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March 5, 2018

Seema Verma, Administrator The Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-2017-0163 P.O. Box 8016 Baltimore, MD 21244-8013

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

Dear Administrator Verma:

Better Medicare Alliance (BMA) is pleased to submit the following comments on the Advance Notice and Draft Call Letter for Calendar Year 2019 ("Advance Notice"). BMA is a community of more than 100 <u>ally organizations</u>, including providers, professional associations, health systems, aging services organizations, business groups, health plans and beneficiaries. Like the nearly 20 million beneficiaries who have chosen Medicare Advantage, we 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 addresses 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 care, improving the health care experience for physicians and their patients.

We appreciate CMS' support and engagement in the Medicare Advantage program. The Advance Notice and recent regulatory activities create a positive environment in which Medicare Advantage plans, providers, and community partners are able continue to lead the way in offering innovative, high-quality, cost-effective care that improves patient's experience and outcomes. We encourage CMS to finalize this strong and stable rate environment for the Medicare Advantage program, with an expected payment impact of +1.84 percent, and to ensure any modifications made in the Final Rate Notice do not materially change this positive rate. BMA greatly appreciates CMS' work to solicit and respond to input from the full spectrum of stakeholders in crafting regulations to modernize and improve the Medicare Advantage program.

BMA supports CMS' proposals, which allow for more flexibility and choice within Medicare Advantage, providing new opportunities for innovation to meet the needs of beneficiaries. BMA's priorities for the Final Rate Notice are:

- Finalization and implementation of changes to uniformity flexibility and meaningful difference requirements,
- Expansion of the definition of health-related supplement benefits,
- A technical adjustment to the calculation of bid-to-benchmark ratios to account for different proportions of HMO vs. PPO plan types in the Employer Group Waiver Plan (EGWP) and individual Medicare Advantage plan markets,



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- Maintenance of the current coding adjustment methodology and to allow for a broader and deeper discussion of any change with stakeholders,
- Application of the statutory minimum coding pattern adjustment in 2019, and
- Delay of the phase-in of encounter data as a diagnosis source until data accuracy and processes are verified and reliable.

Our expanded comments on these priorities and other policy proposals are detailed in Attachment A.

BMA shares the Administration's commitment to ensuring Medicare Advantage payment systems are accurate, adequate, and provide flexibility to offer beneficiaries the care and services they need at an affordable cost. We appreciate the strong and stable rate environment CMS proposes in the Advance Notice and encourage CMS to finalize these proposals. We look forward to working with you and your staff to ensure Medicare Advantage remains a robust, sustainable, high-quality and cost-effective option for current and future beneficiaries.

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

Sincerely,

Allyson Y. Schwartz President & CEO

Better Medicare Alliance

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Attachment A

Overall, as described in our cover letter, BMA supports and looks forward to finalization of the Advance Notice and offers this additional commentary to inform the Final Rate Notice. Our comments below are provided in the order in which the proposals appear in the Advance Notice.

In summary, we ask CMS to consider the following actions in the Final Rate Notice:

Changes to the Risk Adjustment Model (Advance Notice Part 1)

- Explore the addition of conditions reflecting social determinants of health to the risk adjustment model in future years.
- Carefully consider proposed changes to the risk adjustment model to take into
 account each enrollee's total number of diseases of conditions, and ensure the policy
 is achieving the overarching goal of accurately predicting costs for individuals living
 with multiple chronic conditions.
- Delay the phase-in of encounter data as a diagnosis source and review its impact on Special Needs Plans (SNPs).

Changes in the Part C Payment Methodology for CY 2019 (Advance Notice Part 2)

- Adjust the calculation of bid-to-benchmark ratios to account for different proportions of HMO vs. PPO plan types in the EGWP and individual Medicare Advantage plan markets and continue the 2018 payment methodology for EGWPs in 2019, with a gradual phase-in of the individual bid-to-benchmark ratios to set payments in subsequent years.
- Maintain the current coding pattern adjustment to allow for further discussion with stakeholders and finalize as proposed the statutory minimum coding pattern adjustment of 5.90% in 2019 to help advance stability in the Medicare Advantage program.

<u>Draft Calendar Year 2019 Call Letter</u>

- Continue to review and evaluate overlapping Star Ratings measures and consider future Star Ratings measures related to care management.
- Finalize as proposed the expanded definition of health-related supplemental benefits and adopt a holistic view by including benefits that address social determinants of health such as access to nutritious food and transportation. In addition, provide plans with specific guidance to offer certainty as they develop supplemental benefits for their 2019 bids.
- Finalize as proposed the policy to allow D-SNPs and I-SNPs to offer Enhanced Disease Management as a supplemental benefit.
- Finalize as proposed the increased flexibility in the uniformity requirement regarding additional benefits tied to health status or disease state.
- Provide additional guidance to assist Medicare Advantage Organizations in locating Medicare Diabetes Prevention Program-certified providers and allow plans to deliver the benefit virtually.



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- Continue working with stakeholders to develop Special Needs Plan (SNP)-specific network adequacy criteria, particularly with regard to institutional SNPs (I-SNPs) and Medicare-Medicaid Plans.
- Continue efforts within Part D to combat the opioid epidemic and continue working with stakeholders to implement comprehensive, evidence-based strategies to reduce opioid overuse.

A detailed explanation of each of these policies follows.



Changes to the Risk Adjustment Model (Advance Notice Part 1)

Adding condition categories to the risk adjustment model

BMA encourages CMS to explore adding conditions to the risk adjustment model that reflect social determinants of health, as captured by ICD-10 Z codes.

As required by Section 17006(f) of the 21st Century Cures Act (P.L. 114-255), CMS proposes to add conditions to the CMS-Hierarchical Condition Count (CMS-HCC) model related to mental health and substance use disorders to the reflect the severity of chronic kidney disease. CMS further proposes to calibrate the model using 2014 diagnoses and 2015 feefor-service (FFS) Medicare costs.

BMA Comments:

BMA appreciates CMS' responsiveness to these statutory requirements and encourages CMS to explore the inclusion of social determinants of health diagnosis codes in the CMS-HCC model. As we have expressed in the past, two Medicare Advantage beneficiaries with the same health condition may experience very different disease progressions and health care costs due to many factors, including factors related to where they live, learn, work and play – the social determinants of health. Many of these factors are now captured through ICD-10 Z codes related to family and social circumstances that may case potential health hazards.

By accounting for social determinants of health in the risk adjustment model in future years, Medicare Advantage plans may be better able to engage in risk stratification and proactive care management that improves health outcomes, reduces costs, and improves the patient experience of care. As with any change made to the risk adjustment model, health care providers may need education and training about the appropriate use of these codes to ensure conditions are captured and communicated to Medicare Advantage plans for appropriate intervention and care coordination.

> Counting conditions in the risk adjustment model

BMA supports the policy goal of ensuring the risk adjustment model's accuracy in predicting health care costs for Medicare Advantage enrollees with multiple chronic conditions. We ask CMS to ensure the policy is achieving this overarching goal.

As required by Section 17006 of the 21st Century Cures Act (P.L. 114-255), CMS proposes changes to the Medicare Advantage risk adjustment model to take into account each plan enrollee's total number of diseases or conditions with an additional adjustment as these diagnoses increase in number. As CMS notes, the risk adjustment model is already additive — an individual's risk score increases with each condition an enrollee has. The proposed change would add a new variable and coefficient to the risk adjustment model to account for the number, or count, of conditions the beneficiary has.



CMS proposes a new risk adjustment model, the Payment Condition Count Model, which would account for the number of conditions a beneficiary has among those conditions that are included in the payment model. CMS proposes to phase-in use of the Payment Condition Count Model until it is fully implemented in Calendar Year 2022, and CMS would use encounter data-based risk scores in calculating the model. CMS also discusses an alternative, the All Condition Count Model, which would account for all conditions that a beneficiary has, including conditions that are excluded from the payment model.

BMA Comments:

BMA supports the goal of the proposed changes to the risk adjustment model, which is to accurately predict the health care costs of individuals with multiple chronic conditions. Ensuring the risk adjustment model accurately predicts costs for individuals with multiple chronic conditions is critical for the ongoing effectiveness of the Medicare Advantage program. A 2016 Avalere analysis found that the CMS-HCC risk model does not accurately predict health care costs for these enrollees.¹ We appreciate CMS' work to address the challenges of accurate risk adjustment for individuals with multiple chronic conditions. As CMS contemplates these changes, we ask CMS to consider consequences that may result in the event there are reduced resources for the vast majority of Medicare Advantage enrollees who may have fewer chronic conditions but no less significant care coordination needs.

> Use of encounter data as a diagnosis source

BMA asks CMS to delay the phase-in of encounter data as a diagnosis source and continue to review its impact on SNPs. We respectfully request that, before moving forward, CMS continue to work with stakeholders to evaluate the data, address implementation barriers, and analyze stakeholder impacts to ensure risk score accuracy.

CMS is in the midst of changing the system used to gather diagnosis codes and is currently using a blended version of two different systems. Through the Risk Adjustment Processing System (RAPS), Medicare Advantage plans filter diagnosis codes and submit them to CMS, where the files are reviewed and audited for accuracy. With the newer Encounter Data System (EDS), Medicare Advantage plans submit all unfiltered data directly to CMS, which then applies its own filtering logic to extract diagnosis codes from the data.

In 2016, CMS initiated the transition from RAPS to EDS, using a blend of 10% EDS and 90% RAPS data. CMS increased the proportion of EDS data used in 2017, to 25%, but reduced it in 2018, to 15%, due to concerns about data accuracy. In the 2019 Advance Notice, CMS proposes to increase the proportion of EDS data used to 25%. CMS estimates this policy would result in a negative 0.4% payment adjustment to Medicare Advantage plans.

¹ Avalere, Federal Government Underpays Medicare Advantage Plans for Enrollees with Multiple Diseases, January 22, 2016. Web.



BMA Comments:

BMA appreciates CMS' response to thoughts we have shared about the use of encounter data as a diagnosis source and operational challenges surrounding this transition, particularly by reducing the percentage of EDS data used to calculate risk scores from 25% in 2017 to 15% in 2018.

BMA welcomes CMS' recognition of EDS data accuracy challenges and believes additional work is needed to fully validate the EDS. The Government Accountability Office and the Department of Health and Human Services Office of the Inspector General (OIG) have reported on the limited progress made to validate the EDS and offered recommendations for CMS to address encounter data accuracy issues.² BMA was pleased to see CMS concurred with many of the OIG's recommendations. CMS must validate the EDS to ensure accuracy of risk scores for Medicare Advantage enrollees before progressing further with implementation.

In addition, Medicare Advantage providers and plans, as well as CMS, are not yet ready for aggressive implementation of the EDS. We ask CMS to continue its ongoing work with stakeholders to develop a strategy for addressing implementation issues while progressing at a slow and measured pace to adequately prepare all parties for the transition. BMA and its ally organizations look forward to a continuing partnership with CMS in this important work, including with data analytics support.

Finally, we ask CMS to continue its review of the impact of the RAPS to EDS transition on SNPs. Milliman analyses from 2017 and 2018 found that median EDS risk scores were lower than RAPS scores but the difference was more pronounced for SNPs. In 2016, EDS scores were 8.4 percent lower than RAPS scores at the 20th percentile and 5.1 percent lower at the 50th percentile.³ In 2017, EDS scores were 6.6 percent lower at the 20th percentile and 5.2 percent lower at the 50th percentile.⁴ Additional work remains to understand the impact of the EDS on SNPs.

Changes in the Part C Payment Methodology for CY 2019 (Advance Notice Part 2)

Medicare Advantage Employer Group Waiver Plans

BMA encourages CMS to adjust the calculation of bid-to-benchmark ratios to account for different proportions of HMO vs. PPO plan types in the EGWP and individual

² United States Government Accountability Office, Medicare Advantage: Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments, January 2017. Web. See also U.S. Department of Health and Human Services, Office of the Inspector General, "Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements are Needed," January 2018. Web.

³ Deana Bell, David Koenig, and Charlie Mills, "Impact of the transition from RAPS to EDS on Medicare Advantage risk scores," Milliman White Paper, January 2017. Web.

⁴ Deana Bell, David Koenig, Charlie Mills, "Medicare Advantage's transition from RAPS to EDS risk scores: 2017 impact," Milliman White Paper, February 2018. Web.



Medicare Advantage plan markets. In addition, BMA asks CMS to continue the 2018 EGWP payment methodology in 2019. Thereafter, BMA recommends phasing in over several years the complete use of individual market plan bids to calculate bid-to-benchmark ratios. Finally, we ask CMS to revisit its determination that EGWPs may no longer pay the Part B premium on behalf of their enrollees.

CMS proposes to fully transition EGWPs to administratively set payments. In 2017, CMS began phasing-in this new methodology, replacing the previous methodology in which payments were based on Medicare Advantage health plan bids tied to a benchmark adjusted to account for geographic variation in costs relative to benchmarks in the health plan's service area, the quality performance of the plan, and the health status of the plan's enrollees. Following the completion of the bidding process, health plans could negotiate EGWP benefits and premiums with employers. In 2017, CMS ended the bidding process for EGWPs and began transitioning to payments based on the enrollment weighted average bid-to-benchmark ratio for individual Medicare Advantage health plans. In 2017, CMS used a 50/50 blend of the 2016 enrollment weighted average bid-to-benchmark ratio for individual Medicare Advantage health plans. In 2018, CMS maintained this 50/50 blend, rather than continuing the phase-in process, in order to better understand the impact of the new payment methodology on beneficiaries.

For Calendar Year 2019, CMS proposes to fully transition to using only individual Medicare Advantage health plan bids to calculate bid-to-benchmark ratios to set EGWP payments. As an alternative, CMS seeks comment on a continued freeze of the phase-in, maintaining the 50/50 blend for 2019. In addition, if the current 50/50 blend is maintained, CMS seeks comments as to whether it should include an additional step to account for the difference in proportion of beneficiaries enrolled in HMOs vs. PPOs in the individual and employer Medicare Advantage markets. In making this adjustment, CMS would, within each payment quartile, calculate the 2018 bid-to-benchmark ratios for individual HMO and PPO plans, calculate a weighted average 2018 bid-to-benchmark ratio based on the mix of HMO and PPO plans in the EGWP market, and use the resulting weighted average to calculate payments for HMO and PPO EGWPs.

BMA Comments:

BMA strongly supports CMS' proposal to undertake adjustments that account for the different penetration of HMOs and PPOs in the EGWP and individual markets. More than 75 percent of EGWP enrollees participate in a local PPO plan, whereas 73 percent of enrollees in individual Medicare Advantage plans participate in HMOs. The group characteristics and larger geographic coverage of EGWPs lead to more PPOs than HMOs, and the payment methodology should account for this fact.

The proposed approach to accounting for HMO and PPO penetration in the individual vs. EGWP market could be improved with a minor adjustment. Paying HMO and PPO EGWPs

⁵ Centers for Medicare & Medicaid Services. Medicare Advantage enrollment and contract data, January 2018.



based on the same weighted average bid-to-benchmark ratio will result in payments that are not aligned with the very different cost structures of the two plan types. The proposed adjustment would result in overpayments to HMO EGWPs and underpayments to PPO EGWPs, creating inequity among plans. The PPO underpayment, in particular, would disproportionately and negatively impact rural markets, which are primarily served by EGWP PPOs. The proposed approach also does not align with individual market payment structures, where HMOs are paid according to HMO bids and cost structures and PPOs are paid according to PPO bids and cost structures.

We ask CMS to consider slightly modifying its proposed approach to address the issues outlined above. Under this modification, the first step would be the same: CMS would, within each payment quartile, calculate the 2018 bid-to-benchmark ratios, separately, for individual HMO plans and PPO plans. Then, rather than calculating a weighted average of these two ratios, as CMS proposes, we recommend CMS pay EGWP HMOs according to the individual HMO bid-to-benchmark ratio and pay EGWP PPOs according to the individual PPO bid-to-benchmark ratio. We believe this will help mitigate the impact of the proposed changes on EGWP enrollees and address equity issues across EGWP types.

In addition, BMA appreciates CMS' consideration of a continuation of the 50/50 payment blend used in 2018. We support the continuation of the current 50/50 blend for 2019. To facilitate market stability and a smoother transition beyond 2019, we ask CMS to phase-in greater use of the individual market bid-to-benchmark ratios over several years to ease market adjustments resulting from administratively set payment rates. In light of many recent changes, the EGWP market would be strengthened by reducing the frequency and degree of policy and rate changes. Therefore, of the two options CMS proposes, we support maintenance of the current payment methodology for an additional year before continuing to phase-in further payment methodology changes. In general, we ask for a reduction in the frequency and degree of policy and rate changes in the years to come to minimize disruption for EGWP enrollees.

Finally, we ask CMS to reconsider its determination that EGWPs may no longer pay the Part B premium on behalf of their enrollees. We recognize the administrative complexities of such payment, but feel alternative options, such as permitting employer plans to separately reimburse enrollees for their Part B premiums, may present a solution that works for all.

Medicare Advantage Coding Pattern Adjustment

BMA supports CMS' proposal to apply the statutory minimum coding pattern adjustment of 5.90% in 2019 and strongly supports maintenance of this position in the Final Rate Notice to maintain stability and predictability in the Medicare Advantage program. BMA encourages CMS to leave the methodology unchanged for 2019 to allow further time for stakeholder analysis and engagement.

CMS proposes to apply the statutory minimum Medicare Advantage coding pattern adjustment, 5.90%, for 2019. CMS seeks comment on other coding pattern adjustment methodologies for 2019, including: CMS' method for assessing the impact of coding



differences from the Payment Year 2010 Advance Notice, a method using adjusted average per capita cost as an upper limit for risk score increases, from the Payment Year 2016 Advance Notice, and a method recommended by MedPAC and outlined in the March 2017 Report to Congress. CMS also seeks comments on alternative methodologies as it finalizes the coding adjustment factor for 2019.

BMA Comments:

BMA appreciates the opportunity to comment on the alternative coding adjustment methodologies CMS presents, as well as on other methodologies. We believe stakeholders need additional time to analyze and understand the impact of these potential changes in order to ensure they reflect actual coding pattern differences and thus advance the goal of payment accuracy. Because of this, we believe CMS should leave the methodology unchanged for 2019, applying the minimum statutory coding adjustment, and work with stakeholders to develop a future method for addressing coding patterns focused on payment accuracy and fairness. As always, the goal of any adjustment to Medicare Advantage payment should be accuracy, supported by complete and accurate coding.

BMA has long advocated for application of the minimum coding pattern adjustment and supports CMS' proposal to apply it in 2019. To achieve stability and predictability in the Medicare Advantage program, ensure adequacy of prospective, capitated payments, and enable plans and providers to have the data necessary for early intervention and care management, CMS should maintain the coding pattern adjustment at the current statutory minimum in 2019.

<u>Draft Calendar Year 2019 Call Letter</u>

> Enhancements to the 2019 Star Ratings and Future Measurement Concepts

BMA supports the direction of CMS' proposed changes to the Star Ratings for 2019 and encourages CMS to continue evaluation of overlapping measures. We suggest the exploration of future measures related to care management.

CMS proposes several changes to the Star Ratings for 2019. Among these changes are the addition of new measures to the 2019 Star Ratings, including Statin Use in Persons with Diabetes for Part D and Statin Therapy for Patients with Cardiovascular Disease for Part C. CMS also proposes to decouple audits and enforcement actions from the Star Ratings and to modify the Beneficiary Access and Performance Problems Star Ratings measure to include only compliance activity data. CMS proposes to add a measure on Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (Part D) to the display page. CMS also indicates future work on a new Part C measure on opioid overuse, also on the display page, and a new polypharmacy measure for Part D that would, among other things, address concurrent use of opioids and benzodiazepines. Finally, CMS proposes scaled reductions for data completeness issues for appeals measures to avoid different



impacts when a health plan is audited. CMS estimates the impact of all proposed Star Ratings changes is a negative 0.2% payment adjustment.

Following finalization of the 2019 Call Letter, RAND Corporation, the Part C and D Star Ratings contractor, will convene a Technical Expert Panel to provide guidance on the Star Ratings, including on the framework, topic areas, methodology, and operational measures.

BMA Comments:

BMA believes that as the Star Rating System reaches its tenth year, an opportunity exists to improve on the system's success in linking payment to quality by evaluating the current measurement structure, identifying policy issues, and considering specific recommendations for the program's continued improvement. We believe this work is enhanced by the input of experts from across the Medicare Advantage and Part D stakeholder community, and we appreciate CMS' ongoing engagement with stakeholders on the Star Ratings. In guiding future work, BMA recommends several improvements to ensure Star Ratings accurately measure plan performance, such as:

- Developing transparent and prospective processes for measures, allowing adequate time for plans and providers to plan, prepare, and implement system changes to successfully meet new measures and improve care for beneficiaries, and prospective announcement of new measures and cut-points. To this end, BMA commends CMS' previous regulatory proposal to add new measures or substantively update existing measures through the annual rulemaking process;
- Leveraging the work done by the Core Quality Measures Collaborative to promote alignment of quality measures across public programs and to address gaps within the Star Ratings, such as measures associated with mental health and substance abuse;
- Aligning Star Ratings with the National Quality Strategy;
- Modifying the Categorical Adjustment Index to better account for social determinants of health; and
- Better integrating patients and providers in the measure development process.

In addition, we are pleased to see CMS' incorporation of measures related to combating the opioid epidemic, both in adding a measure to the Part D display page in 2019 and considering future Part C and Part D ratings related to opioid overuse and concurrent use of opioids and benzodiazepines.

With regard to future measures, we encourage CMS to explore using the Star Ratings to further emphasize the importance of care management for Medicare Advantage Organizations. At its core, the prospective, capitated payments Medicare Advantage plans receive enable flexibility, collaboration, and continuous learning about care management and chronic disease management. By reviewing the literature, interviewing experts, and studying organizations like CareMore, Indiana University Health, InterMed, and Johns Hopkins, The Robert Graham Center, in partnership with BMA, developed a blueprint for



effective care management. The key components of effective care management are a value-based payment system, a culture of care management, effective teams, customized care, and trust between clinical teams and patients. We hope to work with CMS to incorporate Star Ratings measures focused on care management in the future.

> Health-related Supplemental Benefits

BMA supports CMS' proposed expanded definition of health-related supplemental benefits. The enhanced flexibility will permit Medicare Advantage plans to offer supplemental benefits that aim to improve beneficiaries' health outcomes and quality of life. We ask CMS to consider a holistic view that includes benefits to address social determinants of health. Finally, we appreciate CMS' intent to provide additional guidance on this issue and respectfully request that CMS provide plans with certainty as they develop supplemental benefits for their 2019 bids.

As CMS notes in the Advance Notice, items or services with the primary purposes of daily maintenance are not currently permitted as supplemental benefits, due to the "primarily health-related" standard that a supplemental item or service prevent, cure, or diminish an illness or injury. CMS proposes to expand the scope of the primarily health-related supplemental benefit standard, allowing items or services that diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. CMS indicates it will provide detailed guidance for Medicare Advantage Organizations in the future.

BMA Comments:

BMA strongly supports CMS' proposal to expand the scope of primarily health-related supplemental benefits and asks CMS to consider a holistic view that includes in this expanded definition benefits to address social determinants of health. BMA appreciates CMS' intent to provide additional guidance on this issue and asks CMS to provide guidance on the proposal and how it relates to proposed regulations and statutory changes Congress recently codified in the Bipartisan Budget Act of 2018 so that plans have the certainty required to include additional supplemental benefits in their 2019 bids.

For example, BMA supports CMS' example of fall prevention devices as a supplemental benefit newly-covered under the expanded definition. Medicare Advantage health plans partner with community-based programs to provide evidence-based falls prevention programs.⁷ Fall injuries are among the 20 most expensive medical conditions, costing Medicare \$31 billion annually in health care expenses.⁸ Falls prevention programs sponsored by Medicare Advantage health plans, including those based on the Centers for Disease

⁶ Robert Graham Center, "Bright Spots in Care Management In Medicare Advantage," Report, June 2017. Web.

⁷ Better Medicare Alliance, "Falls Prevention in Medicare Advantage," Fact Sheet, September 2017. Web.

⁸ Burns ER, Stevens JA, and Lee R, "The direct costs of fatal and non-fatal falls among older adults – United States," *Journal of Safety Research*, September 2016. Web.



Control and Prevention's curriculum on fall prevention programs, have proven to reduce falls risk, help older adults stay in their homes, and reduce avoidable health care utilization.⁹

BMA has advocated for enhanced flexibility to include a wider range of supplemental benefits that improve care and address social determinants of health, such as nutrition support via healthy meals, expanded in-home care, home modification, and transportation to medical appointments. We note that these services may be allowable under CMS' proposed expansion because, for example, nutrition support often ameliorates the functional/psychological impact of injuries or health conditions, and transportation to health care appointments may reduce avoidable emergency and healthcare utilization. We also ask CMS to explore the inclusion of therapeutic massage as a supplemental benefit for treatment of chronic pain management, a proposal that complements CMS' other proposals to address the nation's opioid crisis.

In drafting future guidance for Medicare Advantage Organizations regarding supplemental benefits, CMS may consider the experience of Medicare-Medicaid Plans (MMPs) operating in nine states under the Financial Alignment Initiative. MMPs are required to cover all Medicare and Medicaid benefits and many, if not most, MMPs also offer supplemental benefits either required by their three-way contracts with CMS and the state or at the MMP's discretion. One study comparing enrollees in a Medicaid-only program and those in a fully integrated Medicare-Medicaid program found enrollees in the integrated program were 48 percent less likely to have a hospital stay. ¹⁰ In addition, integrated program enrollees were 6 percent less likely to have an emergency department visit, 2.7 times more likely to have a primary care physician visit, and more likely to use home and community based services, assisted living services, and hospice care, among other positive results.

In regards to specific supplemental benefits CMS might consider authorizing, evidence suggests proper nutrition can be a protective factor against the effects of chronic disease, falls, isolation, and loneliness. For example, seniors experiencing hunger are three times more likely to suffer from depression, 50 percent more likely to have diabetes, and 60 percent more likely to have congestive heart failure or a heart attack compared to their peers who do not experience hunger. One study found that 45 percent of patients who fall in the hospital have malnutrition. While this may not directly correlate to in-home falls, a randomized study found that daily delivery of meals may reduce the risk of falls which, as noted above, are responsible for a significant portion of Medicare spending. In general, home delivered meals "improve diet quality and increase nutrient intakes" while also

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⁹ Centers for Disease Control and Prevention, "Preventing Falls: A Guide to Implementing Effective Community-Based Fall Prevention Programs," 2015. Web.

Wayne L. Anderson, Zhanlian Feng, Sharon K. Long, "Minnesota Managed Care Longitudinal Data Analysis," for the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, March 2016. Web.
 National Commission on Hunger, "Freedom from Hunger: An Achievable Goal for the United States of America," 2015.
 Web.

¹² Bauer JD, Isenring E, Torma J, Horsley P, Martineau J, "Nutritional status of patients who have fallen in an acute care setting," *Journal of Human Nutrition and Dietetics*, October 19, 2007. Web.

¹³ Kali S. Thomas, Ravi B. Parikh, Andrew R. Zullo and David Dosa,"Home-Delivered Meals and Risk of Self-Reported Falls: Results From a Randomized Trial," *Journal of Applied Gerontology*, October 25, 2016. <u>Web</u>.



helping to rebalance long-term care spending to include more home and community based services. ¹⁴ In one community partnership, Meals on Wheels America provided a pack of 10 healthy frozen meals to Medicare Advantage enrollees following a hospitalization. ¹⁵ This healthy food delivery resulted in lower hospital readmissions and health care cost savings. Another pilot study in six states found that 30-day readmission rates were 6-7 percent for Meals on Wheels recipients, compared to a national average of 15-33 percent over the same period. ¹⁶ These savings accrue to Medicare, as well as to Medicaid. One study estimates that a one percent increase in the number of older adults receiving home delivered meals in 2009 could have yielded more than \$109 million in savings to state Medicaid programs. ¹⁷ In fact, every \$25 per year per older adult spent on home-delivered meals directly reduces the low-care nursing home population by one percent, yielding hundreds of millions of dollars in savings for individuals and taxpayers each year. ¹⁸

Home modification may also help more seniors age in place and avoid expensive institutional care. A 2010 study found that, using 2009 dollars, the median monthly payment for non-institutional long-term care was \$928, compared with \$5,243 for nursing homes. Yet, more than one million older adults with disabilities live in homes with barriers to meeting their daily needs. Even among the broader population of all older adults, 44 percent of households have some need for home accessibility features due to disability or difficulty using parts of the home, such as the kitchen or bathroom, without assistance. I By modifying seniors' homes to help them age in place, public expenditures may be reduced. One study found that Medicaid home and community based services (HCBS) waivers that kept beneficiaries out of institutional care produced a national average public expenditure savings of \$43,947 per participant in 2002.

Community-based organizations that deliver HCBS can help address social determinants of health issues that often drive higher health services utilization and can lead to poor outcomes. A recent study examined partnerships between Area Agencies on Aging (AAAs), which help coordinate social services for older adults in non-institutional settings, and social

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¹⁴ Huichen Zhu and Ruopeng An, "Impact of home-delivered meal programs on diet and nutrition among older adults: a review," *Nutrition and Health*, June 10, 2014. Web.

¹⁵ Better Medicare Alliance, "The Value of Medicare Advantage: Pioneering Community Partnerships," Fact Sheet, August, 2016. Web.

¹⁶ Meals on Wheels America Care Transition Report, 2013.

¹⁷ Kali S. Thomas and Vincent Mor, "Providing More Home-Delivered Meals is One Way to Keep Older Adults with Low Care Needs Out of Nursing Homes," *Health Affairs*, October 2013. Web.

¹⁸ Kali S. Thomas and Vincent Mor, "Providing more home-delivered meals is one way to keep older adults with low care needs out of nursing homes," *Health Affairs*, October 2013. Web.

¹⁹ H. Stephen Kaye, Charlene Harrington, and Mitchell P. LaPlante, "Long-Term Care: Who Gets It, Who Provides It, Who Pays, and How Much?" *Health Affairs*, January 2010. Web.

²⁰ Andrew Kochera, "Accessibility and Visitability Feature in Single-Family Homes: A Review of State and Local Activity," AARP Public Policy Institute, 2002. Web.

²¹ Abbe Will, "Aging in Place: Implications for Remodeling," Joint Center for Housing Studies of Harvard University, July 2, 2015. Web.

²² Martin Kitchener, Terence Ng, Nancy Miller, and Charlene Harrington, "Institutional and Community-Based Long-Term Care: A Comparative Estimate of Public Costs," *Journal of Health and Social Policy*, November 8, 2010. <u>Web</u>.



services and health care organizations.²³ The study found that AAAs that utilized informal partnerships with a broad range of health care and other organizations had significantly lower hospital readmission rates, compared to AAAs that maintained partnerships with fewer organizations. In addition, county AAAs with programs to divert older adults from nursing home placement had significantly lower avoidable nursing home use compared to counties without such programs. AAAs also offer services to coordinate care as well as community and family services for adults with a chronic physical or mental health conditions and their primary caregiver.²⁴ One study involving patients diagnosed with dementia or memory loss found those receiving coordination services were 50 percent less likely to have an emergency department visit.²⁵ Another study of a similar intervention found significantly fewer hospital readmissions and significantly fewer return emergency department visits among patients who received coordination services.²⁶

Seniors who are able to age in place with home-delivered meals, home modification, and other in-home services may also need transportation assistance to get to health care appointments. At least 3.6 million people miss or delay medical care each year due to lack of transportation.²⁷ One analysis found that providing transportation for this population proved to be cost-effective or cost-saving for all 12 medical conditions studied, including preventive care and care for chronic disease.²⁸ A separate study found that adults without access to transportation are more likely to have chronic diseases that may escalate to the need for emergency care when not appropriately managed, including with regular provider appointments.²⁹ While it can be difficult to isolate the impact of transportation on improving health outcomes and reducing costs, a study by Florida State University determined that even if just one percent of medical trips funded resulted in an avoided emergency department visit, the return on investment for the State would be 1,108 percent, or \$11.08 for each dollar invested in medical transportation.³⁰ Providing patients with transportation services may help reduce non-emergent use of more expensive ambulance services. A draft study found that UberX's entry into a city reduced per capita ambulance volume by at least seven percent.³¹

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²³ Amanda L. Brewster, Suzanne Kunkel, Jane Straker, and Leslie A. Curry, "Cross Sectoral Partnerships by Area Agencies on Aging: Associations with Health Care Use and Spending," *Health Affairs*, January 2018. Web.

²⁴ Administration for Community Living, "BRI Care Consultation," March 2017. Web.

²⁵ Clark, P. A., Bass, D. M., Looman, W. J., McCarthy, C. A., & Eckert, S. (2004). "Outcomes for patients with dementia from the Cleveland Alzheimer's Managed Care Demonstration," *Aging and Mental Health*, January 2004. <u>Web</u>.

²⁶ Bass, D. M., Judge, K. S., Maslow, K., et al., "Impact of the care coordination program 'Partners in Dementia Care' on veterans' hospital admissions and emergency department visits," *Alzheimer's and Dementia: Translational Research and Clinical Interventions*, June 2015. Web.

P. Hughes-Cromwick and R. Wallace et al., "Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation,"
 Transit Cooperative Research Program, October 2005. Web.
 Ibid.

²⁹ Richard Wallace, et al, "Access to Health Care and Nonemergency Medical Transportation: Two Missing Links," *Transportation Research Record: Journal of the Transportation Research Board,*" January 2005. Web.

³⁰ J. Joseph Cronin, Jr., "Florida Transportation Disadvantaged Programs: Return on Investment Study," *Florida State University College of Business and the Marketing Institute,* March 2008. Web.

³¹ Leon S. Moskatel and David J.G. Slusky, "Did UberX Reduce Ambulance Volume?" University of Kansas, October 2017. Web.



As CMS is well aware, pain management is a challenging issue for Medicare beneficiaries. As the nation battles the opioid crisis, more attention should be paid to non-pharmacological treatment for chronic pain, including therapeutic massage. Therapeutic massage can be an effective treatment option for patients with chronic pain.³² Systematic reviews and numerous studies have found potential benefits of massage for many pain indications, including shoulder, neck, and back pain, fibromyalgia, and temporomandibular disorder, as well as numerous benefits for cancer patients including decreased pain, anxiety, and depression.³³ Further, the American College of Physicians' clinical practice guidelines direct clinicians and patients to select non-pharmacological treatments, including therapeutic massage, to address acute, subacute, and chronic low back pain.³⁴

Finally, BMA supported inclusion of an expansion of supplemental benefits for chronically ill Medicare Advantage enrollees included in the recently passed Bipartisan Budget Act of 2018 and we look forward to working with CMS as it develops regulations and guidance implementing this additional flexibility.

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

BMA supports CMS' proposal to allow D-SNPs and I-SNPs to offer Enhanced Disease Management as a supplemental benefit.

CMS proposes to allow D-SNPs and I-SNPs to offer the Enhanced Disease Management supplemental benefit that is currently available to non-SNP Medicare Advantage plans, beginning in 2019. This benefit could include case managers with specialized knowledge about the target disease or condition, educational activities that are focused on the target disease or condition, and routine monitoring of the target disease or condition.

³² Crawford, Cindy, et al. "The impact of massage therapy on function in pain populations—A systematic review and metaanalysis of randomized controlled trials: Part I, patients experiencing pain in the general population." *Pain Medicine,* July 2016. Web.

Miake-Lye, Isomi, et al. "Massage for Pain: An Evidence Map." Department of Veterans Affairs: Evidence-based synthesis program reports, September 2016. Web. See also "National comprehensive Cancer Network: Clinical practice guidelines in oncology: adult cancer pain v1, 2007," Web.; Cassileth BR, et al. "Complementary therapies and integrative oncology in lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition)," Chest, September 2007. Web.; National comprehensive Cancer Network: Clinical practice guidelines in oncology: cancer related fatigue v4, 2007. Web.; Weinrich SP, Weinrich MC. "The effect of massage on pain in cancer patients," Applied Nursing Research, November 1990. Web.; Wilkinson SM, et al. "Effectiveness of aromatherapy massage in the management of anxiety and depression in patients with cancer: a multicenter randomized controlled trial," Journal of Clinical Oncology, February 2007. Web.; Smith MC, et al. "Outcomes of therapeutic massage for hospitalized cancer patients," Journal of Nursing Scholarship, 2002. Web.; Post-White J, et al. "Therapeutic massage and healing touch improve symptoms in cancer," Integrative Cancer Therapies, December 2003. Web.; Cassileth BR, Vickers AJ. "Massage therapy for symptom control: outcome study at a major cancer center," Journal of Pain Symptom Management, September 2004. Web.; Fellowes D, et al. "Aromatherapy and massage for symptom relief in patients with cancer," Cochrane Database of Systematic Reviews, 2004. Web.

³⁴ Qaseem A, et al. "Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians." *Annals of Internal Medicine,* April 2017. Web.

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BMA Comments:

First, BMA appreciates CMS' diligence with regard to the legislative uncertainty that previously surrounded SNP authorization. BMA led a coalition of organizations committed to achieving permanent authorization of SNPs to provide greater stability to the Medicare Advantage program and beneficiaries with special needs who rely on these plans for health care that meets their needs and improves outcomes. We are pleased Congress recently passed and the President signed legislation to permanently authorize SNPs and look forward to working with CMS on regulatory improvements to the program now that its future is more stable.

BMA supports CMS' position that providing enhanced disease management to D-SNP and I-SNP enrollees may improve care coordination and the experience of care. We appreciate the clear guidance from CMS that D-SNP and I-SNP Medicare Advantage plans may offer enhanced disease management as a supplemental benefit. We fully support allowing Medicare Advantage plans the flexibility to tailor benefits and providers to ensure they are meeting the unique needs of beneficiaries with specific diseases or conditions.

Medicare Advantage Uniformity Flexibility

BMA supports CMS' determination that providing access to services or specific cost sharing or deductible amounts that are tied to health status or disease state is consistent with the uniformity requirement, so long as similarly situated individuals are treated uniformly. We appreciate CMS' proposal in a previously proposed rule (CMS-4182-P) to eliminate the meaningful difference requirement, which will allow Medicare Advantage plans to implement this proposed uniformity flexibility. We agree with CMS that this increased flexibility and innovation in benefit design will better serve beneficiaries, ease obstacles to needed health care and social services, and encourage use of appropriate services for high-need beneficiaries, particularly those with serious, chronic conditions.

CMS has determined it has the statutory and regulatory authority to allow Medicare Advantage Organizations "to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situation enrollees...are treated the same and enjoy the same access to these targeted benefits."

BMA Comments:

BMA supports CMS' determination that Medicare Advantage health plans can comply with the uniformity requirement while offering targeted supplemental benefits to better serve beneficiaries, ease obstacles to needed health care and social services, and encourage the use of appropriate services for high-need beneficiaries, particularly those with serious, chronic conditions. We appreciate CMS' accompanying proposed policy change in a previously proposed rule to eliminate the meaningful difference requirement. Together with

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proposed uniformity flexibility, these two regulatory changes will allow plans the ability to effectively customize care to improve patient outcomes. We ask CMS to confirm that Medicare Advantage plans may apply these uniformity flexibilities to out-of-network benefits, which is important for employer group Medicare Advantage plans that use an extended service area waiver.

BMA supported passage of the CHRONIC Care Act as part of the Bipartisan Budget Act of 2018 (P.L. 115-123) and, as mentioned above, has advocated for enhanced flexibility to include a wider range of supplemental benefits that improve care and address social determinants of health, such as nutrition support and transportation, for patients with specific conditions or for specified populations of enrollees.

As we have previously expressed, the Medicare Advantage program would be improved by affording plans greater benefit design flexibility to effectively customize care to improve patient outcomes. In the past, Medicare's uniform benefit and non-discrimination requirements have prevented Medicare Advantage health plans from providing additional services and supports to vulnerable or high-need beneficiaries to encourage them to access needed items and services. While we support the well-intentioned purpose of these requirements, we also recognize the critical importance of tailoring benefits to meet the needs of individual enrollees.

For example, a health plan may choose to waive endocrinology visit cost sharing for enrollees diagnosed with diabetes in order to encourage them to meet with their endocrinologist, who typically manages their diabetic care. Under this new flexibility, plans will have the freedom to offer these benefits only to enrollees with diabetes. 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 appreciates CMS' plan to establish a special mailbox following issuance of the Final Call Letter to assist Medicare Advantage plans with questions about targeted supplemental benefit offerings. In addition, we ask CMS to consider providing additional guidance as to how health plans should operationalize this new guidance as they begin preparing 2019 bids. CMS may also consider providing additional information about the process and timeline for responding to questions submitted by plans through the special mailbox CMS indicates it will establish.

> Medicare Diabetes Prevention Program (MDPP) Services Clarification

BMA appreciates the additional clarification CMS offers with regard to Medicare Advantage plans' responsibility to cover Medicare Diabetes Prevention Program services in accordance with the regulations as well as the option plans have to offer MDPP-like services as a supplemental benefit. BMA asks CMS to consider improvements



to help Medicare Advantage plans locate and engage providers certified to offer this benefit and to permit Medicare Advantage Organizations to offer this benefit virtually.

CMS provides clarifications to the implementation of the Medicare Diabetes Prevention Program (MDPP). CMS finalized a nationwide expansion of the MDPP in the 2017 Physician Fee Schedule, requiring plans to include the MDPP in 2018 bids, with a program start date of April 1, 2018. In the Advance Notice, CMS clarifies that Medicare Advantage Organizations must cover the program and may offer MDPP-like benefits as a supplemental benefit virtually.

BMA Comments:

BMA has previously expressed support for the establishment of evidence-based chronic disease management programs in Medicare Advantage to slow the progression of chronic disease, improve health outcomes, and reduce the costs of disease burden. In fact, Medicare Advantage plans played an important role in testing the MDPP model, which enabled the expansion of the program, and are preparing for successful implementation of the benefit beginning April 1, 2018.

BMA asks CMS to consider providing additional guidance to ensure that suppliers, health plans, and beneficiaries are able to participate in the successful implementation of the MDPP. For example, Medicare Advantage Organizations have shared they are having difficulty identifying and engaging providers certified to provide this benefit, which makes building a network very challenging.

In addition, we ask CMS to explore permitting Medicare Advantage Organizations to offer this benefit virtually. By making only in-person MDPP providers eligible for reimbursement (except for a limited number of make-up sessions, which may be delivered virtually), an opportunity is missed to extend access to this proven program to rural parts of the country and to beneficiaries who may experience difficulties leaving home or finding transportation to MDPP providers. Evidence indicates that virtual MDPP providers can achieve the same or better results as in-person providers. For example, a 2017 study published in the Journal of Aging and Health examined digital and human coaching in MDPP with Humana Medicare Advantage and Omada Health. Ninety-two percent of study participants completed more than half of the core lessons and lost 7.5 percent of their initial body weight after 12 months. The study concluded beneficiaries could meaningfully engage with the digital MDPP program and achieve results that exceed weight loss benchmarks.³⁵

We believe CMS has the statutory authority to allow virtual MDPP visits because limiting the use of virtual MDPP services is a payment policy. Medicare Advantage plans are required to comply with benefit coverage policies applicable to FFS Medicare, however, they are not obligated to comply with FFS Medicare's payment and billing policies. In addition, Section 50323 of the Bipartisan Budget Act of 2018 allows Medicare Advantage plans to include in

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³⁵ M. Castro Sweet, PhD, Cynthia et al. "Outcomes of a Digital Health Program with Human Coaching for Diabetes Risk Reduction in a Medicare Population." *Journal of Aging and Health*, January 2017. <u>Web</u>.



their annual bids telehealth benefits beyond the services that currently receive payment under Medicare Part B, beginning in 2020. Given all of this, we ask CMS to explore options for Medicare Advantage plans to enter into contracts with qualified providers in order to enable the MDPP to be virtually delivered to slow disease progression and achieve cost savings in the Medicare program.

> Special Needs Plan-Specific Networks Research and Development

BMA asks CMS to continue work to develop Special Needs Plan (SNP)-specific network adequacy criteria, particularly with regard to institutional SNPs (I-SNPs) and Medicare-Medicaid Plans.

In the 2018 Final Call Letter, CMS announced it would move forward to develop SNP-specific network adequacy evaluations. CMS noted that current network adequacy is assessed at the contract level, but many Medicare Advantage Organizations offer a variety of plans under a contract, including SNPs. Because SNP populations have unique health care needs, CMS was interested in exploring the benefits of establishing separate network adequacy evaluations for SNPs.

CMS indicated it received many comments in support of SNP-specific network adequacy evaluation and the creation of standards that allowed for flexibility to tailor networks for SNP enrollees with complex, unique health care needs. Some commenters suggested that D-SNP network standards may benefit from the experience of Medicare-Medicaid Plans, and that D-SNP networks need providers that accept both Medicare and Medicaid.

Despite this display of support and work with stakeholders over the past year, CMS announced in the 2019 Advance Notice that is believes current criteria and exception request processes account for the unique health care needs and delivery patterns of SNP enrollees.

BMA Comments:

BMA supports the establishment of SNP-specific network adequacy standards and respectfully requests that CMS resume its work to develop them. SNP enrollees do have exceptional health circumstances, needs, and extraordinary life circumstances (i.e. living in a care institution) that the vast majority of Medicare Advantage enrollees do not share. Applying network adequacy standards developed for the large population of non-SNP-eligible Medicare Advantage enrollees to plans serving beneficiaries with these unique needs is very challenging. SNPs may use the exception request process in some instances, but the network adequacy framework should be more responsive to their needs.

We encourage CMS to review requirements regarding type of provider network requirements, given the fact that not all providers accept Medicaid and likely will not accept dual-eligible beneficiaries. In addition, time and distance standards for SNP networks may need to vary based on SNP enrollee needs and prevailing patterns of care. Finally, the exceptions process may benefit from providing SNPs the ability to utilize additional delivery

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modalities, including telemedicine and mobile health units. CMS may consider looking to state exceptions processes to promote continued alignment for dual-eligible beneficiaries and the plans that serve them.

In addition, we respectfully request that CMS explain what caused it to conclude that the current criteria and exceptions process are adequate for SNPs.

Improving Drug Utilization Review Controls in Medicare Part D - Part D Opioid Overutilization Policy

BMA supports efforts within Part D to combat the opioid epidemic and remains committed to working with CMS and other stakeholders to implement comprehensive, evidence-based strategies to reduce opioid overuse.

CMS proposes new policies within the Part D program to more effectively address the national opioid epidemic, with a focus on beneficiaries prescribed 90 morphine milligram equivalent (MME) or more who do not have multiple prescribers or pharmacies and therefore may not be addressed through existing regulations. These proposals include enhancing the overutilization management system (OMS) with additional flags for high risk beneficiaries who use "potentiator" drugs in combination with prescription opioids; revising and adding new Pharmacy Quality Alliance (PQA) opioid quality measures; requiring all plan sponsors to implement hard, formulary-level, cumulative opioid safety edits (only overridden by the sponsor) at pharmacy point-of-sale at 90 MME per day, with a 7 days supply; implementing a days supply limit for initial fills of prescription opioids for treatment of acute pain; and expecting plan sponsors to implement soft point-of-sale safety edits (may be overridden by the pharmacist) based on duplicative therapy of multiple long-acting opioids.

BMA Comments:

BMA is supportive of statutory and regulatory efforts to combat the national opioid epidemic. We are supportive of the "lock-in" provision enacted in Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198). This provision, which will take effective with the 2019 plan year, allows, but does not require, health plan sponsors to implement drug management programs for at-risk beneficiaries limiting their access to frequently abused drugs to one prescriber and one pharmacy.

BMA supports CMS' proposals in the Advance Notice to continue improving opioid overutilization policies. We appreciate the work that CMS and Part D plans sponsors are engaged in, balancing the need to ensure access to medically necessary drug regimens, reduce the potential for unintended consequences among patients already on higher doses of opioids, address opioid overuse in Part D, and prevent opioid overuse among "opioid naïve" patients prescribed opioids for acute pain. We believe CMS' proposals will advance the Part D program toward achieving these goals.



As CMS moves to finalize these policies, we ask for further exploration of the proposed exceptions process. Excluding hospice and cancer patients from many of these proposed policies likely represents an important but imperfect dividing line, as patients with other diagnoses may have a legitimate need for opioids to control pain and improve quality of life, and not all cancer patients experience the kind of pain that necessitates opioids. For example, CMS may consider also exempting patients who are residents of long-term care facilities, as well as patients receiving palliative care. While we understand existing operations make identification of patient receiving palliative care challenging, we encourage CMS to explore developing a way to do so.

We appreciate CMS' efforts to modify the overutilization management system (OMS) in response to stakeholder feedback, to better incorporate guidance from the Centers for Disease Control and Prevention, including the CDC Guideline for Prescribing Opioids for Chronic Pain, and to reflect research conducted by the Office of the Inspector General, and others, on opioid issues. We look forward to continuing our work with CMS and other stakeholders to further efforts to address opioid overutilization in Part D.