based solely on survey data. Measures based solely on surveys may yield inaccurate, unreliable, or biased data. For example, due to concerns raised about the reliability of using survey data for the Part C pneumococcal vaccine measure, in the final 2018 Call Letter, CMS indicated that the agency is exploring non-survey based methods "to assess pneumococcal vaccination status and

guideline adherence.” Increasing the weight of these measures also does not align with CMS’s principles for the program that indicate future measures for the Star Ratings program should be focused on health outcomes. For these reasons, we recommend that CMS not increase the weighting for the patient experience/complaints and access measures.

- **Improvement Measures.** CMS proposes to codify their existing methodology for calculating improvement measure scores, identify eligible measures through the Call Letter process, and continue to include a hold harmless provision in the calculation of the improvement measure for contracts that achieve 5 stars at the measure level.

We support the improvement measure methodology, but recommend that CMS make the following modification: We believe that CMS should extend the hold harmless provision to include individual measures (included in the Improvement Measure calculation) for which plans achieved and maintained at least 4 stars. The intent of the hold harmless provision for a contract that receives a measure rating of 5 stars for each year is to prevent the measure from lowering a contract’s improvement measure when the contract still demonstrates high performance. Given the high level of performance that 4-star contracts also demonstrate, we recommend that CMS further extend the hold harmless provision to include individual measures for which plans achieved and maintained at least 4 stars.

- **Additional Adjustments to Star Ratings.** CMS solicits comments on additional adjustments to the Star Ratings measures and methodology to account for “unique geographic and provider market characteristics that affect performance.”

We appreciate CMS’s request for comments on this topic. In addition to identifying long-term solutions for adjusting the Star Ratings System to account for socio-economic status (SES) and other risk factors, we believe that geographic and unique characteristics that could affect Star Ratings performance should also be assessed and addressed. Additional adjustments should be considered that would level the playing field more effectively when comparing quality across health plans. Any adjustments should not, however, penalize high performing plans and plans that have made significant investments in attaining high performance. We recommend that CMS follow an approach similar to the one used for assessing the impact of SES and disability status on Star Ratings. CMS should perform detailed impact analyses, share the data and findings, and engage stakeholders in a comprehensive evaluation to identify meaningful, equitable adjustments to the program.

- **Categorical Adjustment Index.** CMS proposes to codify the categorical adjustment index (CAI) in the Star Ratings program. The CAI was implemented as an interim analytic adjustment to account for disparities in MA plan performance associated with SES, and includes adjustments based on LIS and dual eligible (LIS/DE) and disability status. The agency has proposed to continue applying the CAI for 2019 and beyond, according to the original methodology published in the 2017 Call Letter. CMS has noted that it will pursue a long-term solution by taking final recommendations into account from the Assistant Secretary for Planning and Evaluation (ASPE), which are expected to be published in 2019.

Commonwealth Care Alliance supports the continued use of the CAI in the Star Ratings System while CMS develops a long-term solution to this problem. However, we continue to believe that the CAI can be improved. We support AHIPs recommendations to enhancing CAI to make it more impactful by:

- + Relax the Measure Inclusion Criteria. CMS determines which measures should be included in the development of the CAI based on criteria that compare performance between LIS/DE and non-LIS/DE beneficiaries. However, CMS has not demonstrated analytically why their criteria are appropriate to determine which measures to include in the CAI. By applying these criteria, CMS excludes measures that show meaningful differences in plan performance due to beneficiary-level social risk factors.
 - + Incorporate Across-Contract Differences in Performance. The CAI methodology is currently limited to within-contract differences, meaning that the CAI values are developed based only on differences between LIS/DE and non-LIS/DE beneficiaries enrolled in the same contract. However, in their initial report, ASPE found there are real differences in plan performance between contracts serving primarily LIS/DE and disabled populations and those that do not. CMS should investigate how across-contract differences in performance can be appropriately reflected in the CAI.
 - + Hold Plans Harmless. As the CAI is an interim analytic adjustment, we believe that CMS should hold plans harmless from reductions in Star Ratings due to the CAI until various methodological issues – such as the criteria for measure inclusion and the incorporation of across-contract differences – are addressed, and related analytic issues being explored by ASPE, the measure developers, and other stakeholders are better understood.
- **Parts C and D Measure Sets for 2021 Star Ratings.** CMS proposes to add the Part C Statin Therapy for Patients with Cardiovascular Disease measure and the Part D Statin Use in Persons with Diabetes to the measure sets for 2021 Star Ratings. CMS is proposing to categorize the Part C Statin measure as a process measure and apply a weight of 1 to this measure while categorizing the Part D Statin measure as an intermediate outcome measure with a weight of 3.

We seek clarification regarding the categorization and weighting discrepancies between the Part C and Part D Statin measures.

- **Plan Preview Periods.** CMS proposes to continue to hold plan preview periods before the release of Star Ratings so that organizations can preview their Star Ratings data in the agency's Health Plan Management System (HPMS) prior to display of Star Ratings on the MPF. During the plan preview periods, Part C and D sponsors are expected to closely review their measures data and the methodology to identify and alert CMS about issues or problems.

We recommend that CMS post national Star Ratings data during the second plan preview period so that sponsors have access to all the information they need for comprehensive review and evaluation of their Star Ratings data.

*12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types
(\$§ 423.100, 423.505, Preamble p. 56407)*

CMS proposes to make clarifying changes by providing definitions for a mail order pharmacy and a retail pharmacy and establishing deadlines for making standard terms and conditions available to requesting pharmacies. CMS also describes in the Preamble several interpretations of the existing requirement that standard terms and conditions be “reasonable and relevant,” including language reflecting prior sub-regulatory guidance relating to specialty pharmacies and credentialing requirements exceeding state and federal mandates.

We are concerned that the interpretation provided in the Preamble that prohibits credentialing standards exceeding state and federal mandates may be overly broad. Though we agree that duplication of and redundancy with nationwide accreditation criteria is not warranted, we recommend that the policy should offer sponsors with the flexibility to develop criteria they can demonstrate is both reasonable and relevant for the Part D program, such as provisions targeted at preventing specific types of fraud, waste, and abuse, which may exist in specific regions and may vary by region.

In addition, we believe that the two-business day deadline for responding to requests for the sponsor’s standard terms and conditions may be too limited and would not allow for potential extenuating circumstances that can arise. We recommend that CMS use instead a longer timeframe (e.g., five business days upon receipt of the request) for responding to requests for standard terms and conditions.

*13. Changes to the Days’ Supply Required by the Part D Transition Process (§ 423.120(b)(3),
Preamble p. 56411)*

CMS proposes to change the outpatient transition days’ supply from “30 days” to “a month’s supply” and to change the long-term care (LTC) setting required minimum transition days’ supply from between 91 and 98 days to “a month’s supply.”

We appreciate and support the conforming changes to the minimum transition days’ supply for the outpatient and LTC setting. However, we request that the regulation include language from the Preamble which clarifies that “a month’s supply” corresponds to the number of days the Part D sponsor attributed as its retail month’s supply for a given drug in its Plan Benefit Package, as submitted to CMS, for the relevant plan year.

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

CMS proposes to allow sponsors to immediately add or substitute first-to-market therapeutically equivalent generic drugs to its formulary and to immediately remove or change the preferred or tiered cost sharing of the corresponding brand drug without providing notice ahead of time. We appreciate and support the change in policy as it would provide beneficiaries with earlier access to lower cost therapeutically equivalent alternatives to more expensive brands.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic & LIS Cost Sharing (§423.4, Preamble p. 56416)

Under current policy, CMS requires that follow-on biological products be subject to the higher Part D maximum copayments for LIS beneficiaries and for non-LIS beneficiaries during the catastrophic portion of their benefit. CMS is proposing to revise the definition of a generic drug at §423.4 to include follow-on biologic products for the sole purpose of allowing the lower copay option to LIS beneficiaries and the lower coinsurance option to non-LIS beneficiaries during the catastrophic coverage phase.

We appreciate and support changes in policy that incentivize the use of lower cost biologic follow-on options.

B. Improving the CMS Customer Experience

1. Restoration of the Medicare Advantage Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 and 423.40, Preamble p. 56428) & Prohibition of Marketing During the Open Enrollment Period (§§ 422.2268 and 423.2268, Preamble p. 56436)

In this section, CMS eliminates the current MA disenrollment period and replaces it with an open enrollment period, as required by the 21st Century Cures Act. As with our comments regarding the Dual Eligible SEP provisions, we recommend that CMS provide further clarity on allowable marketing during this time period. While the 21st Century Cures Act prohibits unsolicited marketing and mailing marketing materials to individuals eligible for the new open enrollment period, the definition of unsolicited marketing is unclear. We would appreciate sub-regulatory guidance, including updates to the Medicare Marketing Guidelines, that would further explain activities that would be considered unsolicited.

Furthermore, CMS proposes a “knowing” standard to effectuate the statutory provisions prohibiting marketing to eligible beneficiaries. We understand that this “knowing” standard would protect a plan from the marketing prohibition when the plan does not know that the beneficiary is enrolled in an MA plan at the time. We support such an approach and oppose applying an overly broad marketing prohibition to all potential beneficiaries during the open enrollment period.

4. Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128, Preamble p. 56431)

CMS proposes to allow plans to provide certain disclosure materials, such as the Evidence of Coverage (EOC), on the first day of the annual enrollment period, rather than 15 days before. Additionally, CMS proposes to allow distribution of the EOC, summary of benefits, and provider directory through posting on a website or electronic delivery, if notice is provided of the availability of paper copies on request.

Along with AHIP, Commonwealth Care Alliance strongly supports both of these changes, which will reduce unnecessary burdens, while continuing to provide beneficiaries with timely, relevant information in their preferred form.

5. Revisions to Parts 422 and 423, Subpart V, Communication /Marketing Materials and Activities (§§ 422 and 423 Subpart V, Preamble p. 56433)

We strongly support CMS's proposal to revise the definition of marketing and to create a definition for communications. We understand that under the new definition of marketing, many member materials, including the EOC, subscriber agreements, and wallet cards, would no longer be considered marketing. We believe CMS's proposal more appropriately distinguishes marketing materials from more general communication materials. However, we would appreciate more clarity on two issues. First, we understand that communications will not be treated like marketing materials, subject to submission to CMS before use, but we are seeking more clarity on what requirements would be applicable to these materials. Second, although CMS has outlined in the proposed regulatory text a list of marketing materials, that list is not exhaustive. We would appreciate sub-regulatory guidance that provides more details so that plans are able to determine which materials would still qualify as marketing materials and therefore subject to review by CMS before use.

6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§ 423.590 and 423.636, Preamble p. 56437)

CMS proposes to change the timeframe for issuing decisions on Part D payment redeterminations and payment requests at the Independent Review Entity (IRE) reconsideration appeal level from seven to 14 calendar days from the date that the plan sponsor receives the request.

We support CMS's proposal to lengthen the adjudication timeframes from seven to 14 calendar days.

7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§ 422.590, Preamble p. 56438)

CMS proposes to remove the plan requirement to notify a beneficiary when their case is forwarded to the IRE given that the plan notice duplicates the required Part C IRE notification to the beneficiary about receipt and review of their case.

We support CMS's proposal to eliminate the requirement for an MA plan to send a notice to a beneficiary for cases sent to the IRE. We understand that this revision would not prohibit plans from sending additional notices to beneficiaries.

8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (Preamble p. 56438, § 423.160(b)(1))

CMS proposes to adopt the NCPDP SCRIPT version 2017071 as the official Part D E-Prescribing standards for certain transactions and to retire the NCPDP SCRIPT 10.6 standard from use in the Part D program.

We appreciate and support the standards update to the NCPDP SCRIPT version 2017071 as it would improve the effectiveness, efficiency, and user experience of e-prescribing in the Part D program.

9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (Preamble p. 56440, §§ 422.502 and 423.503, Preamble p. 56440)

CMS proposes to reduce the past performance review period from 14 to 12 months for MA and Part D plans. This proposal would create a new review period starting from March 1 of the year preceding the application submission deadline through February 28 (February 29 in leap years) of the year in which the application is submitted.

We support CMS's proposal to limit the period for past performance reviews to 12 months. We believe that limiting the review period to 12 months would eliminate the flaw with the current 14-month review period that could result in the double counting of compliance or performance issues carried over to a second application cycle.

10. Preclusion List – Part D Provisions (Preamble p. 56441, §§ 423.100, 423.120, 460.86) & 11. Preclusion List – Part C/Medicare Advantage Cost Plan and PACE (Preamble p. 56447, §§ 422.2, 422.222, 422.224)

CMS proposes to eliminate both the prescriber and provider enrollment requirements; to create a preclusion list composed of “demonstrably problematic prescribers” and providers as identified, reviewed, and finalized by CMS; and in the case of the prescriber preclusion list, to require that sponsors provide a provisional fill for prescriptions written by a precluded prescriber. MA plans would be prohibited from paying MA claims from individuals or entities on the preclusion list – there is no provision similar to the Part D provisional fill.

We support the elimination of the provider and prescriber enrollment requirements, as the process raised serious beneficiary access and administrative burden issues but have some concerns with the preclusion list as proposed.

First, we believe there may be operational challenges around the creation and maintenance of the preclusion list. We urge CMS to provide more information about how the list will be created and maintained. For instance, it is unclear from the Preamble how the Office of the Inspector General (OIG) exclusion list is separate or different from the preclusion list. We recommend that CMS provide sponsors with clarifications on the process of creating and maintaining the preclusion list, followed by an opportunity to submit comments and feedback.

Second, we support AHIP's recommendation that CMS give prescribers the ability to appeal their designation as a precluded prescriber before they are placed on the preclusion list, instead

of adopting the proposed approach of allowing for appeals after placement on the preclusion list. A finalized list would minimize administrative burdens and beneficiary confusion and, as noted below, we believe it eliminates any need for provisional fills.

Additionally, we have several concerns around the need for and burdens of the provisional fill policy for the Part D preclusion list. The provisional fill requirement was included in the current prescriber enrollment provision (which, as noted above, is proposed to be eliminated) to preserve access to drugs for beneficiaries whose prescribers were not necessarily found to have engaged in any problematic behavior, but rather, had not enrolled in Medicare. It was designed to minimize potential disruptions in access to needed drugs while prescribers were enrolling into Medicare. The requirement as proposed here would instead require sponsors to fill prescriptions written by prescribers that CMS has identified as “demonstrably problematic” after a review process. Provisional fills are not available for prescriptions written by excluded prescribers; we are unaware of any policy justification for having provisional fills for prescribers who have engaged in similar “demonstrably problematic” activities. Therefore, we recommend that the provisional fill requirement be eliminated.

Commonwealth Care Alliance shares AHIPs concerns around the burdens of operating and administering the provisional fill policy. Due to the time and resources required to make necessary updates required to sponsors’ and their contracted PBMs’ IT systems, policies and procedures, and operational policies, we believe that the 2019 start date would not be feasible.

Therefore, if CMS were to retain the requirement, we strongly recommend that the implementation date be delayed to a date determined to be feasible after consultation with sponsors and their contracted PBMs.

12. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152, Preamble 56454)

CMS proposes to remove the Quality Improvement Project (QIP) requirement to eliminate redundancies with other quality improvement initiatives undertaken by the MA plan.

We support CMS’s proposal to remove QIPs from the MA Quality Improvement Program requirements.

13. Reducing Provider Burden – Comment Solicitation

CMS has asked for feedback on how the agency can reduce the burden on providers associated with MA plan requests for medical record documentation. CMS notes that many of these requests can be to provide data for Risk Adjustment Data Validation (RADV) audits, as well as for other purposes. While we generally support the agency’s interest in reducing administrative burdens placed on providers, we have concerns that CMS’s perspective in considering this issue may be overly narrow and not take into account the necessary and important purposes for which medical records may be needed.

For example, MA plans are required via regulation to submit risk adjustment data to CMS that identifies health conditions diagnosed and documented by certain types of health care providers. CMS requires plans to attest to the accuracy of these data. In addition, medical records are an important source of information that plans use to develop and target clinical management and quality improvement activities. For beneficiaries with multiple chronic conditions, plans use medical record information to coordinate care delivered across primary care providers and numerous specialists. Therefore, we would have significant concerns with any barriers that CMS might impose on the ability of plans to develop compliance programs or enhance quality of care through the sharing of medical records.

In addition, we would note that §1854(a)(6)(B)(iii) of the Social Security Act prohibits CMS from interfering in the terms and conditions of an MA plan's contracts with providers. Accordingly, proposals that place restrictions on or otherwise interfere with plans' ability to obtain medical records or attestations from providers pursuant to CMS requirements regarding the completeness and accuracy of risk adjustment data or for other purposes could raise serious statutory concerns.

Finally, as CMS notes, some of the challenges associated with medical record requests occur from requests associated with CMS's national and contract-level RADV audit processes. We welcome the opportunity to collaborate more closely with CMS on implementing changes to the RADV audit process that could ease the burden on providers, such as by increasing transparency and predictability in the audit process, providing incentives for electronic medical record transmission and attestation, developing an alternative process for solo practitioners, and allowing the use of alternate sources of reliable data to substantiate diagnoses. We stand ready to engage in dialogue with CMS on how to improve the RADV process.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (§§ 422.2420, 423.2430; Preamble p. 56456)

CMS proposes to significantly reduce the burden of medical loss ratio (MLR) requirements while also recognizing that plans should not be penalized for fraud prevention and Medication Therapy Management (MTM) activities designed to provide more efficient care to their members. In particular, CMS proposes the following:

- Changing the calculation of the numerator of MLR to include all expenditures for fraud prevention;
- Clarifying that compliant Medication Therapy Management (MTM) programs can be included in numerator; and
- Reducing MLR reporting to four data elements: Organization Name, Contract Number, Adjusted MLR percentage, Remittance Amount (if MLR is under 85 percent).

Commonwealth Care Alliance fully supports these proposed changes. Insurers' anti-fraud programs play a key role in contributing to improving the quality of health care for enrollees,

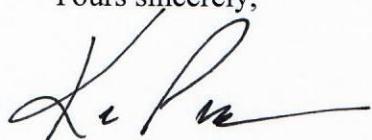
while MTM activities are a critical tool for plans to improve medication adherence and outcomes.

7. Changes to Agent/ Broker Requirements (§§ 422.2272(e), 423.2272(e); Preamble 56465)

CMS proposes to give plans additional discretion than currently permitted in how the plans can treat agent/brokers who become unlicensed. Under the proposed change, plans will no longer be required to terminate agents/brokers upon determining that they are unlicensed. CMS notes that plans should have flexibility to determine the appropriate disciplinary action in these cases.

Commonwealth Care Alliance supports this change, as it provides flexibility for plans to determine the most effective and appropriate approach based on given facts and circumstances.

Yours sincerely,

A handwritten signature in black ink, appearing to read "K. Preede".

Ken Preede
Vice President, Government Relations