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January 16, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

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 ("Proposed Rule")

Dear Administrator Verma:

America's Health Insurance Plans (AHIP) appreciates the opportunity to comment on the Proposed Rule. AHIP is the national association whose members provide coverage for health care and related services. We share your strong commitment to delivering better health outcomes, value, and satisfaction to beneficiaries under the Medicare Advantage and Part D programs.

We commend CMS for proposing a range of creative ideas that build on the successes in these programs, and improve on them by encouraging innovation, allowing additional flexibility, and reducing unnecessary burden. We believe that many of the proposals would result in beneficiaries having more options for finding the high quality, cost-effective plan that best meets their needs. We also recommend that CMS modify or eliminate certain proposals to ensure continued program stability for beneficiaries. We summarize our major comments below and have attached our complete comments that discuss these and other issues in detail.

The Value of Medicare Advantage and Part D

Medicare Advantage. Approximately 19 million Americans, or one third of all Medicare beneficiaries, have chosen to enroll in a Medicare Advantage plan. Enrollment in Medicare Advantage plans has increased by 8 percent in the last year alone and by more than 60 percent since 2010. Compared with Medicare fee-for-service (FFS), consumers recognize that Medicare Advantage plans lead the way in advancing innovative, patient-centered programs that integrate and coordinate care; effectively help patients prevent, detect, and manage chronic conditions; provide greater health and financial security; and better address the needs of low-income and other vulnerable individuals.

Medicare Advantage plans provide a different approach to care delivery. While the benefit package in the Medicare FFS program is largely stuck in time, reflecting its 1960s origins, Medicare Advantage plans often offer a more comprehensive benefit package. Additional valuable benefits may include vision, dental, and hearing coverage. Many plans also offer drug coverage at no additional cost to enrollees. And unlike Medicare FFS, the financial stability of Medicare Advantage enrollees is protected by annual out-of-pocket caps on their benefits.

Medicare Advantage plays a crucial role in enhancing the delivery of high quality care. A recent peer-reviewed study found that on average, Medicare Advantage provides "substantially higher quality of care" by outperforming Medicare FFS on 16 out of 16 clinical quality measures, and achieving equivalent or higher scores on five out of six patient experience measures.[1] Another recent study found that value-based care in Medicare Advantage has resulted in lower costs while improving survival rates.[2] In other studies, Medicare Advantage has proven to reduce hospital readmissions[3] and institutional post-acute care admissions[4] while also increasing rates of annual preventive care visits[5] and screenings.[6] Further, the Medicare Advantage program has a beneficiary satisfaction rate of 90 percent for plans, as well as preventive care coverage, benefits, and choice of provider.[7]

Medicare Advantage has also proven to be cost-effective. For many years, average Medicare Advantage plan bids for delivering the basic Medicare benefit have been well below Medicare FFS costs. Further, in 2018, average payments to Medicare Advantage plans will be roughly equivalent to Medicare FFS costs, according to the Medicare Payment Advisory Commission (MedPAC). Moreover, in many geographies with high Medicare Advantage enrollment, increases in Medicare Advantage enrollment reduce Medicare FFS spending. As Medicare

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[1] Timbie, Justin W., et al. Medicare Advantage and fee-for-service performance on clinical quality and patient experience measures: Comparisons from three large states. *Health Services Research* 52(6), Part I: 2038-2060. December 2017.
[2] Mandal, Aloke K., Tagomori, Gene K., Felix, Randell V., Howell, Scott C. Value-based contracting innovated Medicare Advantage healthcare delivery and improved survival. *American Journal of Managed Care* 23(2): e41-e49. January 2017.
[3] Lemieux, Jeff, Sennett, Cary, Wang, Ray, Mulligan, Teresa, Bumbaugh, Jon. Hospital readmission rates in Medicare Advantage plans. *American Journal of Managed Care* 18(2): 96-104. February 2012.
[4] Huckfeldt, Peter J., Escarce, Jose J., Rabideau, Brendan, Karaca-Mandic, Pinar, Sood, Neeraj. Less intense post-acute care, better outcomes for enrollees in Medicare Advantage than those in fee-for-service. *Health Affairs* 36(1): 91-100. January 2017.
[5] Sukyung, Chung, Lesser, Lenard I., Lauderdale, Diane S. et al. Medicare annual preventive care visits: Use increased among fee-for-service patients, but many do not participate. *Health Affairs* 34(1): 11-20. January 2015.
[6] Ayanian, John Z., Landon, Bruce E., Zaslavsky, Alan M., et al. Medicare beneficiaries more likely to receive appropriate ambulatory services in HMOs than in traditional Medicare. *Health Affairs* 32(7): 1228-1235. July 2013.
[7] Morning Consult National Tracking Poll. March 11-16, 2016.

Advantage providers adopt changes in practice patterns and care guidelines into their care of patients with Medicare FFS, these changes have positive "spillover" effects.[8] In fact, Medicare Advantage plans pioneered many of the payment and delivery reforms that have been tested in Medicare FFS.

Part D. Approximately 43 million seniors and individuals with disabilities are covered under Part D, with more than 17 million receiving their benefits through a Medicare Advantage plan and more than 25 million through a stand-alone Prescription Drug Plan (PDP).

Part D plans have been a model of consumer choice and market competition that have improved access to prescription drugs and reduced out-of-pocket costs for tens of millions of beneficiaries. The Part D program covers most medications approved by the Food and Drug Administration – including many biologics and vaccines – that are not otherwise covered by Medicare Part A (hospital insurance) or Part B (medical insurance). Now in its second decade of operations, the program is highly popular, as nearly 90 percent of beneficiaries are satisfied with the Part D program.[9]

In addition, the Part D program has been shown to significantly improve the health outcomes of Medicare beneficiaries. A 2014 study found that beneficiaries with Medicare Part D coverage, on average, experienced 8 percent fewer hospital admissions, incurred 7 percent lower Medicare expenditures, and used 12 percent fewer total healthcare resources than beneficiaries without Part D coverage, and taxpayer costs were reduced approximately $1.5 billion each year.[10] Another study estimated that Part D coverage reduced cardiovascular-related mortality by up to 26,000 lives in its first year alone.[11]

Part D premiums also have been largely stable over time. Prior to 2018, CMS projected that the average Part D premium (weighted by enrollment) would fall versus 2017 by 3 percent, from $34.70 to $33.50, the first premium decrease since 2012.

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[8] Johnson, Garret, Figuero, Jose F., Zhou, Xiner, Orav, E. John, Jha, Ashish K. Recent growth in Medicare Advantage enrollment associated with decreased fee-for-service spending in certain US counties. *Health Affairs* 35(9):1707-1715. September 2016.

[9] Morning Consult for Medicare Today, "Ten Years After Implementation, Nearly Nine in 10 Seniors are Satisfied with Part D" (July 2016).

[10] Kaestner, Robert, Long, Cuiping, Alexander, G. Caleb. Effects of prescription drug insurance on hospitalization and mortality: Evidence from Medicare Part D. National Bureau of Economic Research Working Paper 19948. February 2014.

[11] Dunn, Abe, Adam H. Shapiro. Does Medicare Part D save lives? Federal Reserve Bank of San Francisco Working Paper 2015-04. September 2015.

Key Improvements Introduced in the Proposed Rule

AHIP and our members strongly support many of the provisions in the Proposed Rule. These changes will enhance benefit flexibility, allow beneficiaries to have more plan choices, unlock the innovative nature of the private sector, reduce reporting burdens, and generate savings for the Medicare program. Key improvements include the following:

- **Greater Flexibility**: CMS would permit Medicare Advantage plans to offer flexible, value-based benefit designs that encourage enrollees with chronic conditions to use high-value clinical services. This flexibility can promote better health and reduce costs by limiting utilization of low-value or unnecessary services.
- **Meaningful Differences**: CMS would eliminate the current "meaningful difference" requirement for Medicare Advantage plans and enhanced Part D plans. This will increase market competition and give beneficiaries more opportunities to find plans that best meet their needs based on factors such as premiums, cost sharing, and provider networks.
- **Star Ratings Transparency**: The Proposed Rule would codify the details of the Star Ratings program in regulation, and include elements that are critically important in improving program transparency and predictability. For example, CMS has articulated key principles to guide program changes. CMS also proposes a clearer structure for adding, updating, and removing measures that would ensure measures are added or changed prospectively in advance of measurement periods. These changes will foster continued quality improvement by enhancing program stability and supporting plan/provider value-based arrangements and other activities.
- **Administrative Burden**: The Proposed Rule would modify or eliminate a number of unnecessary and burdensome administrative requirements. For example, it would eliminate a requirement (scheduled to take effect in 2019) for physicians and other eligible professionals who write prescriptions for Part D drugs to be enrolled in Medicare in an approved status or to have a valid opt-out affidavit on file with Medicare. It would also eliminate a similar rule that had been scheduled to apply under Part C. Eliminating these provisions would avoid potentially significant adverse impacts, including inhibiting enrollee access to medications, impairing the development of robust, high quality networks, and imposing complex operational and reporting requirements that would raise program costs and create beneficiary confusion. Other improvements in the Proposed Rule include a better targeted annual marketing review process; a more cost-effective and customer-centric approach that makes more beneficiary materials available electronically with paper copies upon request; and less burdensome Medical Loss Ratio reporting that also recognizes the importance of fraud prevention activities.
- **Multiple Prescribers and Pharmacies**: CMS proposes a thoughtful and comprehensive set of rules that would allow Part D plans to address inappropriate use of multiple prescribers and pharmacies by certain at-risk beneficiaries. These rules can play an important part in the broader national strategy to combat the opioid epidemic.

- **Generic Drugs**: Under the Proposed Rule, Part D sponsors could immediately add to their formularies first-to-market generic drugs and remove or change the cost sharing of the corresponding brand drugs. By allowing generic substitution without advance approval and at any time during the year (including the first two months), the proposal would provide important flexibility for plans to make appropriate adjustments when lower cost drugs become available. This in turn lowers costs for beneficiaries and taxpayers.

Key Issues of Concern

While we strongly support many of the proposals in the Proposed Rule, AHIP and our members also have significant concerns with some proposals, including elements of the Star Ratings program and especially the Request for Information (RFI) on Part D rebates and price concessions.

- **Star Ratings Measurement Issues**: Although the Proposed Rule includes important Star Ratings improvements, we are concerned that CMS is maintaining the existing methodologies to establish annual Star Ratings cut-points for measure scores. Improvements that increase transparency and avoid inappropriate year-to-year shifts are needed to ensure Star Ratings are appropriate and encourage steady improvement. We also are concerned that the Proposed Rule maintains a link between agency compliance and enforcement activities with Star Ratings. This approach is fraught with problems for both policy and methodological reasons. And, we continue to urge CMS to develop improvements to the Categorical Adjustment Index, so Star Ratings more meaningfully address the unique circumstances currently faced by Medicare Advantage plans with substantial enrollment by low-income populations until a long-term solution to this issue is implemented.
- **Prescription Drug Rebates**: Part D sponsors currently use savings negotiated with pharmaceutical manufacturers and pharmacies to reduce costs for all beneficiaries through lower premiums. These proven approaches have generated substantial savings and worked effectively for the vast majority of enrollees since the start of the Part D program in 2006. Therefore, AHIP and our members have significant concerns with the potential policy changes described in the RFI, which would limit or eliminate proven approaches by requiring rebate amounts be applied toward point-of-sale prices.

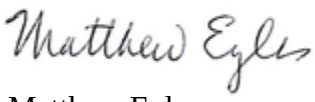
  While AHIP strongly believes that we must take serious action to address the impact of rising drug prices and costs, the RFI misses the mark by focusing on approaches that fail to address the root problem: excessive list prices for drugs and excessive price increases that are set solely by and fully within the control of manufacturers.

  Contrary to CMS's bigger goal, the agency's proposal in the RFI would in fact raise costs for most Medicare beneficiaries. With nearly 90 percent of Part D prescriptions filled by

generic drugs and only a portion of branded drug manufacturers offering rebates, CMS's proposal would benefit only a small minority of beneficiaries. At the same time, it would create new operational challenges for plans and increase administrative burdens. AHIP strongly urges CMS and other policymakers to focus on the underlying cause of high drug costs – manufacturer pricing practices – by advancing solutions that address high list prices and continuous and excessive list price increases.

Our attached comments address the foregoing provisions and other proposals in more detail. The comments include recommendations for clarifications and changes needed to protect and improve access to care for Medicare beneficiaries by ensuring the stability of the Medicare Advantage and Part D programs.

Sincerely,



Matthew Eyles
Senior Executive Vice President & Chief Operating Officer

AHIP Detailed Comments on CMS Proposed Rule

Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

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

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

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

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

- **Frequently Abused Drugs.** The Proposed Rule limits the 2019 designation of frequently abused drugs to opioids, except for buprenorphine when used as a medication-assisted treatment for opioid addition. In light of the overwhelming evidence that beneficiaries taking opioids in addition to other high-risk medications, such as hypnotic-sedatives and muscle relaxants, are at a higher risk of harm, we recommend that CMS continue to review evidence around the use of such high-risk medications in conjunction with opioids and update the drugs designated as frequently abused drugs when appropriate. Additionally, we request clarification from CMS that Methadone would be considered a frequently abused drug when used to treat pain.

- **Exempted Beneficiaries.** The Proposed Rule exempts certain beneficiaries – those electing to receive hospice care, residents of certain facilities, and patients with a cancer diagnosis – from being designated at-risk beneficiaries. AHIP recommends that CMS provide further clarifications around when and how to apply these exemptions. For example, it is unclear whether long-term care (LTC) exemptions apply to DUR processes or are applicable only to coverage limits (i.e., point-of-sale edits, lock-ins). It is also unclear how the cancer diagnosis exemption is to be applied. For instance, should the cancer diagnosis be an active diagnosis? Should the cancer diagnosis be coupled with a pain diagnosis? Additionally, we urge CMS to

provide clearer guidance on appropriately exempting beneficiaries well before sponsor bid applications are due to ensure successful implementation by 2019.

- **Case Management, Clinical Contact and Prescriber Verification.** The Proposed Rule requires clinical staff to contact prescribers to verify that a potentially at-risk beneficiary is in fact at-risk. We believe that the expectation of three prescriber outreach attempts by phone after a written attempt is burdensome and unnecessary. We ask that CMS consider a potentially less burdensome approach (e.g., two prescriber outreaches). We also ask for some clarification on potential scenarios. For instance, it is unclear from a reading of the Preamble how a sponsor should act in the beneficiary's best interest if an at-risk beneficiary's prescribers disagree with each other on a proposed edit or lock-in.

- **Limitations on Access to Coverage for Frequently Abused Drugs.** AHIP strongly supports providing Part D plan sponsors with the option to use point of sale edits and prescriber and/or pharmacy lock-in programs as part of the broader national strategy to stem the misuse and abuse of opioids. However, we have concerns with the proposal to prohibit the use of prescriber lock-ins until at least six months after the beneficiary was first identified as a potential at-risk beneficiary in an OMS report. We recognize CMS expects prescriber lock-in to be implemented as a last resort after other options are exhausted. However, facts and circumstances in some cases may indicate that other options are clearly not sufficient. We recommend that a shorter waiting period be used instead (i.e., one to three months). This would provide sponsors with more flexibility in structuring beneficiary protections against misuse or abuse of opioids. Additionally, we have concerns about the potential impacts of lock-in provisions on other MA and Part D program requirements such as Star Ratings and the handling and reporting of complaints/appeals. We recommend that CMS ensure that plans choosing to implement lock-in procedures are not adversely impacted in these other areas.

- **Beneficiary Preferences.** The Proposed Rule provides that a sponsor must select a network prescriber and pharmacy in accordance with an at-risk beneficiary's preference. AHIP supports reasonable rules that honor beneficiary preferences. However, we find the beneficiary's unlimited opportunity to change preferences for prescribers and pharmacies to be problematic and burdensome. First, frequent changes run counter to the general intent of a lock-in program to limit the at-risk beneficiary's access to opioids. Second, implementing a high number of preference changes would be administratively burdensome. Instead, we recommend that CMS place a limit – such as once per year – on the number of times a preference change can be made. We also suggest that CMS consider requiring an at-risk beneficiary provide a reasonable rationale for a prescriber change (e.g., moving from a current residence or a prescriber's retirement).

- **Chain Pharmacies and Group Practices.** For purposes of determining whether an individual is an at-risk beneficiary due to use of multiple pharmacies or prescribers, the

Proposed Rule treats pharmacies with multiple locations as a single pharmacy if they share real-time electronic data. In addition, prescribers in a group practice using a shared tax identification number (TIN) are considered a single prescriber. AHIP appreciates and supports the concept of treating chain pharmacies and group practices as single entities. However, we understand that sponsors and their contracted pharmacy benefit managers (PBMs) often do not have access to prescriber TINs as they are absent from pharmacy submitted claims. We recommend that CMS re-evaluate the proposed policy of using TINs and offer another more feasible option for those with difficulties in obtaining and working with TINs. We also recommend that CMS re-evaluate its policy for determining chain pharmacies, as identification of which pharmacies share real-time data may be difficult in many situations.

- **Termination of a Beneficiary's Potential At-Risk or At-Risk Status.** The Proposed Rule provides that a beneficiary's at-risk identification terminates after 12 months (or if earlier, the date the beneficiary demonstrates the beneficiary is no longer at-risk). AHIP urges CMS to allow the sponsor, prior to the expiration of the 12-month period, to determine if a continuation is warranted, and if so, to allow for extension of the designation for another 12-month period. We believe this flexibility to continue limits without interruption is necessary to best protect against misuse and abuse of opioids. Beneficiaries could then be allowed to seek a redetermination of the extension.

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

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

AHIP strongly supports and commends CMS for adopting an interpretation that allows plans to structure benefits to encourage the use of high-value clinical services. Patient-centered benefit designs can promote better health and outcomes by increasing prevention, early detection, and care management; reducing beneficiary costs; addressing the needs of low-income beneficiaries and individuals with disabilities; and applying clinical best practices to increase patient safety and to limit unnecessary utilization of services.

In the Preamble, CMS indicates that for CY 2019, the agency is considering issuing guidance to clarify the flexibility that MA plans would have to offer targeted supplemental benefits. We support CMS's plans to provide this guidance. We recommend that CMS also provide guidance about other permissible flexibilities, including the offering of enhanced benefits and reduced cost sharing and deductibles. Additionally, we recommend that CMS provide guidance about the

marketing rules for these new benefit designs so that plans can effectively communicate with and educate beneficiaries. To avoid potential future uncertainties, we also urge CMS to include regulatory text in the Final Rule that supports the flexibility that will be allowed in the MA uniformity requirements.

Further, we strongly recommend that this new interpretation be extended to Part D benefits. We are not aware of any statutory or regulatory restrictions to extending this flexibility to Part D benefits. This extension would maximize health outcomes through improved care coordination and medication use. Enabling plans to offer comprehensive care that covers both medical services and drug benefits would provide beneficiaries with access to high quality care tailored to meet their individual holistic care and needs.

3. Segment Benefits Flexibility (Preamble p. 56361)

CMS indicates they have developed a new interpretation of the MA statute (Section 1854(h) of the Social Security Act) and regulation (§422.262(c)(2)) to allow MA plans to vary supplemental benefits by segment within a plan's service area. This is in addition to current law flexibility for segmented plans in premium and cost sharing.

We strongly support this approach. This type of flexibility in the benefit rules enables MA plans to offer targeted supplemental benefits to most effectively serve the needs of enrollees. Similar to our comment above, we recommend including regulatory text in the Final Rule to support this new interpretation. We also recommend that CMS provide clarifying guidance about the scope of this change to the benefit design rules.

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

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

While we support CMS's proposals to use FFS data to establish MOOP and cost sharing limits, we have concerns at this time with the use of plan encounter data to establish these limits. There continue to be numerous challenges associated with the Encounter Data System (EDS), including unresolved operational, technical and other issues in the collection, processing, and validation of these data. Given the current challenges and concerns, we believe it is premature for CMS to use encounter data to inform the setting of MOOP or cost sharing limits. We therefore recommend that CMS defer use of MA encounter data to establish appropriate MOOP or cost sharing limits

until the EDS and related data issues are resolved and, per recommendations made by the Government Accountability Office,[12] CMS has shown the encounter data to be complete, accurate, and reliable.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256; Preamble p. 56363)

CMS proposes to eliminate the meaningful difference requirement beginning with MA bid submissions for CY 2019. On page 56365 of the Preamble, CMS indicates that MA organizations would then be able to offer "a portfolio of plan options with clear differences between benefits, providers, and premiums which would allow beneficiaries to make more effective decisions." In addition, CMS proposes to take steps to improve information available through Medicare Plan Finder (MPF) and 1-800-MEDICARE to help inform beneficiaries about their plan choices.

AHIP strongly supports and commends CMS's proposal to eliminate the MA meaningful difference requirement. The current requirement limits the number of plan offerings and beneficiary choices because it does not recognize factors such as provider networks and premiums, which are extremely important to beneficiaries in making enrollment decisions. Eliminating the meaningful difference requirement would allow market competition and choice to determine the appropriate number and types of plan options. While we support the change, we recommend that CMS provide further detailed guidance regarding the distinctions in plan options that would be permissible.

We also support CMS's plans to improve the MPF and 1-800-MEDICARE to enhance the availability of information to beneficiaries about plan choices. We urge CMS to develop a task force comprised of plans, beneficiary advocates, providers, and other stakeholders to develop solutions for improving the information navigation process so that beneficiaries can better understand and compare plan options and select the plan that best meets their unique care and financial needs.

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68; Preamble p. 56365)

CMS proposes to lift the existing moratorium on plans implementing a seamless conversion option. (Plans using the option prior to the moratorium have been permitted to continue its use.) CMS would also codify the seamless conversion rules in regulation. At the same time, CMS is proposing to impose significant new restrictions on all plans. Specifically, seamless conversion would apply only for Medicaid managed care plan members becoming eligible for Medicare.

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

Further, they could be seamlessly converted only into dual-eligible special needs plans (D-SNPs), and only if five conditions are met:

+ The individual is enrolled in an affiliated Medicaid managed care plan operated by the MA organization;
+ The state has approved use of the seamless conversion process and provided Medicare eligibility information to the MA organization;
+ The MA organization provides an opt-out notice that meets CMS requirements;
+ The individual does not opt-out; and
+ CMS has approved the MA organization's use of seamless conversion.

CMS indicates in the Proposed Rule that violation of these requirements could result in the suspension or rescission of a plan's authority to use seamless conversion. CMS is also proposing to establish a new simplified opt-in election process that would be available to MA organizations for purposes of converting non-dually eligible enrollees from existing non-Medicare coverage to MA coverage offered by the same organization.

We support CMS's proposal to codify the seamless conversion rules. However, we urge the agency to reinstate the original seamless conversion policy, so it would not be limited by plan type and would be available with respect to all newly eligible Medicare beneficiaries who are currently enrolled in other health plans offered by the MA organization. Limiting use of seamless conversion programs likely will lead more newly eligible Medicare enrollees to default into FFS Medicare rather than into MA plans, which have a proven track record of higher quality, better outcomes, more comprehensive benefits, and lower costs for Medicare beneficiaries. Given the demonstrated value and popularity of MA plans, CMS should expand the seamless conversion program to cover all MA plan types.

We recognize CMS has certain concerns about the original policy. They include the ability of plans to effectively identify members becoming eligible for Medicare based on disability; whether beneficiaries are fully aware of their new coverage under seamless conversion and their other coverage options; and challenges plans could face in obtaining an individual's new Medicare Beneficiary Identifier (MBI). AHIP stands ready to work with CMS and other stakeholders to identify and implement improved processes that, based upon multi-stakeholder experiences and plan best practices, would enable plans to identify commercial members who are approaching Medicare eligibility, confirm eligibility, and improve beneficiary education and outreach. Additionally, CMS and plans have secure mechanisms for exchanging information and that should be able to extend to the MBI.

We also recommend that CMS not expand grounds for rescission or impose time limits on seamless conversion approvals, but proactively work with stakeholders to resolve issues that arise under the program.

Further, we do not support CMS's opt-in election process proposal as a substitute for seamless conversion. On page 56367 of the Preamble, CMS states that this "new mechanism would allow for a less burdensome process for MA organizations to offer enrollment in their MA plans to their non-Medicare health plan members who are newly eligible for Medicare." As noted above, we recommend that CMS allow plans to use seamless conversion if they are approved by CMS to participate, are able to identify eligible individuals for seamless conversion (based on age and/or disability), and can operationalize CMS's requirements. Rather than expend resources to develop an alternative election process, we recommend that the agency devote its resources to address operational issues with the current seamless conversion program.

8. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§422.60(g); Preamble p. 56369)

CMS proposes to authorize passive enrollment of full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP under certain limited circumstances. Passive enrollment would be permitted only when all of the following conditions are met:

+ It is necessary to promote integrated care and continuity of care;
+ Such action is taken in consultation with the state Medicaid agency;
+ The D-SNP into which individuals would be passively enrolled has a contract with the state Medicaid agency to provide Medicaid services; and
+ Certain other conditions are met to promote continuity and quality of care (e.g., MA plans receiving passive enrollment must be a FIDE SNP or highly integrated, have a provider network substantially similar to the enrollee's current SNP, have a minimum overall Star Rating of 3 stars, have appropriate limits on premiums and cost sharing, etc.)

The integration of Medicare and Medicaid services in D-SNPs is an important goal for all stakeholders – CMS, states, plans, and beneficiaries. D-SNPs coordinate and integrate Medicaid benefits and services to provide a more seamless experience of care for dually eligible beneficiaries that reduces patient burden and improves health. Medicare-Medicaid beneficiaries enrolled in these plans benefit from the coordinated care, disease management, and other initiatives D-SNPs have pioneered to ensure that beneficiaries receive high quality health care.

AHIP strongly supports integrated care. However, we also want to ensure CMS has considered other potential implications of this proposal. For example, passive enrollment from an existing plan into another plan raises the potential for disruptions in care. In addition, the agency has exclusive regulatory authority over enrollment in the Medicare program; the approach suggested by CMS could raise questions about the extent to which enrollment authority is being delegated to states as a result of this proposal.

9. Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c); Preamble p. 56371)

Part D requires that a beneficiary be permitted to request an exception, under certain circumstances, from a plan's cost sharing tiering rules. When a tiering exception is granted, it allows the beneficiary to pay the cost sharing that applies to an "alternative" drug on a lower cost sharing tier. The current Part D regulation specifies circumstances under which a sponsor is permitted to limit the application of tiering exceptions. CMS is proposing several revisions to these permissible limits. CMS also proposes to clarify that an alternative drug for tiering exception purposes is a drug on a lower cost sharing tier that is appropriate for treating a beneficiary, taking into consideration the facts and circumstances of the individual's specific clinical condition, including comorbidities and characteristics of the enrollee and/or drug regimen.

AHIP supports CMS's clarification on "alternative" drugs for purposes of these tiering exception rules. We believe as a matter of statutory interpretation that these rules are intended to apply to actual clinical alternatives rather than to any drug that shares an indication. An inappropriately broad interpretation of the tiering exception policy would be inconsistent with the legislative intent and would also substantially inhibit the proven ability of Part D plans to use formulary tiering as a means of ensuring cost-effective Part D coverage for beneficiaries.

However, AHIP recommends that CMS offer further clarity of what constitutes an "alternative" drug by producing sufficient examples of "alternatives" to non-preferred drugs in the final regulation and through sub-regulatory processes (i.e., updates to the Medicare Prescription Drug Benefit Manual and annual MA and Part D Call Letter). These clarifications would help to minimize any potential disputes over the facts and circumstances of a beneficiary's case or situation. Such clarifications from CMS would also ensure that plans can continue to offer clinically-sound formulary structures that provide high quality, cost-effective coverage for beneficiaries.

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

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

AHIP appreciates and supports the change to the SEP policy as it would support continuity of care for the dually eligible population and thereby improve the care they receive.

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

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

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

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

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

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

work, including impact analysis, and alternative methodologies the agency considered, and provide plans with an opportunity for additional comment.

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

  AHIP strongly supports these proposals, which would enable plans and their network providers to implement and gain experience with new measures and substantive changes to existing measures prior to the measurement period. This approach fosters stability and transparency in the Star Ratings System and supports plan and provider value-based arrangements that include quality and performance metrics that need to be assessed and/or modified when changes occur. However, we recommend that the regulation also require that new measures be fully defined, tested, and validated by measure stewards (e.g., National Committee for Quality Assurance, Pharmacy Quality Alliance) prior to being considered for Star Ratings.

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

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

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

  We acknowledge that physician experience surveys can provide helpful information and data on which to build quality improvement efforts. Plans value their partnerships with providers to improve beneficiary access to high quality care and beneficiary care experiences. Plans work closely with their network providers to develop and implement innovative ways to

deliver better health care through streamlining administrative processes and use of better technology. However, we are very concerned about the burden impact on physicians if they are required to complete a survey for every health plan with which they contract. This high burden level is likely to lead to unreliable results. Additionally, we are concerned about potential bias in survey responses given that it may be difficult in some cases for physicians to distinguish plan types and contracting entities. We therefore recommend that CMS not include survey measures of physicians' experiences in the Star Ratings System.

- **Measure Cut Points**. CMS proposes to codify existing policy to determine cut points by applying either a relative distribution and significance testing methodology to Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures or the clustering methodology to non-CAHPS measures. CMS solicits comments on determination of cut points, including publishing of pre-determined cut points. Our specific comments and related recommendations on cut points follow below.

  + Pre-determined Cut Points. AHIP continues to urge CMS to re-establish pre-determined cut points and publish them well in advance of the measurement period. This approach enables plans and their network providers to set markers for quality improvement activities and goals. For value-based arrangements to work best, plans and providers need to assess and modify performance goals. Pre-determined cut points based on industry performance trends will enhance the ability of plans and their providers to set their own performance benchmarks and evaluate the effectiveness of their efforts to improve the quality of care and reduce costs while maintaining high rating levels. The setting of pre-determined 4-star thresholds also aligns with CMS's set of guiding principles that calls for stability and transparency in the rating system.
  + Greater Transparency through Access to Data. The clustering methodology that CMS would continue to apply to all Star Ratings measures except for the CAHPS measures is complex, and cannot be replicated through publicly available data. In line with CMS's set of principles that calls for transparency in the rating system, we recommend that CMS provide greater transparency about its methodology – whether the methodology uses clustering or another approach to set pre-determined cut points – and public access to more granular data that would allow plans to replicate and validate the published cut points.
  + Shifts and Meaningful Differences in Cut Points. CMS's set of guiding principles calls for ratings to be stable over time. However, certain measure cut points in the Star Ratings System have experienced significant year-to-year shifts (up or down), which make it very challenging for plans and their providers to know what the standards are in advance and work towards them. For example, the 2017 and 2018 Star Ratings 4- and 5- star cut points for the Part C Breast Cancer Screening and SNP Care for Older Adults -

Medication Review measures significantly shifted.[13] We recommend that CMS limit year-to-year cut point changes to a range based on industry performance trends to minimize wide fluctuations. Also, as previously indicated, we recommend that CMS ensure that Star Ratings measure cut points reflect meaningful differences so that goal lines for 4- and 5- Star thresholds are clearly delineated.

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

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

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

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

  We do not support increasing the weight of measures that are based solely on survey data. Measures based solely on surveys may yield inaccurate, unreliable, or biased data. For example, due to concerns raised about the reliability of using survey data for the Part C

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

pneumococcal vaccine measure, in the final 2018 Call Letter, CMS indicated that the agency is exploring non-survey based methods "to assess pneumococcal vaccination status and guideline adherence." Increasing the weight of these measures also does not align with CMS's principles for the program that indicate future measures for the Star Ratings program should be focused on health outcomes. For these reasons, we recommend that CMS not increase the weighting for the patient experience/complaints and access measures.

- **Improvement Measures**. CMS proposes to codify the current methodology for calculating improvement measure scores. CMS would also continue to include a hold harmless provision in the calculation of the improvement measure for contracts that achieve 5 stars at the measure level.

  We generally support the improvement measure methodology, but recommend that CMS extend the hold harmless provision to individual measures in the Improvement Measure calculation for which plans achieved and maintained at least 4 stars. The intent of the hold harmless provision is to prevent a measure from lowering a contract's improvement score when the contract still demonstrates high performance for that measure from year to year. Given the high level of performance that a 4-star rating demonstrates, we believe plans should be similarly held harmless when they achieve and maintain at least 4 stars for a measure.

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

  We appreciate CMS's request for comments on this topic. As in the case of socio-economic status (SES) and other beneficiary risk factors, we believe it is important for CMS to rigorously analyze factors outside a plan's reasonable control that may create an unlevel playing field when comparing quality across health plans. We recommend that CMS follow an approach similar to the one used for assessing the impact of SES and disability status on Star Ratings. CMS should perform detailed impact analyses, share the data and findings, and engage stakeholders in a comprehensive evaluation to identify meaningful, equitable adjustments to the program that also do not penalize high performing plans or those that make significant investments in attaining high performance.

- **Categorical Adjustment Index**. CMS proposes to codify the categorical adjustment index (CAI) in the Star Ratings program. The CAI was implemented as an interim analytic adjustment to account for disparities in MA plan performance associated with SES, and includes adjustments based on LIS and dual eligible (LIS/DE) and disability status. The agency has proposed to continue applying the CAI for 2019 and beyond, according to the original methodology published in the 2017 Call Letter. CMS has noted that it will pursue a

long-term solution by taking final recommendations into account from the Assistant Secretary for Planning and Evaluation (ASPE), which are expected to be published in 2019.

AHIP supports the continued use of the CAI in the Star Ratings System while CMS develops a long-term solution to this problem. However, we continue to believe that the CAI can be improved. As we have noted in prior comments submitted to the agency, we believe that – within the current analytic framework – CMS could make the CAI more impactful with the following enhancements:

+ Relax the Measure Inclusion Criteria. CMS determines which measures should be included in the development of the CAI based on criteria that compare performance between LIS/DE and non-LIS/DE beneficiaries. However, CMS's own analysis demonstrates there are additional measures that show meaningful differences in plan performance due to beneficiary-level social risk factors. A median difference in plan performance of less than 5 percent is meaningful in measures where the cut point range is tight. For example, for Monitoring Physical Activity, which CMS excluded from its calculation of the CAI for 2018 Star Ratings, plans achieving less than 45 percent received 1 star while plans achieving greater than or equal to 57 percent received 5 stars (a difference of 12 percentage points). AHIP recommends that those measures also be included.
+ Incorporate Across-Contract Differences in Performance. The CAI methodology is currently limited to within-contract differences, meaning that the CAI values are developed based only on differences between LIS/DE and non-LIS/DE beneficiaries enrolled in the same contract. However, in its initial report, ASPE found there are real differences in plan performance between contracts serving primarily LIS/DE and disabled populations and those that do not. CMS should investigate how across-contract differences in performance can be appropriately reflected in the CAI.
+ Hold Plans Harmless. As the CAI is an interim analytic adjustment, we believe that CMS should hold plans harmless from reductions in Star Ratings due to the CAI until various methodological issues – such as the criteria for measure inclusion and the incorporation of across-contract differences – are addressed, and related analytic issues being explored by ASPE, the measure developers, and other stakeholders are better understood.

- **Parts C and D Measure Sets for 2021 Star Ratings**. CMS proposes to add the Part C Statin Therapy for Patients with Cardiovascular Disease measure and the Part D Statin Use in Persons with Diabetes to the measure sets for 2021 Star Ratings. CMS is proposing to categorize the Part C Statin measure as a process measure and apply a weight of 1 to this measure while categorizing the Part D Statin measure as an intermediate outcome measure with a weight of 3.

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

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

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

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

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

Although some of the proposed changes closely reflect current CMS sub-regulatory guidance, AHIP remains concerned whether the proposed interpretations, impacting preferred pharmacy networks and classification of retail and mail-order pharmacies, could interfere with plan sponsors' ability to negotiate terms and conditions that are beneficial to consumers and taxpayers. We urge CMS to seriously consider the impacts to market competition and to the concerns raised by stakeholders.

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

In addition, AHIP believes that the current two-business day deadline for responding to requests for the sponsor's standard terms and conditions, as codified in the rule, may be too limited and not allow for potential extenuating circumstances that can arise. AHIP recommends that CMS use instead a longer timeframe (e.g., five business days upon receipt of the request) for responding to requests for standard terms and conditions.

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

CMS proposes to change the outpatient transition days' supply from "30 days" to "a month's supply." The Proposed Rule would also change the minimum transition days' supply in the long-term care (LTC) setting from between 91 and 98 days to "a month's supply."
AHIP appreciates and supports the conforming changes to the minimum transition days' supply for the outpatient and LTC setting. However, to avoid potential confusion, we request that the regulation include language from the Preamble which clarifies that "a month's supply" corresponds to the number of days the Part D sponsor designated as its retail month's supply for a given drug in its Plan Benefit Package, as submitted to CMS, for the relevant plan year.

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

CMS proposes to allow sponsors to immediately add or substitute first-to-market therapeutically equivalent generic drugs to its formulary and to immediately remove or change the preferred or tiered cost sharing of the corresponding brand drug without providing notice ahead of time.
We appreciate and strongly support the change in policy. AHIP believes it would provide plans with more flexibility to react to the introduction of lower cost drugs. This in turn will result in lower costs for beneficiaries and taxpayers.

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

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

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

16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences (§ 423.265; Preamble p. 56417)

CMS proposes to modify the meaningful difference requirement for Part D plans by eliminating threshold differentials used to distinguish two alternative plans offered by the same parent organization in the same region. CMS is also proposing to maintain the requirement that

enhanced plans be meaningfully different from the basic plan offered by the same plan in the service area.

AHIP appreciates and supports this change in policy. For reasons similar to those noted above regarding the elimination of the meaningful difference requirement for MA plans, the proposal would provide more meaningful options and choices for beneficiaries and incentivize market innovations.

17. RFI Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at POS (Preamble p. 56419)

As part of the rule, CMS has issued a Request for Information (RFI) on potentially requiring a minimum percentage of manufacturer rebates and all pharmacy concessions negotiated by the plan sponsor or its contracted PBM be incorporated into a Part D drug's negotiated price at point-of-sale (POS).

As noted in our cover letter, the Part D program has improved access to prescription drugs and has reduced out-of-pocket costs for tens of millions of beneficiaries by promoting consumer choice and supporting market competition. Not only does the program remain extremely popular and improve health outcomes, but Part D premiums have also remained largely stable despite rising drug prices. For example, Part D drug costs increased by 8 percent annually, from about $67 billion to almost $100 billion, between 2011 and 2016. However, the average premium paid by beneficiaries increased by only $2, or about 1 percent annually.[14]

Despite the success of the program to date, AHIP strongly believes significant actions are required to address the threat that continuously rising drug prices pose to Part D beneficiaries and taxpayers. However, we have very serious concerns that both POS ideas as discussed in the RFI could have significant adverse impacts on the program, including that:

+ The fundamental problem of high list prices is not addressed by either POS idea,
+ An anticompetitive advantage would be created for drug companies,
+ Though CMS acknowledges that premiums will increase, more comprehensive and independent analyses are needed to accurately understand the extent of this impact,
+ Most beneficiaries would see little to no benefits,
+ The proposed ideas conflict with prior CMS interpretations, and
+ Implementation would be both challenging and burdensome.

[14] Medicare Trustees 2017 Report.

- **Incorporating Manufacturer Discounts at POS**

  + Does Not Address the Root Cause. The root cause of all consumer affordability and taxpayer concerns around prescription drugs stems from a single source: the excessive list prices for drugs and excessive price increases that are set by, and that are solely and fully within the control of, drug manufacturers. Rather than being caused by Part D plan designs, PBMs, pharmacies, or any other stakeholders in the supply chain, high negotiated prices are, instead, a direct result of actions by the pharmaceutical industry to take advantage of a broken market. For example, MedPAC has shown that only 27% of Part D beneficiaries account for 81% of annual prescription drug spending[15], which is directly attributable to high drug prices. In fact, the current HHS Secretary-nominee, Alex Azar, recently stated that "[t]he most important thing we have to figure out is, can we reverse the incentive on list prices?"[16] Therefore, we strongly urge CMS to avoid new proposals that could inadvertently distract attention away from the root cause and create new constraints on the ability of Part D plans to provide high quality, cost-effective coverage for all enrollees.
  + Anticompetitive Advantage for Drug Companies. The POS idea as proposed in the RFI creates a serious risk that drug companies would be able to reverse-engineer rebate levels that their competitors have negotiated. It is well understood that giving drug companies access to proprietary rebate levels would have the anticompetitive effect of raising net prices and increasing costs to beneficiaries and the government.[17] AHIP is concerned that the POS idea as discussed in the RFI would singularly benefit only the pharmaceutical industry through increased profits, an outcome acknowledged in the Preamble. Therefore, before considering any POS idea, AHIP believes rigorous study would be needed to analyze the probability and impact of this serious consequence and to determine the necessary level of data aggregation to prevent this risk.
  + Independent Analyses Needed to Accurately Determine Premium Growth and Other Cost Impacts. In the rule, CMS has acknowledged that beneficiaries would pay higher premiums as a direct result of implementing the POS idea as discussed in the RFI. However, our members have serious concerns that CMS has significantly underestimated the potential impacts on premiums and programmatic costs. Before CMS considers a proposal that could have adverse impacts on Part D, AHIP believes more robust, independent analyses would need to be performed in collaboration with Part D sponsors to ensure that there is a true and accurate understanding of the cost implications. We

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[15] MedPAC, Prescription Drugs Databook, June 2017.
[16] HealthcareDIVE, "Azar talks list prices, mandatory Medicare pilots" (January 9, 2018). https://www.healthcaredive.com/news/alex-azar-senate-finance-hearing-hhs/514421/.
[17] FTC comment letter to NYS Senator Seward, March 31, 2009. https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.

believe that such independent and comprehensive analyses must be completed before CMS can seriously consider any POS idea.

+ Most Beneficiaries Would See Nominal or Marginal Benefits. Part D plans use an estimate of aggregate rebates they expect to receive when designing their benefits and bids for the upcoming year. Typically, the savings from the estimated rebates are passed on through lower premiums or enhanced benefit packages, which provides a broad and direct benefit for millions of consumers. In contrast, the POS idea as proposed is unlikely to produce meaningful benefits for the vast majority of Part D beneficiaries. Almost 90 percent of prescription claims are for generic products that typically have no rebates associated with them and thus would be unaffected by the change.[18] In addition, a number of brand Part D drugs do not generate significant rebates, such as those with little or no direct market competitors.
+ Administratively and Operationally Challenging. Rebate amounts are usually calculated and paid by a manufacturer to a health plan on an aggregate basis, long after an individual prescription is filled by a consumer. Because rebates are extended based on actual aggregated utilization by a specific population, they are paid at least several months after the drug has been prescribed and dispensed and after all the data has been reconciled. As such, implementation of the POS idea as discussed in the RFI would raise significant operational challenges and increase program costs. It would likely require costly and resource-intensive changes to countless contracts, IT systems used by sponsors and contracted vendors, prescription drug event (PDE) submissions, and beneficiary materials. In addition, entirely new systems and capabilities would need to be developed, operationalized, and tested before any POS idea could be implemented.
+ Conflict with Prior CMS Interpretations. Flexibility for plan sponsors in how to apply manufacturer rebates has been a core feature since the start of the Part D program. In the original 2005 rule that implemented the Part D program, CMS considered and rejected the idea described in the RFI as inconsistent with the basic structure created by and the intent of Congress for the Part D program. CMS further noted that "minimum threshold levels for the pass-through of negotiated price concessions would have the effect of undercutting market competition" and that CMS intended that "competition will create incentives for Part D sponsors to offer reasonable negotiated prices."[19]
+ Part D Sponsors Deliver Value to Consumers and Taxpayers. AHIP also strongly disagrees with CMS assertions that plan sponsors somehow prefer higher negotiated prices and are not applying POS rebates to increase profits at the expense of beneficiaries. As noted, it is critical to not lose sight of the fact that high drug prices stem from the excessive list price for drugs and excessive price increases set by, and solely and

[18] MedPAC has found that between 2007 and 2014, the average generic dispensing rate (GDR) in part D increased from 61 percent to 85 percent. It was 87 percent for non-low-income subsidy beneficiaries. See: Report to the Congress: Medicare Payment Policy. March 2017.
[19] Medicare Program; Medicare Prescription Drug Benefit, 70 FR 4193, at 4244.

fully within the control of, drug manufacturers.[20] When faced with high list prices, Part D sponsors vigorously negotiate with drug companies for the highest possible rebates, and thereby the lowest net price. For the reasons described above, plans pass these savings through to beneficiaries in ways they believe are most cost-effective and appropriate.

- **Incorporating All Pharmacy Discounts at POS**. We also have serious concerns with any change that would effectively preclude Part D sponsors from using pharmacy price concessions to reduce premiums or broad-based cost sharing levels.

  + Inconsistent with Prior Policies. Under previous Administrations, CMS considered but rejected the change described in the RFI. For example, in the CY 2015 MA and Part D Final Rule, CMS changed the definition of "negotiated prices" at §423.100 to include price concessions from network pharmacies. However, CMS rejected the approach it originally proposed, which would have required all pharmacy concessions in the negotiated price. Instead, CMS settled on the current rule that exempts contingent price concessions that cannot reasonably be determined at POS. The RFI does not provide evidence or policy arguments for why this change should now be revisited, particularly given the success of the Part D program.
  + Interference with Negotiations. We are concerned that requiring all potential price concessions be incorporated into POS negotiated prices unnecessarily and improperly interferes with the ability of Part D sponsors to negotiate incentive arrangements with network pharmacies. Quality and efficiency targets provide important incentives to ensure access to high quality, affordable care for enrollees and cost savings to the Part D program overall. The approach described in the RFI would inject the agency into negotiations between sponsors and pharmacies in a way that is inconsistent with the statutory non-interference provision as it has long been interpreted by CMS.
  + Compliance and Administrative Challenges. We are concerned that the RFI approach could potentially expose sponsors to compliance issues and challenges relating to the estimation of aggregate price concessions and then assignment of such payments to specific dispensing events. Also, similar to manufacturer rebates, we are concerned about the administrative costs and challenges in incorporating pharmacy concessions at POS. For example, the cost and resources required to update all pharmacy network contracts would likely be burdensome for plan sponsors and their contracted vendors.
  + Beneficiary Choice and Part D Program Costs. The mandate to include pharmacy price concessions in POS prices would preclude sponsors from using them to reduce premiums or otherwise benefit all plan enrollees. This will limit beneficiary choices for lower premium options and likely increase federal premium subsidies.

[20] NY Times, "Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher." (January 6, 2018). https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html?rref=collection%2Ftimestopic%2FHealth%20Insurance%20and%20Managed%20Care

B. Improving the CMS Customer Experience

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

In this section, CMS eliminates the current MA disenrollment period and replaces it with an open enrollment period (OEP), as required by the 21st Century Cures Act. The Proposed Rule also includes the 21st Century Cures Act prohibition on unsolicited marketing and mailing marketing materials to individuals eligible for the OEP. Furthermore, CMS proposes a "knowing" standard to effectuate the statutory provisions prohibiting marketing to eligible beneficiaries.

We understand that this "knowing" standard would protect a plan from the marketing prohibition when the plan does not know that the beneficiary is enrolled in an MA plan at the time. We support such an approach and oppose an alternative approach CMS noted, which would broadly prohibit marketing to all potential beneficiaries during the open enrollment period. However, we also believe the definition of unsolicited marketing for purposes of this OEP is unclear, and recommend that CMS issue sub-regulatory guidance that would further address this limitation.

3. Medicare Advantage Plan Minimum Enrollment Waiver (§ 422.514(b); Preamble p. 56431)

CMS proposes to remove the requirement that an MA organization receiving minimum enrollment waivers in its initial contract re-submit the waiver requests for the second and third years. Instead, plans would receive a waiver for a three-year period.

We are supportive of this change since, as CMS notes, an organization must have already demonstrated its capacity to bear the necessary risk for the first three years when initially submitting the waiver.

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

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

AHIP strongly supports both of these changes. They would reduce unnecessary burdens, while continuing to provide beneficiaries with timely, relevant information in their preferred form.

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

CMS proposes to revise the definition of marketing and create a definition for communications. We understand that under the new definition of marketing, many member materials, including the EOC, subscriber agreements, and wallet cards, would no longer be considered marketing.

AHIP strongly supports this proposal. We believe it more appropriately distinguishes marketing materials from more general communication materials. However, we would appreciate more clarity on two issues. First, we understand that communications will not be treated like marketing materials, subject to submission to CMS before use. However, we recommend that CMS provide more clarity on what requirements would be applicable to these materials. Second, although CMS has outlined in the proposed regulatory text a list of marketing materials, that list is not exhaustive. We would appreciate sub-regulatory guidance that provides more details so that plans are able to determine which materials would still qualify as marketing materials and therefore subject to review by CMS before use.

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

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

We support CMS's proposal to lengthen the adjudication timeframes from seven to 14 calendar days to establish consistency in the adjudication timeframes for payment requests and to ease administrative burdens.

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

CMS proposes to remove the plan requirement to notify a beneficiary when a case is forwarded to the IRE given that the plan notice duplicates the required Part C IRE notification to the beneficiary about receipt and review of the case. We also understand that this revision would not prohibit plans from sending additional notices to beneficiaries.

We support CMS's proposal to eliminate this requirement.

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

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

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

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

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

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

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

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

AHIP strongly supports the elimination of the provider and prescriber enrollment requirements, as the process raised serious beneficiary access and administrative burden issues. However, AHIP has several concerns with the preclusion list as proposed.

First, we believe there may be operational challenges around the creation and maintenance of the preclusion list. We urge CMS to provide more information about how the list will be created and maintained. For instance, it is unclear from the Preamble how the Office of the Inspector General

(OIG) exclusion list is separate or different from the preclusion list. AHIP recommends that CMS provide sponsors with clarifications on the process of creating and maintaining the preclusion list, followed by an opportunity to submit comments and feedback.

Second, AHIP recommends that CMS give prescribers the ability to appeal their designation as a precluded prescriber before they are placed on the preclusion list, instead of adopting the proposed approach of allowing for appeals after placement on the preclusion list. A finalized list would minimize administrative burdens and beneficiary confusion and, as noted below, we believe it eliminates any need for provisional fills.

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

AHIP is also concerned around the burdens of operating and administering the provisional fill policy. Due to the time and resources required to make necessary updates required to sponsors' and their contracted PBMs' IT systems, policies and procedures, and operational policies, AHIP believes that the 2019 start date would not be feasible. Therefore, if CMS were to retain the requirement, AHIP strongly recommends that the implementation date be delayed to a date determined to be feasible after consultation with sponsors and their contracted PBMs.

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

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

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

13. Reducing Provider Burden – Comment Solicitation (Preamble p. 56455)

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

For example, medical records are an important source of information that plans use to develop and target clinical management and quality improvement activities. For beneficiaries with multiple chronic conditions, plans use medical record information to coordinate care delivered across primary care providers and numerous specialists. Therefore, AHIP would have significant concerns with any barriers that CMS might impose in this area.

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

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

C. Implementing Other Changes

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

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

- Changing the calculation of the numerator of MLR to include all expenditures for fraud prevention;

- Clarifying that compliant MTM programs can be included in numerator; and
- Reducing MLR reporting to four data elements: Organization Name, Contract Number, Adjusted MLR percentage, Remittance Amount (if MLR is under 85 percent).

AHIP fully supports these proposed changes. Insurers' anti-fraud programs play a key role in contributing to improving the quality of health care for enrollees, while MTM activities are a critical tool for plans to improve medication adherence and outcomes.

Reducing reporting burden on the part of plans was one of AHIP's requests as part of the Request for Information that CMS issued with the 2018 Final Rate Notice/Call Letter. As such, AHIP very much appreciates the agency's desire to reduce reporting burden on MLR data. The four data elements that CMS proposes to collect on MLR will allow CMS to meet statutory obligations on MLR while not creating unnecessary reporting on the part of plans. We commend the agency for making this change.

3. Late Contract Non-Renewal Notifications (§§ 422.506, 422.508, 423.508; Preamble p. 56460)

CMS proposes to eliminate the use of late non-renewals. Under the proposed change, contracts that request contract non-renewals for the following year are treated as mutual terminations if the request is made after the first Monday in June.

While AHIP appreciates this clarification, we would ask that CMS further clarify how this policy impacts the notification requirements for members and/or other processes for non-renewing plans. That is, would the process be different if the non-renewal request is made after the first Monday in June vs. before the first Monday in June? We would encourage the agency to share this guidance with plans as soon as possible so that plans can notify their members appropriately in the case of a non-renewal or mutual termination.

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

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

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