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January 16, 2018

Seema Verma, Administrator
The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8016
Baltimore, MD 21244-8013

Submitted electronically via http://www.regulations.gov.

RE: CMS-4182-P: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

Dear Administrator Verma:

Better Medicare Alliance (BMA) is pleased to submit the following comments on the proposed rule updating Medicare Advantage, the Medicare Prescription Drug Benefit, and other Medicare programs for the 2019 Contract Year. BMA is a community of more than 100 ally organizations, who, like the nearly 19 million beneficiaries who have chosen Medicare Advantage, share a commitment to a strong Medicare Advantage option.

Medicare Advantage is an important part of the Medicare program. It represents a public-private partnership that is addressing the needs of today's beneficiaries, while looking to technology and innovation to meet the needs of millions of future beneficiaries. Medicare Advantage payment systems and flexibilities are moving providers towards high-value, high-quality care, improving the health care experience for physicians and their patients.

We appreciate the opportunity to offer comments to help ensure Medicare Advantage plans, providers, and community partners continue to lead the way in offering innovative, high-quality, cost-effective care that improves patient experience and outcomes. We particularly support proposals to ***enhance Medicare Advantage benefit design*** through flexibility in the uniformity requirements, in segment benefits, and in meaningful differences, ***codify the Star Ratings methodology***, ***provide beneficiaries with actionable information about their Medicare enrollment choices*** through changes to disclosure requirements and communications regulations, and ***permit seamless conversion*** for certain dual-eligible beneficiaries.

Our comments below are provided in the order in which they appear in the proposed rule. We urge CMS to take the following actions in the Final Rule:

<u>Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability</u>

- Expand the definition of supplemental benefits when finalizing the policy on Flexibility in the Medicare Advantage Uniformity Requirements (§ 422.100(d)).
- Clarify applicability of proposed Segment Benefit Flexibility in the final rule and in sub-regulatory guidance.

- Finalize as proposed the codification of Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101) with clarification of what would constitute a "significant" change under the proposal.
- Finalize as proposed the policy on Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review and provide appropriate beneficiary education to minimize confusion and aid in plan selection (§§ 422.254 and 422.256).
- Finalize as proposed the policy on Coordination of Enrollment and Disenrollment Through Medicare Advantage Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68) and, with appropriate consumer protections and clear, adequate beneficiary information, allow broader expansion of seamless conversion.
- Medicare Advantage and Part D Prescription Drug Plan Quality Rating System:
    - Finalize as proposed the policy on Star Ratings for Contract Consolidations (§ 422.162(b)(3)).
    - Finalize as proposed the policy on Adding, Updating, and Removing Measures (§ 422.164) in the Star Ratings System and clarify the timing of the rulemaking process.
    - Finalize as proposed the policy on scaled Star Rating reductions for data integrity issues surrounding appeals measures (§ 422.164(g)(1)(iii)).
    - With regard to Measure-Level Star Ratings (§ 422.166(a)), release cut points prospectively to simplify and stabilize the process and explore methodologies that minimize year-to-year changes in the cut points.
- Reconsider proposed changes to the Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505) policy, including a comprehensive analysis of the adequacy of existing regulations and how best to resolve any issues not addressed in current regulation.
- Consider alternatives to the Application of Manufacturer Rebates options proposed in CMS' Request for Information.

Improving the CMS Customer Experience

- Finalize as proposed the policy on Revisions to Timing and Method of Disclosure Requirements (§ 422.111).
- Finalize as proposed Revisions to Communication/Marketing Materials and Activities (§§ 422 and 423 Subpart V).
- Address implementation challenges associated with the policies to create a Part D Prescriber Preclusion List (§ 423.100) and a Part C/Medicare Advantage Cost Plan and PACE Preclusion List (§ 422.224).

Implementing Other Changes

- Finalize as proposed the policy to change to the calculation of the Medical Loss Ratio related to fraud reduction activities (§§ 422.2420, 422.2430, 423.2420, and 423.2430).

A detailed explanation of our comments follows.

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Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

- **Flexibility in the Medicare Advantage Uniformity Requirements (§ 422.100(d))**

BMA supports CMS' proposal to increase flexibility and innovation to better serve beneficiaries, ease obstacles to health care and support services, and encourage use of additional, tailored services, supports or benefits targeted to high-need beneficiaries, particularly those with chronic conditions to maintain health and improve outcomes. We are grateful for CMS' attention to this issue and urge the agency to consider an expansion of the regulatory definition of supplemental benefits in the final rule.

CMS proposes to reinterpret uniformity requirements in Medicare Advantage benefits to provide flexibility for customized benefit designs that address the specific health needs of certain beneficiaries. This proposed flexibility would permit reduced cost-sharing for additional or customized benefits, tailored supplemental benefits, and lower deductibles for enrollees with specific diagnoses certified by a physician. Notably, all enrollees meeting a plan's diagnostic criteria must have access to the tailored benefit package and plans must still abide by non-discrimination rules. CMS proposes that plans will present their customized benefit designs for approval during the plan bid process.

BMA Comments:

As BMA has previously expressed, the Medicare Advantage program does not afford plans the benefit design flexibility needed to most effectively customize care to improve patient outcomes. We called for enhanced flexibility to include a wider range of supplemental benefits that improve care and address social determinants of health, such as nutrition support, transportation, and home modification, for patients with specific conditions or for specified populations of enrollees. We support the final rule and urge CMS to take a holistic view of beneficiary health and use its regulatory authority to expand the definition of supplemental benefits to include these and other benefits that allow Medicare Advantage plans to customize care and improve patient outcomes. Medicare's uniform benefit and non-discrimination requirements as currently interpreted inhibits Medicare Advantage plans from providing additional services and supports to vulnerable and high-need beneficiaries to enable them to access needed items and services. While we support the purpose of these requirements, which is to prevent Medicare Advantage plans from discriminating against individuals with higher needs, we support changes that recognize the value of enhanced benefits tailored to meet the needs of individual enrollees in Medicare Advantage.

CMS' proposal maintains all Medicare benefits for all Medicare Advantage enrollees, but would allow enhanced benefits for certain groups of high-need enrollees. CMS's proposal would permit benefit design tailored to the needs of beneficiaries with a specified diagnosis. For example, Medicare Advantage plans may choose to offer reduced or zero copayments to beneficiaries with diabetes for endocrinology visits, or to beneficiaries with congestive heart failure for cardiology visits. We agree with CMS that providing this benefit design flexibility will allow plans to incorporate evidence-based interventions and protocols that respond to the specific needs of beneficiaries with certain diagnoses. With this proposal, plans are incentivized to customize benefits in ways that help beneficiaries access services and supports that keep them healthy and manage their illnesses.

BMA is grateful CMS has taken this opportunity to better target innovative benefit designs and coordinate care for high-need beneficiaries. We support this proposal and urge CMS to extend these flexibilities to Part D benefits. This will encourage the offering of all evidence-based interventions and encourage medication adherence which is crucial to the successful management of many conditions. Finally, we urge CMS to expand the definition of supplemental benefits in the Final Rule.

- **Segment Benefits Flexibility**

BMA supports CMS' proposal to increase flexibility and innovation by permitting variation in supplemental benefits by population segmentation and urges CMS to clarify this proposal in the final rule and in sub-regulatory guidance.

Under current policy, Medicare Advantage plans are permitted to vary premiums and cost sharing by segment, so long as benefits, premiums and cost-sharing are uniform for all beneficiaries within each segment. A segment is a county-level portion of a plan's service area. CMS proposes to revise its current interpretation to permit variation of supplemental benefits by segment, with the requirement that supplemental benefits be uniform for all beneficiaries within a segment.

BMA Comments:

BMA supports proposals to provide additional flexibility for Medicare Advantage plans to tailor benefits to meet the needs of specific populations. We recognize that the ability to customize supplemental benefits for specific geographic areas allows plans to be responsive to the needs of beneficiaries at the local level.

CMS does not propose new or revised regulatory language to implement this revised interpretation. We urge CMS to offer sub-regulatory guidance for both plans and beneficiaries regarding both how plans may implement this new flexibility and how CMS intends to protect beneficiaries. For example, CMS may consider updates to the Medicare Managed Care Manual, particularly Chapter 4 relating to Benefits and Beneficiary Protections, as an opportunity to provide additional guidance. Furthermore, in the preamble to the proposed rule (p. 56361), CMS uses both "supplemental benefits" and "benefits" in describing this flexibility. We encourage CMS to explicitly clarify that this new segment benefit flexibility applies only to supplemental benefits and not to the core Medicare Advantage benefit package to which beneficiaries are entitled.

- **Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101)**

BMA supports the proposal to codify the discretion CMS has used to stabilize annual changes in enrollee maximum out-of-pocket spending limits and make other regulatory amendments to the maximum out-of-pocket (MOOP) limit establishment process. We urge CMS not to use encounter data to establish MOOP limits until the issues that we and other stakeholders have previously raised are resolved. Finally, we urge CMS to clarify in the final rule the standard for a "significant" change subject to a multi-year transition and the terms of such transition.

Under current regulation, all Medicare Advantage plans must establish limits on enrollee out-of-pocket cost sharing for Part A and Part B services, called maximum out-of-pocket (MOOP) limits. Those limits may not exceed amounts that are set by CMS annually, and CMS encourages plans to adopt a voluntary, lower MOOP limit by affording those plans greater flexibility in establishing cost sharing amounts for Part A and Part B services. To arrive at MOOP limits, CMS currently identifies the 95th percentile of FFS out-of-pocket spending to establish the maximum MOOP limit, and the 85th percentile for establishing the lower, voluntary MOOP limit. CMS notes it would have the authority under the proposal to increase the voluntary MOOP to another percentile level of Medicare FFS spending.

CMS is proposing to codify the MOOP limit establishment process, including consideration of changes in market conditions and availability of different types of data (e.g., encounter data) when establishing MOOP limits. As under current practice, the agency would exercise this proposed new authority in advance of each plan year through the Call Letter, in advance of bid deadlines. CMS would use the annual call letter and other guidance documents to explain its application of the proposed regulatory standard and the data used to establish limits. CMS plans to transition any "significant" changes under this proposal over time, to avoid disruption to benefit designs and minimize potential beneficiary confusion, though the agency does not define what would be a "significant" change under this proposal.

BMA Comments:

BMA supports the proposed codification of the process for establishing annual MOOP limits and supports CMS' use of FFS data to establish MOOP limits. However, we reiterate our various policy concerns about the use of encounter data and urge CMS not use encounter data in this way until the issues that we and others have raised are resolved. Additionally, we request that CMS clarify what would be considered a "significant" change, and therefore subject to a multi-year transition under the proposal.

- **Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)**

BMA supports the proposal to encourage the creation of plans that better meet beneficiary needs by modifying existing meaningful difference requirements and encourages CMS to finalize this provision as proposed. In addition, we note CMS' responsibility to provide appropriate beneficiary education to minimize confusion and aid in plan selection.

Under current regulations, CMS will approve a bid submitted by a Medicare Advantage organization only if it is meaningfully different, with respect to premiums, cost sharing, or benefit design, from other plans the organization offers in the area. CMS proposes to eliminate these meaningful difference requirements beginning with contract year 2019 with the goal of improving "competition, innovation, and available benefit offerings."

BMA Comments:

As noted above, BMA has advocated for providing Medicare Advantage plans the benefit design flexibility needed to effectively customize care to improve patient outcomes. In our responses to other rules and

information requests, we have called for relief from requirements preventing Medicare Advantage plans from providing additional services and supports to vulnerable or high-need beneficiaries to encourage them to access needed services and supports. We are grateful CMS proposes to provide additional flexibility in Medicare Advantage uniformity requirements.

This proposal regarding meaningful differences in Medicare Advantage plans is important because the methodology CMS uses to evaluate meaningful differences between plans only analyzes "key plan characteristics" such as premiums, cost sharing, and benefits. The current methodology fails to capture differences in benefits or cost sharing tied to specific health conditions. Such differences are certainly "meaningful" to beneficiaries with a specific health condition but, because the condition-specific differences may not be" meaningful" at the plan level, CMS would reject the plan's bid under current regulation.

CMS should lift the meaningful difference requirement, with appropriate safeguards, in order to implement the proposed flexibility in the uniformity requirement. Only by lifting the meaningful difference requirement will CMS have the authority to ensure that beneficiaries may access plans with benefit packages customized to their specific health condition. BMA is grateful to CMS for supporting the calls of BMA and other organizations to increase plan design flexibility and urges CMS to finalize to the proposal to ensure smooth implementation of the uniform benefits flexibility. In addition, BMA notes CMS has a responsibility to provide beneficiaries with appropriate education in order to minimize confusion, inhibit undue proliferation of similar plans, and ensure beneficiaries have the information they need to select the best plan for their individual circumstances.

- **Coordination of Enrollment and Disenrollment Through Medicare Advantage Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)**

BMA supports CMS' proposal to enable seamless conversion for certain beneficiaries into a Dual-eligible Special Needs Plan, under specific conditions. BMA recognizes and supports appropriate consumer protections and clear, adequate beneficiary information in the Seamless Conversions program and appreciates CMS' willingness to include such protections. BMA also supports CMS' proposed simplified positive election process ("opt in") to allow Medicare Advantage organizations to enroll commercial, Medicaid, or other members in a Medicare Advantage plan upon becoming Medicare eligible. We further urge CMS to explore re-starting the program to enroll certain new beneficiaries from similar managed care plans into Medicare Advantage as they become eligible for Medicare, with appropriate beneficiary protections.

CMS proposes to permit the seamless conversion of beneficiaries from a Medicaid managed care plan into a Dual-eligible Special Needs Plan (D-SNP) operated by the same parent organization when the enrollee becomes Medicare-eligible. CMS separately proposes to permit passive enrollment from one D-SNP into another D-SNP when the original D-SNP does not renew its contract with CMS (§ 422.60(g)). This proposal aims to avoid disruption to the beneficiary's integrated care coverage. Finally, CMS proposes to establish, through sub-regulatory guidance, a simplified positive election process that would allow Medicare Advantage organizations to enroll non-Medicare plan (i.e. commercial, Medicaid, etc.) members into a Medicare Advantage plan upon becoming Medicare eligible.

CMS proposes to subject these seamless enrollments to five conditions designed to protect beneficiaries, including state approval of the process and provision of Medicare eligibility information to the Medicare Advantage organization, an individual opt-out opportunity, provision of notice to the beneficiary by the Medicare Advantage organization, and CMS approval of the organization's use of seamless enrollment.

BMA Comments:

We appreciate CMS' steps to allow seamless conversion, with appropriate beneficiary protections, and support finalization of the policy relating to dually-eligible beneficiaries as proposed.

To better understand beneficiaries' perspectives on seamless enrollment, BMA polled nearly 70,000 BMA advocates and found that more than 96% of respondents held positive view of the program. In follow-up phone conversations, beneficiaries stated they view seamless conversion as a way to help alleviate the complexity and confusion surrounding researching the many options for Medicare coverage, including traditional Medicare, Medigap, and Medicare Advantage.

BMA welcomes an opportunity to work with CMS and other stakeholders to expand seamless conversion in the future. We fully support inclusion of appropriate beneficiary protections, such as those CMS proposes in this rule, and understand that implementation challenges and potential unintended consequences must be addresses should CMS move forward. For example, complexities associated with the upcoming switch to new Medicare Beneficiary Identifiers must be addressed, because Medicare Advantage organizations will not know beneficiaries' new identifiers. We believe this issue may be resolved through creation of a secure look up tool, similar to the one CMS expects to launch for providers in June 2018.[1] We look forward to working with CMS on solutions to operationalize any expansion of seamless conversion in the future. For example, CMS might next explore allowing seamless conversion from a non-Medicare HMO to a Medicare Advantage HMO.

Finally, BMA supports CMS' proposal to permit Medicare Advantage organizations to use a simplified positive election process ("opt in") to enroll non-Medicare plan members (i.e. those enrolled in commercial, Medicaid, or other non-Medicare coverage) in a Medicare Advantage plan when the enrollee first becomes eligible for Medicare. We hear anecdotally from beneficiaries about the level of confusion during the annual election period (AEP). Therefore, we anticipate that BMA advocates would be supportive of a simplified election process that allows them to remain with the insurer through which they have their non-Medicare coverage and ease the transition to a similar Medicare Advantage plan. This proposal ameliorates some of the complexity and confusion surrounding a newly-eligible beneficiary's Initial Coverage Election Period. We look forward to working with CMS and stakeholders in the development of sub-regulatory guidance to assist Medicare Advantage plan in operationalizing this proposal.

- **Medicare Advantage and Part D Prescription Drug Plan Quality Rating System**

[1] Centers for Medicare & Medicaid Services, "New Medicare Card Project: Critical Access Hospitals," December 12, 2017, slide 16. Available at: https://www.cms.gov/Medicare/New-Medicare-Card/Open-Door-Forums.html.

- **Contract Consolidations (§ 422.162(b)(3))**

BMA supports CMS' proposed changes to the current calculation of Star Ratings for consolidated contracts.

As CMS notes in the proposed rule, contract consolidation is permitted when a contract substitution occurs or to better align business practices. Under current practice, CMS assigns the surviving contract the Star Rating it would have earned in absence of the consolidation. CMS notes that this practice for calculating Star Ratings following contract consolidation may unintentionally mask the true performance of the consumed contract.

CMS proposes a new methodology for calculating the Star Rating of a surviving contract following a consolidation using an enrollment-weighted average of the two plans' Star Ratings. In general, during the first and second plan years following most contract consolidations, CMS proposes to use the enrollment-weighted means of the measure, domain, summary, and overall ratings. For the third and subsequent years following contract consolidation, the performance period for all measures would be after the consolidation, so modifications to Star Ratings are not necessary.

BMA Comments:

BMA supports CMS' proposal to modifying the Star Ratings for consolidated contracts to ensure the Star Ratings that CMS communicates to consumers are as accurate as possible. We note that consumers often benefit from contract consolidations when they gain access to the quality and care management tools, resources, and focus of the surviving contract. However, it does take time to fully integrate contracts and raise the overall performance of the consolidated contract to the highest standards. For this reason, we believe CMS' two-year transition is a reasonable approach.

- **Adding, Updating, and Removing Measures (§ 422.164)**

BMA strongly supports the proposal to codify the Star Ratings methodology, including more clearly defined rules for adding, updating, and removing measures. We believe CMS' proposals will enhance transparency and predictability of changes to the Star Ratings methodology and process. We ask CMS to further clarify in the final rule the timing of the notice and comment process proposed.

CMS proposes to codify a number of rules and processes currently used in the Star Ratings System to add, update or retire measures, to measure plan performance, and to assign each plan a score. CMS also proposes to codify the set of guiding principles it has historically used to make changes to both the Medicare Advantage and Part D Star Ratings. Finally, CMS proposes to add new measures to the Star Ratings, or make substantive updates to existing measures, through the rulemaking process and prior to such rulemaking, proposes to announce new and updated measures through the annual Call Letter. New measures would be incorporated into the display page for two years. Non-substantive updates to existing measures as well as the removal of measures, either due to a change in clinical guidelines, or if CMS

identifies reliability issues in advance of the measurement period, would continue to be announced through the Call Letter and not subject to the rulemaking process.

BMA Comments:

BMA supports the codification of current practice to enhance transparency and predictability of changes for plans, with additional reforms. BMA's priorities for reforming the Star Ratings system serve the goals of transparency and predictability while ensuring effective measurement of clinical outcomes and care management. These include:

- Improve measurement of clinical outcomes and address measurement gaps;
- Improve care management measures;
- Address geographic inequities in quality incentives and social determinants of health;
- Remove audit and enforcement actions from Star Ratings calculations;
- Align measures across Medicare and other public programs; and
- Release Star Ratings measurement target (cut points) prospectively.

As we have communicated in previous communications to CMS, a transparent and prospective measure inclusion, exclusion, and modification process will lend stability to the Medicare Advantage program and allow adequate time for plans and providers to prepare for and implement system changes to successfully meet new measures and improve care for beneficiaries.

A more stable Star Ratings System will allow plans to engage providers in longer-term, value-based contracts using quality measures that align with the Star Ratings measures. These longer-term contracts will improve stability of the system for patients, helping to ensure their providers continue to participate in their Medicare Advantage plan. In addition, when plans are able to prepare for new quality measures in advance, they are better able to improve or maintain their rating and retain any associated Quality Bonus Payments, which are used to provide enhanced benefits to beneficiaries.

While we note, as does CMS in the preamble, that the proposed changes will increase the time required to add new measures or make substantive changes to existing measures, we believe the stability and transparency these new rules will bring to the Medicare Advantage program are well worth it. However, we ask CMS to clarify in the final rule the timing of the rulemaking process as it relates to the addition of new measures or substantial updates to existing measures. If CMS releases a proposed rule relating to new or substantially changed measures after the Call Letter is finalized, we want to ensure that this timing will not interfere with finalization of the rate notice. We encourage CMS to allow adequate time for stakeholder feedback and implementation of any potential new or updated measures by plans and providers.

- **Data Integrity (§ 422.164(g)(1)(iii))**

BMA supports CMS' proposal to modify the Star Rating reduction for data integrity issues associated with appeals measures.

Under current practice, if CMS identifies issues or errors with data submitted by a plan related to appeals measures, the plan receives an automatic 1 Star rating for those measures. Upon review, CMS found this practice to be the leading cause of a plan's inability to achieve a 4 Star rating and earn Quality Bonus Payments, which are used to enhance plan benefits for beneficiaries. CMS proposes to use a scaled reduction for data integrity issues related to appeals measures. In general, plans with a higher incomplete data error rate would receive a greater reduction in their Star Rating for appeals measures. CMS proposes to reduce a plan's Star Rating by 1, 2, 3, or 4 Stars, depending on the severity of the data error rate.

BMA Comments:

BMA strongly supports CMS' proposal to scale Star Rating reductions for data integrity issues around appeals measures and urges CMS to finalize the rule as proposed. BMA believes this proposal will help mitigate the problem of plans not earning Quality Bonus Payments for relatively minor data integrity infractions. We further believe this proposal will better serve beneficiaries, providing them access to enhanced supplemental benefits.

- **Measure-Level Star Ratings (§ 422.166(a))**

BMA urges CMS to release cut points prospectively to simplify and stabilize the process and to explore methodologies that minimize year-to-year changes in the cut points.

CMS establishes raw score thresholds, called cut points, that define the score a plan receives on a scale from 1 to 5 on a Star Ratings System. In prior years, CMS published in advance the raw score thresholds needed to achieve a score equivalent to four stars for certain measures, but CMS halted this practice beginning with the 2016 star ratings. In this rule, CMS proposes the methods by which it will break the distribution of measure-level scores into non-overlapping groups, which determine the cut points.

BMA Comments:

The current, retrospective establishment of cut points, combined with large year-to-year fluctuations in the cut points themselves, creates uncertainty in establishing quality improvement goals. The lack of predictability also makes it more challenging for Medicare Advantage plans to integrate performance goals into value-based provider contracts and impedes longer-term contracts between plans and providers, which would stabilize plans' networks and improve beneficiary continuity of care. BMA urges CMS to prospectively establish quality measure cut points to improve the stability, effectiveness, and accountability of the Star Ratings System.

In addition, BMA supports the exploration of methodologies that may minimize the year-to-year changes in the cut points. We would welcome an analysis of the impact of both methodologies CMS identifies; using a moving average of cut points from the past 2 to 3 years or setting caps on the degree of cut point change permitted from one year to the next. We note that the use of a moving average cut point drawn from previous years would seem to lend itself well to prospective assignment for Quality Bonus Payment qualification purposes. We appreciate CMS' acknowledgement of the potential for "cliffs" in star ratings to develop between plans with nearly identical star ratings on either side of a fixed cut point threshold. BMS

urges CMS to explore methodologies for smoothing these cliffs, particularly among plans with 3.5-to-4.5 star ratings.

Moreover, to better inform Medicare beneficiaries regarding their Medicare plan options, we urge CMS to include Medicare Advantage plan quality ratings in the Medicare Handbook. Each fall, Medicare beneficiaries receive, either via mail or electronically, a Medicare and You Handbook. The Handbook includes a list of available health and drug plans in a beneficiary's area. While the Handbook directs beneficiaries to the Medicare Plan Finder to obtain more information about the Star Ratings System, a recent poll found that only 3% of the Medicare-eligible population use the Medicare Plan Finder Tool.[2] Furthermore, of the 19 million Medicare Advantage enrollees and 44 million Part D enrollees, less than 2 million people enroll through the Medicare Plan Finder.[3]

We believe CMS misses an opportunity to provide this information to beneficiaries in the Handbook itself. We encourage CMS to include each plan's overall star rating in the Handbook and provide beneficiaries additional information about the Star Ratings System itself. CMS could use the "overall star rating" definition available on the Medicare Plan Finder website to provide beneficiaries with an overview of the Star Ratings System, as well as include the descriptor associated with each star level (i.e. 5 stars = Excellent, 4 stars = Above Average, etc.). While we understand the timing of both star rating determination and Handbook printing may present some challenges, we urge CMS to pursue this opportunity to provide beneficiaries with information related to quality of Medicare Advantage plan options available to them.

Finally, data from 2015-2016 illustrate that 39% of the Medicare-eligible population initially use a smartphone or tablet to shop for Medicare coverage.[4] But the Medicare Plan Finder tool is not designed for use on a mobile device. CMS should consider making an easy-to-use Medicare Plan Finder app to allow a growing population of tech-savvy beneficiaries to compare their coverage options from their phones and tablets.

- **Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)**

BMA is concerned that the proposed policy will impede the ability of Part D plan sponsors to both establish high quality, affordable pharmacy networks and to provide the lowest total cost for covered beneficiaries. We urge CMS to omit this proposal from the Final Rule.

CMS proposes changes to the statutory and regulatory requirement that Part D plan sponsors contract with any pharmacy that meets the plan sponsor's standard terms and conditions for network participation. Additional regulatory guidance permits a Part D plan sponsor to vary its standard terms and conditions to accommodate different geographic areas or types of pharmacies so long as all similarly

[2] Morning Consult and Better Medicare Alliance administered survey. November 2017.

[3] Improving Beneficiary Choices: Medicare Plan Finder. Smart Choices Campaign. December 2017.

[4] Medicare Plan Finder Updates. CMS.gov. October 2017.

situated pharmacies are offered the same terms and conditions. Specifically, CMS proposes to clarify the applicability of the any willing pharmacy requirement, revise the definition of retail pharmacy and newly define mail-order pharmacy, clarify regulatory requirements for "reasonable and relevant" standard contract terms and conditions, and establish deadlines by which Part D plan sponsors must provide standard terms and conditions to requesting pharmacies.

BMA Comments:

BMA appreciates the care with which CMS seeks to balance the goals of two different statutory requirements: the any willing pharmacy requirement (section 1860D—4(b)(1)(A) of the Social Security Act) and provisions permitting Part D plan sponsors to offer beneficiaries reduced cost sharing at preferred pharmacies (1860D—(b)(1)(B)). However, we have concerns about the proposal's potential impact on the ability of Part D plan sponsors to establish affordable, high-quality pharmacy networks for beneficiaries that meet network adequacy standards while protecting Trust Fund expenditures from waste, fraud, and abuse. We also note that a plan's pharmacy network influences many star ratings measures, which directly affect payments to plans from CMS. Part D plan sponsors must retain the ability to impose quality standards on participating pharmacies, including accreditation requirements, to ensure beneficiary safety and improve star rating performance.

We feel that these proposals are not in the interests of Part D beneficiaries and will undermine Part D plan sponsors' ability to provide the lowest total cost for covered beneficiaries. We urge CMS to reconsider these proposed changes and not to proceed without conducting a comprehensive analysis of the adequacy of existing regulations and how best to resolve any issues not addressed in current regulation.

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

BMA appreciates CMS' issuance of a Request for Information, rather than making specific policy proposals, and the Agency's interest in the critical issue of drug pricing. As CMS considers whether to pursue policy options in this area, we urge the Agency to focus on options that will reduce costs for all beneficiaries and provide beneficiaries with greater transparency about drug pricing they will pay to better inform their Medicare choices.

CMS requests information for future rulemaking regarding requiring Part D plan sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. The negotiated price is defined in regulations as the price paid by the plan sponsor at the point of sale to the network pharmacy or other network dispensing provider for a covered drug dispensed to an enrollee and reported to CMS. Under current law, plan sponsors may choose whether to apply certain pharmacy price concessions, and all manufacturer rebates, to the negotiated price or retain the savings and report it to CMS as direct or indirect remuneration (DIR). Plan sponsors must factor in an estimate of the DIR expected to be generated in its plan bid, which are used to reduce bids, premiums paid by enrollees, and premium subsidies for which the federal government is liable.

The focus of our response to this Request for Information on manufacturer rebates is the possible requirement that plan sponsors be required to provide price transparency and will be required to pass through a minimum percentage of manufacturer rebates at the point of sale.

BMA Comments:

BMA appreciates CMS' attention to the critical issue of drug pricing and drug costs to beneficiaries, plan sponsors, and the federal government. We also appreciate the opportunity to respond to policy alternatives CMS has presented in this proposed rule. We agree with CMS that beneficiaries would be better served by increased transparency around drug pricing. This is a complex issue and we are concerned that changes proposed for plan sponsors do not capture the extent of the issues involved and have potential negative consequences for beneficiaries.

First, while plan sponsors play a role in the final price of a drug to beneficiaries, there are numerous others in the process who set the initial price and engage in the determination of drug prices before the point of sale. It may well be the plan sponsors and benefits managers who have the interest and opportunity to negotiate the lowest price possible for beneficiaries through bulk purchasing, formularies and price negotiations. Imposing price transparency requirements on plan sponsors, absent similar requirements on manufacturers or others, will address just one piece of this very complicated issue. We urge CMS to consider the full spectrum of entities from manufacturers to point of sale that affect drug price and explore policy options that would more completely provide price transparency.

Second, we note that CMS raises concerns about the impact of DIR on plan premiums and revenue. By retaining manufacturer rebates as DIR, plan sponsors are able to submit lower bids, which reduces plan premiums for all enrollees and reduces government spending on premium subsidies. CMS notes that "DIR amounts Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts" in recent years. However, CMS fails to note that since the 2014 contract year, Medicare Advantage organizations, Part D plan sponsors, and cost plans have been subject to the Medical Loss Ratio (MLR) requirement. Plans must have an MLR of at least 85% or remit the difference to the Secretary of Health and Human Services. This MLR requirement ensures that plans use DIR to reduce premiums for beneficiaries.

As CMS notes in its analysis, all Part D enrollees benefit when plans use manufacturer rebates to reduce plan premiums. When manufacturer rebates are included in the negotiated price, only beneficiaries who use those specific, rebated drugs experience a financial benefit, while all beneficiaries pay higher premiums. In fact, CMS' own analysis finds that if plan sponsors included all manufacturer rebates in the negotiated price, Part D premiums would increase by 11% over 10 years, an increase of $43.84 per month over current law projections, rather than the premium reduction projected for 2018 (and the very low premium growth rates experienced over the past several years).

We agree that beneficiaries who rely on very expensive brand drugs deserve lower prices and transparency. However, such discounts for these drugs should not come at the expense of increased cost to all other beneficiaries' in their Part D premiums. We encourage CMS to investigate the causes of the high prices of specialized drugs and consider policy options that treat beneficiaries more equitably.

Improving the CMS Customer Experience

- **Revisions to Timing and Method of Disclosure Requirements (§ 422.111)**

BMA strongly supports efforts to facilitate better education of beneficiaries, including CMS' proposal to provide Medicare Advantage enrollees with meaningful, actionable information about their health plan electronically and by mail upon beneficiary request.

First, CMS proposes to allow Medicare Advantage organizations to electronically deliver (with beneficiary notification) the Evidence of Coverage, Summary of Benefits, and provider directory, and require mail delivery upon request, to reduce the amount of mail beneficiaries receive from plans. Second, CMS proposes to allow plans to provide the Evidence of Coverage by the first day of the annual coordinated election period (rather than 15 days before the start of the election period). Plans will continue to deliver the Annual Notice of Change 15 days before the annual coordinated election period.

BMA Comments:

One important focus of BMA's advocacy efforts is on the development of consumer friendly, accessible decision-making tools that help beneficiaries make informed choices. BMA has previously called on CMS to customize the Annual Notice of Change and update the Evidence of Coverage to make both documents more useful for enrollees. We noted that beneficiaries are often overwhelmed by the quantity of information Medicare and Medicare Advantage plans are required to provide them. CMS notes in the proposed rule that its own consumer testing revealed that beneficiaries are overwhelmed by the Evidence of Coverage and were more likely to review the Annual Notice of Change to make coverage decisions. The lengthy Evidence of Coverage document provides exhaustive information on medical coverage, the provider directory, and the pharmacy directory. The Annual Notice of Change, by comparison, is relatively short and is intended to convey actionable information essential to beneficiaries' enrollment decisions for the following year.

BMA supports CMS' proposal to reduce beneficiary mail and related confusion while helping beneficiaries focus on information critical to their enrollment decision. We urge CMS to carefully monitor and test beneficiaries understanding of their options and work to maintain parity in their understanding of Medicare Advantage and Original Fee-For-Service Medicare. BMA believes efforts to streamline delivery of information to include that which is meaningful and actionable will provide beneficiaries with a better opportunity to review important information and make informed decisions.

- **Revisions to §422 and §423 Subpart V, Communication/Marketing Materials and Activities**

BMA supports CMS' proposal to streamline government review of materials Medicare Advantage plans use to communicate with beneficiaries by more clearly defining marketing materials and establishing a definition for communication materials.

CMS proposes simplifying government review and approval of the materials Medicare Advantage plans use to communicate with beneficiaries. Under current practice, marketing materials are defined quite broadly and include most materials that plans provide to enrollees and potential enrollees. Plans must submit all marketing materials to the Secretary of Health and Human Services, who then has 45 days to review and disapprove materials it considers inaccurate or misleading. Upon the expiration of the 45-day review period, plans may use materials that have not been disapproved. CMS proposes to more clearly distinguish marketing materials, which are likely to lead to enrollment decisions and are subject to CMS review and approval, from communications materials, which convey information not likely influence enrollment decisions. CMS will continue to conduct review and oversight of communications materials.

BMA Comments:

BMA supports CMS' proposal to more clearly define marketing and non-marketing materials. We believe this will allow CMS to focus its review efforts on materials that are more likely to influence beneficiary enrollment decisions and improve the efficiency and accuracy of CMS' review. By clearly identifying non-marketing materials, and eliminating them from the 45-day review period, beneficiaries will have more timely access to information about the plan in which they are currently enrolled, as well as, the different benefits available to them to achieve better health outcomes.

It is important to note marketing materials will still be subject to submission to CMS 45 days in advance of use and may be disapproved at the Secretary's discretion. While non-marketing materials will not be subject to the 45-day submission requirement, CMS will continue to review and oversee these communications materials.

- **Part D Prescriber Preclusion List (§ 423.100) and Part C/Medicare Advantage Cost Plan and PACE Preclusion List (§ 422.224)**

BMA supports CMS' reconsideration of the Medicare enrollment requirement for Medicare Advantage and Medicare Advantage-Prescription Drug plan providers and suppliers. We further support program integrity efforts to ensure the appropriate use of Medicare dollars. We urge CMS to address the operational challenges presented by the preclusion list proposals.

Current regulations require that providers delivering health care items or services to Medicare beneficiaries through a Medicare Advantage organization, including a Medicare Advantage-Prescription Drug plan, must enroll in Medicare. CMS proposes to rescind this requirement and instead prohibit Medicare Advantage organizations from paying for items or services provided by individuals or entities included in a "preclusion list" of providers prohibited from participating in the Medicare program. The preclusion list would contain individuals or entities revoked from Medicare.

BMA Comments:

BMA supports policies that expand and ensure access by Medicare Advantage beneficiaries to all appropriate and necessary health care services. BMA has previously noted the burden of Medicare enrollment requirements on providers and called on CMS to create a more customized certification

process. In addition, the current policy may limit the availability of providers in Medicare Advantage networks and discourage their participation in Medicare Advantage.

The proposed policy relieves the provider enrollment burden and provides fraud protection and accountability to ensure providers who are excluded from Medicare do not provide services to Medicare Advantage beneficiaries. BMA supports the intention of this proposed rule. However, we have concerns about the operational complexity that may surround use of the preclusion lists. For example, it is not clear in the proposed rule, whether CMS proposed to create two preclusions lists, one for Part C and one for Part D. In the event CMS intends to create two preclusion lists, we ask that the agency clarify how it will reconcile the appearance of a provider on one list and not the other, as well as whether one list will take precedence over the other list. We urge CMS to offer solutions for these and other operational complexities as it seeks to replace the provider enrollment requirement.

Implementing Other Changes

- **Proposed Regulatory Changes to the Calculation of the Medical Loss Ratio (§§ 422.2420, 422.2430, 423.2420, and 423.2430) – Fraud Reduction Activities**

BMA supports this proposal to better combat fraudulent Medicare Advantage payments.

For contract year 2014 and subsequent years, Medicare Advantage Organizations and Part D sponsors are required to report their medical loss rations (MLRs) and are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent. Historically, CMS has adopted Medicare MLR rules that aligned with commercial insurance MLR rules, which have excluded fraud prevention activities from being considered quality improvement activities (QIA), which are included in the numerator of the MLR calculation. CMS has reconsidered this position and is proposing to revise the MLR calculation to include in the MLR numerator expenditures related to fraud reduction activities (including fraud prevention, fraud detection, and fraud recovery) and Medication Therapy Management (MTM) programs.

BMA Comments:

BMA supports CMS' proposal to allow plans to include expenditures related to fraud reduction activities in the numerator of the MLR calculation. We believe this change has the potential to increase the incentive for plans to engage in fraud reduction activities, which would have the impact of reducing overall expenditures to the Medicare Trust Fund as fraudulent providers are identified and precluded from receiving payments from CMS, as well as better ensure quality providers and suppliers for Medicare Advantage beneficiaries.

Conclusion

Medicare Advantage addresses the needs of today's beneficiaries with innovations in financing and care delivery important to meeting the needs of millions of future beneficiaries. BMA shares the Administration's commitment to ensuring Medicare Advantage payment systems move providers towards

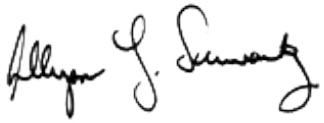
high-value, high-quality care and continues to offer beneficiaries the care and services they need, at an affordable cost.

We are grateful for CMS' attention to policy proposals for which BMA has advocated that enhance Medicare Advantage benefit design flexibility, improve the transparency and stability of the Star Ratings System, and provide beneficiaries with actionable information about their Medicare enrollment choices.

We look forward to working with you and your staff to ensure Medicare Advantage remains a strong, stable, sustainable, and cost-effective option for current and future beneficiaries.

Thank you for the opportunity to submit these comments. We welcome further discussion.

Sincerely,



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