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Matthew Eyles
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January 25, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CMS-4180-P; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses ("Proposed Rule")

Dear Administrator Verma:

America's Health Insurance Plans (AHIP) appreciates the opportunity to comment on this Proposed Rule, which is intended to lower prices for prescription drugs and out-of-pocket costs for seniors and other Medicare beneficiaries who are covered through the Medicare Advantage (MA) and Part D programs. As a result, the Proposed Rule is also intended to reduce the cost to hardworking taxpayers who fund those programs.

AHIP is the national association whose members provide coverage for health care and related services for millions of Americans. Our members include MA and Part D coverage providers that work hard to negotiate lower drug prices for the consumers we serve. AHIP and its members join you in your commitment to lower drug prices, supporting free market solutions that encourage both innovation and affordability.

Drug prices are out of control. This is not a subjective opinion; it is supported by recent media reports[1] about the behavior by branded drug makers from across the pharmaceutical industry to raise prices in January on their portfolio of medicines by an average increase of 6.3 percent, rates that far exceed rates of general inflation or even medical inflation. Why? Simply because they can, given their government-granted monopolies through the patent system. Many Americans, including Medicare beneficiaries, are having to make the tough choice between paying their bills and paying for the medications they need.

More than 45 million seniors and persons with disabilities have chosen to enroll in Part D to help them afford their prescription drugs. They include almost 20 million in MA plans that integrate Part D coverage and more than 25 million in standalone Part D plans. Despite exorbitant launch prices for new drugs and outrageous drug price increases on old medicines, Part D premiums have remained steady for many years due to the efforts of Part D plans to negotiate lower costs using tested and

[1] See, e.g., Reuters article from January 2, 2019: "Drug companies greet 2019 with U.S. price hikes." Accessed at: https://www.reuters.com/article/us-usa-drugpricing/drug-companies-greet-2019-with-u-s-price-hikes-idUSKCN1OW1GA

effective cost management and negotiating tools when available, and the unique underlying structure of the Part D benefit. Consequently, health insurance providers continue to deliver high rates of quality, value, and beneficiary satisfaction through their Part D and MA solutions.

AHIP supports provisions in the Proposed Rule that would allow Part D coverage providers to expand the use of clinically-appropriate, evidence-based medical management and formulary tools for certain high-cost "protected class" drugs and employ these tools for physician-administered medications covered by MA plans. For decades, these strategies and resources have been employed widely by commercial health plans, and have applied to most medications covered by Part D. They are proven to help ensure safe, effective care that improves health, reduces costs, and increases value for all Americans. CMS' thoughtful and targeted proposals would ensure continued access to prescription drugs through strong beneficiary protections; promote safe, appropriate, and cost-effective use and clinical best practices; reduce overutilization of off-label indications; and enable plans to negotiate lower prices on behalf of Medicare beneficiaries and taxpayers.

At the same time, the Proposed Rule raises some serious concerns, including:

- **The proposal to require that all possible pharmacy concessions be included in a Part D plan's point-of-sale "negotiated price" will not address the root cause of the pharmaceutical price and cost crisis, which is high drug prices and price increases driven entirely by drug manufacturers.** The proposal on price concessions would raise Part D bids, which will lead to higher premiums and/or reduced benefits for all 45 million seniors and persons with disabilities in Part D. It also would expand CMS' role in private contracting arrangements in an unprecedented way and likely have a chilling effect on the use of evolving and innovative performance-based contracts with pharmacies. Further, while CMS raises concerns about how pharmacy price concessions are included in Part D plan bids, the Part D bidding process is well proven, is subject to rigorous CMS oversight, and is a key reason we have a robust and competitive Part D marketplace.

- We share CMS' goal of providers and patients having better information at the point of prescribing about patient cost-sharing, including clinically-appropriate alternatives that are covered on plan formularies. However, the Proposed Rule would require Part D plans to implement electronic tools for exchanging this information before uniform standards have been developed by standard-setting organizations. **We believe standardization is critical for any exchange of healthcare information in a well-functioning electronic system. The proposal, if finalized, would inadvertently create significant burdens and duplication of efforts by plans and providers and hinder the development of these tools within Part D.**

Lastly, given the complexities of the drug distribution and payment system, we believe CMS would benefit from more frequent engagement with stakeholders outside of the formal regulatory process. For example, regular in-person meetings with Part D plan sponsors that permit a true exchange of ideas and feedback between and among CMS, health and prescription drug insurance providers, and/or other key stakeholders could help facilitate the development of practical solutions to lower drug costs.

Accordingly, we recommend that the agency explore development of one or more technical expert panels, as well as other regular interactions with stakeholders including prescription drug and health insurance providers. AHIP and our members look forward to working closely with CMS to achieve our shared goals of improving access, cost, and quality of prescription drug coverage.

Our attached comments offer specific recommendations for clarifications and changes needed to protect and improve Part D coverage and costs for beneficiaries and taxpayers. Seniors and people with disabilities deserve to know they can count on the stable benefits and reliable high-quality coverage that MA and Part D deliver. We look forward to our continued work together to ensure that Americans get the medications they need at a price they can afford.

Sincerely,

Matthew Eyles

Matthew Eyles
President and CEO

AHIP Detailed Comments on CMS Proposed Rule:
Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (83 FR 62152, November 30, 2018)

A. Providing Plan Flexibility to Manage Protected Classes [§423.120(b)(2)(vi)] (Preamble p. 62154)

Since the start of Medicare prescription drug coverage and launch of a new and untested benefit program in 2006, CMS has required all Part D plans to cover "all or substantially all" drugs in six protected classes: (i) anticonvulsants, (ii) antidepressants, (iii) antineoplastics, (iv) antipsychotics, (v) antiretrovirals, and (v) immunosuppressants. Now, starting in coverage year (CY) 2020, CMS proposes to provide Part D plans with certain formulary management tools currently unavailable for protected class drugs. At the same time, the proposal would maintain protections to ensure beneficiaries have access to the Part D drugs they need.[2] AHIP supports these proposals. Given nearly 13 years of Part D plan and beneficiary experience with protected class drugs, we believe CMS' proposals would provide plans with the ability to encourage safe, clinically appropriate, and cost-effective treatments as well as the leverage to negotiate lower drug costs with manufacturers. AHIP urges CMS to finalize the proposal largely as proposed. Our specific feedback and recommendations are discussed below.

1. *Concerns with Current Rules*

CMS seeks feedback on concerns around the cost and clinical management of protected class drugs under the current regulatory structure. In the January 2014 Proposed Rule, CMS noted that the open coverage of protected class drugs presents both "financial disadvantages and patient welfare concerns for the Part D program as a result of increased drug prices and overutilization."[3] CMS acknowledges that the rules impose substantial limits on Part D plans' ability to negotiate price concessions. These adverse impacts are exacerbated by drug makers promoting overutilization of off-label indications for protected class drugs. In fact, the Congress has clearly expressed its intent that the Secretary be able to evaluate both potential new exclusions as well as the categories and classes of concern, applicable under the protected class policy.[4]

CMS correctly points out serious concerns regarding overutilization of off-label indications among protected class drugs. For example, one study showed that 45.1 percent of prescriptions for antidepressants were used for an off-label indication.[5] Another two studies showed that chemotherapeutic drugs (antineoplastics) were used for off-label indications at a rate of 29 percent[6]

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[2] These beneficiary protections include mandated coverage of "significantly all" protected class drugs, application of the nondiscrimination clause, and beneficiary appeals and formulary exception requests. See also generally 42 CFR §423.120(b)(2): "Provision of an Adequate Formulary"
[3] 79 FR 1937.
[4] See §176 of MIPPA and §3307 of PPACA. In both instances, the Congress contemplates and permits the Secretary applying exclusions to the policy and reassessing the appropriateness of the specified categories and classes.
[5] Lai LL, et al. Prevalence and factors associated with off-label antidepressant prescriptions for insomnia. Drug Healthc Patient Saf. 2011; 3:27-36.
[6] Kalis JA, et al. Prevalence of off-label use of oral oncolytics at a community cancer center. J Oncol Pract. 2015 Mar; 11(2):e139-43.

to 30 percent.[7] Also, a study looking at off-label utilization for erythropoietin-stimulating agents found that more than half of utilization was for off-label indications, of which 83.2 percent were for indications unapproved by the FDA or unsupported by scientific evidence.[8] These statistics reinforce the importance of plans having medical management tools available to identify potential patient risk. AHIP shares CMS' concerns about the impacts of current protected class drug policies. Program data and recent analyses support the urgent need for reforms in this area. For example, in the preamble to the Proposed Rule, CMS acknowledges that its own analyses and an AHIP-commissioned report by Milliman[9] both support the conclusion "that Part D sponsors obtain substantially smaller rebates for protected class drugs than they do for non-protected class drugs."

Several data in the Milliman study show the depth of the impact of current protected class policies. For example, the study found that for the 2016 Part D drugs analyzed:

- only 13 percent of all 2016 protected class brand drugs analyzed had manufacturer rebates versus 36 percent of all brand Part D drugs; and

- among brand drugs that received rebates in 2016, rebates for protected class drugs averaged 14 percent of drug spend – significantly lower than rebate levels for drugs with direct brand competition (39 percent of drug spend).

CMS found that the allowed cost per days' supply increased at a higher rate for protected class drugs between 2015-2016 (24 percent versus 16 percent) and 2016-2017 (14 percent versus 0 percent). CMS also noted that all protected class drugs, on average, only receive a 6 percent discount compared to 20 to 30 percent in private markets.[10]

A recent analysis from the Pew Charitable Trusts shows that protected class drugs accounted for 20 percent of Part D spending in 2015 but only for 14 percent of prescriptions.[11] In fact, this finding was strongest for antineoplastics, antipsychotics, and antiretrovirals. AHIP believes these findings clearly show the negative impact that current protected class policies have on price negotiations for protected class drugs with manufacturers.

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[7] Conti RM, et al. Prevalence of off-label use and spending in 2010 among patent-protected chemotherapies in a population-based cohort of medical oncologists. J Clin Oncol. 2013 Mar 20; 31(9):1134-9.
[8] Seetasith A, et al. On-label and off-label prescribing patterns of erythropoiesis-stimulating agents in inpatient hospital settings in the US during the period of major regulatory changes. Res Social Adm Pharm. 2017 Jul - Aug; 13(4):778-788.
[9] "AHIP-Commissioned Milliman Study: Prescription Drug Rebates and Part D Drug Costs Analysis" cited at 83 FR 62157. See also https://ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf. CMS further cites the Milliman analysis as finding "brand drugs in the protected classes had the lowest portion of drugs with rebates as a percentage of gross drug costs for those drugs receiving rebates."
[10] Proposed Changes to Lower Drug Prices in Medicare Advantage and Part D. November 26, 2018. Accessed at https://www.cms.gov/blog/proposed-changes-lower-drug-prices-medicare-advantage-and-part-d
[11] Policy Proposal: Revising Medicare's Protected Classes Policy. March 7, 2018. Accessed at https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy

2. *Broader Use of Medical Management*

CMS proposes to expand plans' ability to use medical management for protected class drugs, including step therapy programs, combined with robust rules that protect beneficiaries and ensure clinically appropriate and timely access. CMS' objective is not to remove or change the current requirement that Part D plans cover substantially all drugs in each of the six protected classes. Rather, the proposal is designed to achieve several goals: allow plans to promote clinically appropriate use of protected class drugs; ensure Part D plans can limit protected class drug requirements to the relevant indications, thereby preventing manufacturers from skirting appropriate formulary management tools for other conditions; and promote the most cost-effective utilization of generic and brand protected class drugs.

Under the proposal, prior authorization and step therapy programs for protected class drugs would apply to the same extent as for other Part D drugs, relying on evidence-based and rigorous processes that ensure beneficiaries get the drugs they need. Thus, CMS would generally lift the current restriction on applying medical management tools to therapies of protected class drugs. Though step therapy would now be allowed, CMS indicates it would be unlikely to approve step therapy for enrollees stabilized on existing therapies. Protected class drugs would be covered by well-established exceptions processes and other beneficiary protections, including comprehensive review and approval of formulary designs and tools by CMS and by a Pharmacy & Therapeutics (P&T) Committee; CMS compliance reviews and audits; and a transitional supply policy for formulary changes. These processes ensure that Part D beneficiaries have clinically appropriate access to the drugs they need.

AHIP strongly supports the proposal. We commend CMS for proposing a targeted and balanced approach to expanding the use of medical management tools and techniques that Part D plans have widely used since the start of the program while ensuring beneficiaries maintain access to necessary medications. The use of medical management tools combined with strong beneficiary protections has a track record of success in Part D where more than 45 million enrollees are receiving comprehensive, high-quality drug coverage and report high satisfaction rates (85 percent) with their benefits.[12] Moreover, medical management tools have played a key role in helping Part D plans offer affordable coverage despite increasingly high drug prices.

Given the deep experience stakeholders have developed in applying patient protections and otherwise managing the Part D program, we believe this is an appropriate time for CMS to extend the use of broader formulary management tools and techniques to protected class drugs. The changes will promote clinical best practices, reduce overutilization of off-label indications, promote safety and cost-effectiveness, and save beneficiaries and taxpayers money. AHIP believes this proposal is critical to support the continued improvement of the Part D program, and we urge CMS to finalize the changes as proposed.

[12] See Medicare Today's 2018 Senior Satisfaction Survey for Part D services. Accessed at http://medicaretoday.org/resources/senior-satisfaction-survey/

3. *Exclusions for Certain New Formulations*

Under current regulations, Part D plans are generally not required to include new formulations of a protected class drug on their formularies if an older formulation is still available. For example, if a manufacturer introduces a more expensive, extended-release version of an immediate-release drug, plans would not be required to cover the new drug under the "substantially all" coverage standard that applies to protected class drugs. However, coverage of the new formulation is required if the manufacturer removes the original, less expensive formulation from the market. This latter rule can encourage manufacturer gaming, as companies use the protected class rules to force more expensive drugs onto formularies at the expense of cheaper, effective drugs that exist on the market. The Proposed Rule would address this problem by allowing plans to exclude the new formulation from their formulary (in the above example, the more expensive extended-release version) under the protected class rules. Other Part D formulary rules and processes, such as requirements concerning coverage of at least two drugs in each class or category and the exceptions process, would still apply.

AHIP supports this change and recommends that CMS finalize it as proposed. Manufacturer gaming leads to higher costs not only for Medicare beneficiaries but for taxpayers who help finance these benefits. AHIP also suggests that CMS work with Part D plans to explore potential changes to address other areas of concern involving manufacturer practices, e.g., in the evolving use of authorized generics.

4. *Exclusions for Drugs That Exceed Price Increase Thresholds*

The Proposed Rule would exempt a protected class drug from the "substantially all" coverage requirement and thereby allow a Part D plan to exclude the drug from its formulary if that drug's Wholesale Acquisition Cost (WAC) increases by more than the cumulative increase in the Consumer Price Index-Urban (CPI-U) over an applicable period. The proposal also addresses several operational and implementation details, including the applicable measurement periods and the timing for potential formulary exclusions.

AHIP supports the proposal. We believe it offers another opportunity to increase a plan's leverage to negotiate greater savings from manufacturers. It is particularly important to have such rules in place with respect to drugs that increase significantly in price for two main reasons. First, it would give plans the leverage to negotiate discounts in such cases. Second, the policy would likely create a disincentive for such high price increases in the first place.

Therefore, AHIP recommends that CMS finalize this policy largely as proposed. In addition, we offer the following perspectives and recommendations on several specific components of the proposal:

- We support CMS' proposal to use WAC and CPI-U. We believe they are both appropriate and reasonable measures, are transparent, and are indices that stakeholders have experience with in the Part D program. We also believe it is more appropriate for CMS to use the broad CPI-U index rather than the prescription drug component of that index. Use of the latter would essentially reward manufacturers for rising drug prices across the market. As overall drug prices rise, manufacturers would have a greater ability to increase protected class drug prices without pressure to negotiate concessions.

- CMS solicits comment on whether a Part D plan should be able to exclude from its formulary all National Drug Codes (NDCs) associated with a protected class drug when a single NDC increases in price beyond the cumulative CPI-U. AHIP supports this approach. A manufacturer is likely to increase its price for all formulations of a protected class drug. Extending the proposal to all NDCs will help plans negotiate deeper discounts for the appropriate formulation that best fits its formulary design and strategy.

- AHIP supports the proposal to have the applicable period for measuring price increases run from September 1 to August 31. We believe it would provide enough time for plans to negotiate with manufacturers and incorporate the results in their annual formulary submissions and bids.

- CMS envisions that each Part D plan would determine whether a drug exceeds the price threshold. AHIP recommends that CMS consider an alternative proposal under which CMS would monitor WAC increases, measure them against CPI-U, and provide a list for plans of drugs eligible for this provision. This approach would eliminate redundant plan functions, reduce program costs, streamline the process, and minimize potential errors and inconsistencies in measurement. Our members believe that if CMS were to release this list after August 31 and before the end of each calendar year, sufficient time would still exist for negotiation under the annual Part D bid cycle.

- Under the proposal, a Part D plan could exclude, for one plan year, a protected class drug that exceeds the price threshold. We recommend that CMS consider extending this exclusion period to at least two years. This would further discourage significant price increases and allow plans a greater ability to respond appropriately to significant price increases.

- CMS should consider allowing Part D plans to exclude not only the NDCs associated with a protected class drug, but all other protected class drugs offered by a manufacturer, if any of the manufacturer's protected class drugs are affected by this provision. Such a change would serve as an even stronger deterrent against manufacturers unreasonably raising drug prices.

- CMS should also consider applying this policy solution to any authorized generic drugs within protected classes, based on an adjusted inflation rate. Given the prevalence of authorized generics with high prices, and their rising cost, such a policy would also help moderate drug spending increases.

B. Prohibition Against Gag Clauses in Pharmacy Contracts [§423.120(a)(8)(iii)] (Preamble p. 62164)

The Proposed Rule incorporates the provisions of the "Know the Lowest Price Act of 2018" and prior CMS sub-regulatory guidance. It provides that a Part D plan cannot restrict a network pharmacy from informing enrollees about a prescription drug cash price that is below the cost-sharing or negotiated price amount for the same drug under the Part D plan. AHIP supported the Act and similarly supports CMS' proposal.

We also note that CMS – in the Prescription Drug Benefit Manual[13] – acknowledges the potential for cash prices to be below negotiated prices but indicates that the agency generally encourages enrollees to use the Part D benefit. According to CMS, in most cases a plan's negotiated price will be the lowest price available. Moreover, CMS notes the advantages of obtaining benefits through the Part D program, such as enrollees obtaining access to the plan's drug utilization review and other safety measures which help ensure they are protected from potential adverse drug interactions and other harms. AHIP believes it is important for beneficiaries to understand these advantages of the Part D program. Accordingly, we suggest it would be beneficial for CMS to work with Part D plans and other stakeholders to consider ways the agency might directly engage with Part D enrollees on this issue. CMS may also want to evaluate how often beneficiaries purchase prescription drugs outside of the benefit and potential adverse beneficiary impacts.

C. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards [§423.160] (Preamble p. 62164)

The Proposed Rule would require plans to implement, by no later than January 1, 2020, one or more electronic real-time benefit tools (RTBTs) capable of integrating prescribers' e-prescribing (eRx) and electronic medical records (EMR) systems. The RTBTs would be required to provide the prescriber with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information at the point of e-prescribing. The information must include certain specified data such as cost-sharing, clinically appropriate formulary alternatives when available, and any utilization management restrictions for each alternative. The preamble notes that a plan would "implement at least one RTBT of its choosing that is capable of integrating with prescribers' e-Rx and EMR systems." CMS is proposing to impose this requirement despite recognizing that no uniform standards have been developed for RTBTs. However, the agency notes it may consider retraction of this proposal for a future year if the policy detracts from efforts to build fully interoperable RTBT capabilities in the Part D program, a standard has been voted on by a standard setting organization, or there are other indications a standard would be available for use before January 1, 2020.

AHIP supports the goal of having interoperable RTBTs available to help inform the decisions of both prescribers and Part D beneficiaries. However, we have very strong concerns with the agency's proposal to mandate use of a technology before uniform standards have been established. Standardization in the exchange of healthcare information is a critical component of a well-functioning electronic system.[14] Thus, we do not support this proposal. If the proposal is adopted, we believe there is a serious risk that CMS would inadvertently create significant burdens and duplication of efforts by plans and other industry stakeholders. For example, it would require that Part D plans incur the costs associated with implementation of RTBTs that might shortly thereafter need to be replaced once standards are developed. This unintended consequence could create significant issues not only for plans, but for providers in terms of wasted costs, training time, or other

[13] Chapter 14, Section 50.4.2, Medicare Prescription Drug Benefit Manual.
[14] See Office of National Coordinator on Health Information Technology Report: "Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap." Accessed at https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf

resources. The costs and frustrations associated with an industry-wide implementation effort that is not uniform or strategic could actually hinder efforts to advance the development of RTBTs. AHIP believes CMS should engage with appropriate standard-setting organizations to complete the rigorous process of creating and approving standards.

In addition to our serious concerns about the proposal in concept, we have concerns about the actual scope of the proposal. The preamble language suggests the requirement would be satisfied by an RTBT that is interoperable with one eRx system and one EMR system. However, the proposed regulatory language is unclear on this issue. It could be interpreted to require Part D plans to offer an RTBT that is workable with all potential e-prescribing and EMR systems that their network prescribers utilize. Such an approach would be particularly problematic and burdensome.

If CMS does move forward with the proposal despite the burdens and concerns noted above, it would be critical to at least minimize the adverse impacts by clarifying that a plan would satisfy these requirements by implementing a single RTBT that is interoperable with just one eRx system and one EMR system.

Finally, we understand that the 2020 implementation date would not be practicable for many Part D plans. Plans must have sufficient time – typically at least 18 months – to assess, procure, design, develop, test, and implement technology-based systems. The additional time would also allow for more prescriber training and engagement, to increase the chance for successful and robust implementation of this policy. We recommend that if CMS does move forward with this proposal, a 2022 effective date would be more reasonable. This deadline would also make it far more likely that uniform standards could be developed sufficiently in advance to allow for the effective implementation of RTBTs.

D. Part D Explanation of Benefits [§423.128] (Preamble p. 62167)

The Proposed Rule would require that each explanation of benefits (EOB) include information about (i) cumulative negotiated price increases since January 1 of the current benefit year, and (ii) any therapeutic alternatives on the formulary that treat the same indication but have a lower out of pocket cost or negotiated price. In the preamble, CMS indicates that information about formulary alternatives need not be beneficiary-specific, though the agency would encourage that the EOB be customized to include information such as specific diagnoses and indications. CMS also notes that plans currently have the option to use existing notes field in the EOB to inform beneficiaries of price increases and alternatives.

AHIP supports CMS' goal to ensure beneficiaries have useful and practical information in an appropriate setting and manner. However, AHIP has several concerns with the proposal. First, this information could raise significant questions and confusion for beneficiaries and their prescribers, particularly when the EOB is received a significant time after a prescription has been obtained and dispensed. We believe therapeutic alternatives are best considered by patients with their prescribers or pharmacists at the point of prescribing or when prescriptions are filled. As noted, we support the development of RTBTs. We do not support CMS' proposal and strongly recommend against its

finalization by the agency. Instead, we recommend that CMS work with stakeholders on implementation of RTBT technology as the most effective way to assist decision-making.

Second, we understand that adding such information to EOBs by CY 2020 would be impracticable and burdensome for many plans. Adding such information to an EOB would require a significant amount of time and resources. Plans will need to develop a list of potential therapeutic alternatives for each covered Part D drug; implement a process for updating the list during the year; and develop, implement, and test other necessary systems changes. Accordingly, we urge CMS not to finalize this requirement.

E. Pharmacy Price Concessions in the Negotiated Price [§423.100] (Preamble p. 62174)

Current CMS regulations provide that "negotiated prices" at § 423.100 should include all price concessions from network pharmacies except those that cannot reasonably be determined at point of sale (POS). The negotiated price is used to determine a number of elements of the Part D benefit, such as beneficiary co-insurance amounts, the rate at which beneficiaries progress through various benefit stages, drug manufacturer coverage gap discount program obligations, and government low-income subsidy payments.

CMS is considering whether to finalize a proposal, for CY 2020 or later, that would eliminate the exception in the definition of negotiated price for concessions that cannot be determined at POS. For such concessions, the proposal would require that the negotiated price reflect the lowest possible reimbursement a pharmacy may receive for dispensing a Part D drug according to contractual terms negotiated and agreed upon by the plan and the pharmacy. While the Proposed Rule does not contain specific regulatory language, the preamble describes details of the proposal under consideration. In particular:

- The negotiated price would be reduced by potential fees and concessions that a pharmacy could end up paying to a plan after POS.

- The negotiated price would not be increased by potential incentive payments or other contingent amounts like quality bonuses that a pharmacy might receive from a plan after POS.

- If a plan ultimately pays a pharmacy more than the lowest possible contingent incentive amount (e.g., the pharmacy receives a bonus payment at the end of the year), the difference between the negotiated price at POS and the final payment would be reported as negative Direct and Indirect Remuneration (DIR).

- CMS is considering, and requests comment on, potential alternatives to the proposal. Issues include whether to exclude the manufacturer coverage gap discount program from this price concession change; whether to require that less than 100 percent of the price concessions be included in the negotiated price; and whether to establish some type of contracting metrics relating to pharmacy price concessions.

AHIP strongly opposes the proposal. Our key concerns relate to:

- **Faulty Rationale.** The proposal rests on unsupported criticisms of the incentive structure in the Part D program and fails to acknowledge that robust competition has allowed plans to deliver affordable, high-quality coverage to millions of beneficiaries.

- **Higher Premiums.** We have very serious concerns with government proposals that will increase premiums for 45 million seniors and persons with disabilities.

- **Contracting Interference.** We have serious concerns the proposal would significantly expand CMS' role in private contracting arrangements. The proposal will likely have a chilling effect on the use of evolving and innovative performance-based contracts with pharmacies, and limit both the progress made and growth seen for performance-based arrangements over recent years. More fundamentally, the proposal is at odds with the overall structure of the Part D program, as reflected in the statutory "non-interference" clause. In addition, CMS suggests that such interference is justified in part by concerns that contracting arrangements can adversely affect pharmacy competition, but the agency offers no data or analyses to support this suggestion.

- **Substantial Burdens.** The proposal would create substantial burdens for plans by effectively creating two pricing mechanisms that must be monitored, followed, and reported. Not only will this create more complexity when monitoring and reporting drug reimbursements and DIRs, but it will significantly increase the resources spent by plans, thereby increasing Part D program costs.

- **Drug Maker Benefit.** The proposal would effectively lower the discounts that drug manufacturers would be required to pay in the coverage gap discount program, which we believe is inappropriate. Also, applying the new definition to the coverage gap discount program potentially runs afoul of statutory rules for the coverage gap discount program.

- **Potential Effective Date.** If CMS were to move forward with the proposal notwithstanding the numerous concerns raised in this comment, the technical and operational challenges would require an implementation date after CY 2020.

Our concerns and recommendations are addressed in more detail below.

1. *The Incentive Structure in the Part D Program Works*

CMS' primary concern appears to stem from its view of the Part D risk-based payment structure. Plans submit bids seven months prior to the start of a coverage year, which reflect the estimated cost of delivering the benefit. A significant portion of plan payments are capitated, providing per member monthly plan payments based on these bids. Part D plans must take full symmetrical risk (i.e., both upside and downside) within a certain range. Both CMS and plans share the risk for gains above and losses below this range. This structure not only allows plans to avoid excessive profits or losses, but also ensures stability in the Part D program.

CMS' symmetrical risk structure incentivizes plans to engage in activities that reduce costs, which in part has led to low and stable premiums since the start of the Part D program. However, CMS now seems to believe this structure, in its own words, reflects "distorted incentives" and exposes a flaw in the system. CMS points to the trend of plans typically receiving slightly higher price concessions than estimated in bids as proof of such "distorted incentives." CMS takes issue with another similar design of the Part D benefit, suggesting that high government liability in the catastrophic phase, which is higher than other parts of the benefit, creates weak or no incentives for Part D plans to provide lower prices at POS for their enrollees.

AHIP strongly disagrees. The Part D program should be viewed as a model for expanding health coverage in a cost-effective way through competition, flexibility, and innovation. The program incorporates a private-public partnership for delivery of coverage that has a track record of success and bipartisan support. The Part D risk sharing structure has been a key reason for beneficiaries enjoying competitive prescription benefit choices with low premiums, taxpayers being responsible for lower costs, and enrollees having high levels of satisfaction since the program's inception in 2006. Rather than distorting behavior, the Part D payment structure, including symmetrical risk corridors, incentivizes cost-effective delivery of drug benefits, which reduce bids and save taxpayers money.[15]

Further, CMS' assessment of bid trends fails to consider the following critical facts that undermine the agency's views.

- **CMS Approves Bids.** Every component of a plan's bid – including estimates about future pharmacy concessions – is based on the plan's prior year experience and actuarially supported cost projections as the bid is reviewed and approved by a certified actuary. The bid is then, again, rigorously reviewed and approved by CMS' Office of the Actuary to ensure that strict standards, regulations, and guidelines set by the federal government are met. In other words, CMS is not a passive observer of data and trends; CMS plays an active and critical role in this process. If CMS determines that a bid does not reflect an actuarially sound estimate of the coming year's pharmacy costs and concessions, it will not approve the bid. Accordingly, CMS' proposals to address bid estimates are entirely unnecessary. CMS can preemptively and quite easily remedy any calculation or estimate it determines to be inappropriate through current oversight and approval processes.

- **Bid Estimates Are Improving.** In a recent *Wall Street Journal* article, the agency states that recent data suggests Part D bid estimates continue to get closer to actual costs.[16] This reinforces the clear absence of any inherent structural problem. Instead, the Part D program uses risk sharing payment processes that rely heavily on actuarial projections based on past

[15] According to the 2018 Trustees report, the symmetrical risk corridor program brought a net savings of $9 billion to the government over the last 12 years (2006 – 2017). The Trustees report also projects that the program will bring another net savings of $8.5 billion over the next 9 years (2019 – 2027).
[16] 'CMS, the Medicare agency, said recent data "suggest that, on average, plans' estimates of future costs in their bids are closer to their actual costs, resulting in a significant decline in revenue retained by Part D plans."' https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082

experience. It is not a fee-for-service program that pays for each item and service delivered, thereby encouraging higher costs and wasteful utilization. Also, when actuarial projections are involved, one would expect continued incremental improvements as the program matures. Given the relatively recent introduction of performance-based contracting with pharmacies, it would not be surprising if similar trends occur for pharmacy concession estimates.

- **Medical Loss Ratio Requirement Applies.** CMS fails to acknowledge another important check placed on plans. Under current medical loss ratio (MLR) requirements, margins and other non-claims expenses that exceed a certain threshold must be returned to the government. These MLR standards act as a separate check on any improper estimates in bids.

- **Risk Corridors Save Taxpayers Money.** The 2018 Trustees Report indicates that the risk structure has brought net savings of nearly $9 billion to the government since the start of the program.

We also take strong issue with CMS' suggestion that the Part D benefit structure incentivizes plans to favor higher POS prices because of the Part D benefit design. AHIP's members are incentivized to negotiate low net drug costs for consumers, employers, the government, and other parties. The competitive Part D environment fully incentivizes plans to design and offer competitive and attractive benefits, negotiate lower costs to allow for lower premiums, and thereby attract more enrollees. Importantly, this formula for success does not change or waver depending on how the benefit incorporates rebates, discounts, and other concessions. Rather, a plan's ability to lower costs through competitive negotiation and innovative formulary management directly determines its level of success.

In summary, AHIP believes that current plan payment structure applies appropriate incentives and allows for appropriate oversight (including active CMS approval of bid projections) to ensure that private market innovation delivers competitive and meaningful choices to beneficiaries and financial savings to taxpayers. We have serious concerns that CMS' assertions in support of the proposal fail to adequately consider these facts and could undermine the overall success of a program built on a private-public partnership and robust competition.

2. *CMS Should Not Raise Premiums*

CMS notes that, under current rules, pharmacy concession estimates reduce pharmacy cost estimates as reflected in Part D bids. Lower costs in bids translate into lower premiums. CMS acknowledges that average Part D basic beneficiary premiums have grown at an average rate of only about 1 percent per year between 2010 and 2017 and have declined each year since 2017, due in part to current Part D payment structures. In fact, CMS estimated that premiums would decline by 3 percent to $32.50 per month in 2019 for the basic Part D benefit. Overall, Part D premiums have remained far below initial projections from the Congressional Budget Office.

This stability has continued even as drug prices remain out of control. A June 2018 report from the HHS Office of Inspector General found that costs for brand-name drugs in the Part D program rose nearly six times faster than inflation from 2011 to 2015.[17] The agency also notes how Medicare direct subsidies have declined, by an average of 9.4 percent per year between 2010 and 2017, partly for the same reasons.

Though data clearly suggest that plans should continue to keep premiums low and affordable, CMS wants to change course with its proposal. CMS concedes its proposal would raise beneficiary premiums by an estimated $4.7 billion and increase government costs by $13.6 billion over the next 10 years. We believe that keeping premiums low and affordable for the 45 million beneficiaries who rely on the Part D program is critically important. Rather than pursuing policies that it acknowledges will raise premiums, CMS should instead focus on disincentivizing manufacturers from setting high prices and increasing them at exorbitant rates, thereby making prescription drugs affordable for everyone (for example, by providing more plan flexibility in managing drug cost and utilization for Part B and protected class drugs).

3. *The Non-Interference Clause Must Remain the Cornerstone of the Part D Program*

AHIP is concerned that this proposal moves CMS policies too far from the original design and vision of the Part D program. The non-interference clause has been a cornerstone of the Part D program's success. It balances the need for reasonable federal government oversight and the need for fostering competition and innovation that can only exist with a private market-based system. AHIP is concerned that further, incremental increases in government restrictions will have serious and lasting consequences on the Part D program, perhaps putting the program's long-term success at risk.

In fact, several elements of the proposal raise concerns. At its core, the proposal is designed to directly affect the contracting processes between plans and pharmacies by directly changing POS prices. Rather than allowing plans to negotiate freely to design the most attractive package of benefits that will increase enrollment and satisfaction of the customers they serve, CMS seems to suggest that it should decide what negotiated package is most appropriate for the industry and its 45 million beneficiaries throughout the country. CMS seems to be espousing a troubling and entirely misplaced distrust of the private health care system, especially given the success of the Part D program and high satisfaction rates of enrollees.

Further, CMS indicates it is considering whether to require the use of standardized pharmacy metrics in performance-based arrangements with pharmacies. Such a step would directly limit competitive negotiation between a plan and pharmacy, once again conflicting with the purpose of the non-interference clause. Though there may be some benefit to having a measure developer experienced with pharmacy metrics (e.g., Pharmacy Quality Alliance) develop metrics for use as market participants individually see most beneficial, we do not support the required use of such measures in contracts.

[17] See OIG Report (June 2018): "Increases in Reimbursement for Brand-Name Drugs in Part D." Accessed at: https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf

Also, CMS appears to justify its proposal by stating that the growth of quality-based price concessions "creates competition concerns by discouraging independent pharmacies from participating in a plan's network and thereby increasing market share for the plans' or PBMs' own pharmacies." We are troubled by this statement, especially because CMS makes such assertions in the absence of any supporting data or analysis that would suggest there actually is a competitive problem. We are also concerned about the suggestions about plan intentions that underlie CMS' assertions. Plans negotiate vigorously to reduce drug costs for over 45 million Part D enrollees and lessen the financial burden placed on taxpayers. We urge CMS to not consider policies that might advantage particular stakeholders and instead continue the focus on our shared goals of best serving seniors and persons with disabilities who rely on the Part D program.

4. *Increased Burden and Confusion for Plans, Pharmacies, and Beneficiaries*
The burden and confusion created by this proposal will impact a plan's ability to effectively and efficiently administer benefits and will have a chilling effect on performance-based arrangements with pharmacies. First, the Proposed Rule would effectively require plans to create and monitor two different prices: (i) the actual reimbursement amount that plans negotiate with pharmacies to pay during the year, and (ii) the negotiated price for benefit purposes. Both prices would be monitored at POS and retrospectively when reconciling DIR reports. This will create significant burdens for plans, increase Part D administrative costs, and usurp resources that could be spent on improving the quality and value of care Part D beneficiaries receive at the pharmacy.

5. *Manufacturers Should Not Receive Almost $6 Billion in Funding, Financed by Seniors and Taxpayers*
The Proposed Rule estimates that the new definition of negotiated price would lower drug manufacturer liability by an estimated $4.9 billion over the next 10 years, or by $5.8 billion if the new definition applies under the coverage gap discount program. We believe this is a further reason why CMS should not finalize the proposal. It would be inappropriate to implement a policy that lowers drug manufacturer liability by billions of dollars while at the same time increasing costs for seniors, persons with disabilities, and taxpayers.

However, if CMS were to move forward with this proposal, we urge CMS, at a minimum, to not apply the new definition of negotiated price to the coverage gap discount program. CMS notes that "we do not believe it would be appropriate to require plans to include all price concessions in the negotiated price for purposes of the coverage gap discount program." We strongly agree. CMS should retain separate definitions of negotiated price in 42 CFR §423.100 and §423.2305. This, at least, would reduce the relief for the pharmaceutical industry by $0.9 billion. We also believe this distinction is mandated by statute, given the specific statutory definition of negotiated price that applies for coverage gap discounts.[18]

6. *Effective Date Must be Workable*
CMS suggests that it could make the proposal effective as early as 2020, a date that is clearly impracticable. By the time CMS finalizes a rule, there would not be nearly enough time for Part D

[18] SSA §1860D-14A(g)(6) cites to the definition of negotiated price used in 42 CFR §423.100 as of March 23, 2010, which is currently codified at 42 CFR §423.2305.

plans and their contracted pharmacy benefit managers to review and assess the provisions of a final rule, engage with pharmacies on potential contracting changes, and determine how to incorporate those provisions into 2020 bids. Moreover, we believe it would be appropriate under the Administrative Procedures Act (APA) for CMS to issue a proposed rule that incorporates specific regulatory language and allows stakeholders the opportunity for comment before finalizing any change in policy, a process which would render a 2020 effective date impossible.

To reiterate, we strongly object to the proposal and urge CMS not to adopt it. However, if CMS were to move forward with such a rule despite the serious concerns noted above, the effective date should be no earlier than the calendar year beginning two years after the rule is finalized through rulemaking that is compliant with the APA. For example, if finalized in CY 2019, the rule should not take effect any earlier than CY 2021.

F. Medicare Advantage and Step Therapy for Part B Drugs [§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619] (Preamble p. 62168)

The Proposed Rule would codify, with certain modifications, prior sub-regulatory guidance[19] that allows Medicare Advantage (MA) plans to implement step therapy requirements involving Part B covered drugs. This allows MA plans to utilize tools permitted in commercial plans, which cover a large portion of the U.S. population, and in the Part D program, allowed since the program began in 2006. These step therapy provisions provide more flexibility to MA plans to encourage the use of certain clinically appropriate, cost-effective drugs, thereby enhancing the limited leverage plans currently have in attempting to negotiate discounts with drug makers. This flexibility also would extend to integrating step therapy requirements across Part B and Part D-covered drugs (i.e., a Part B or D drug required before coverage of a Part B drug; or a Part B drug required before coverage of a Part D drug).

Importantly, the proposal would ensure that robust beneficiary protections apply to step therapy for Part B drugs in ways that are aligned with existing protections for Part D drugs. This would include similar timeframes as in the Part D program for coverage determinations; an exceptions process that includes various levels of internal, independent, and government reviews so enrollees can obtain coverage without regard to step therapy requirements when needed; and limiting step therapy to new starts rather than existing therapies. Other elements of the proposal include requiring that MA plans use a P&T Committee for the review and approval of any step therapy program involving a Part B drug, clarifying the use of a 108 day "lookback" period to identify ongoing Part B therapies that will be exempt from step therapy programs, and requiring plans to disclose that Part B drugs may be subject to step therapy in the explanation of coverage and annual notice of change documents.

AHIP very strongly supports the proposals. We commend CMS for strengthening the ability of private sector plans to implement market-based solutions that can lower drug costs for enrollees and lessen financial burdens for taxpayers. As noted by CMS in the preamble, the approximately $12 billion spent on Medicare Part B drugs represents a significant lost opportunity to negotiate

[19] HPMS memo, "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," August 7, 2018 See also, "Part B Step Therapy FAQ document," August 29, 2018.

concessions from manufacturers, ensure Part B drugs are utilized for clinically appropriate indications, and to promote the use of cost-effective treatments. Further, step therapy would provide MA plans with another evidence-based medical management tool, in addition to tools such as disease management and care coordination, that is important for the continued success and stability of the MA program.

We also strongly support the proposed beneficiary protections, which are a critical component of the proposal. These protections ensure patients can have confidence they will have access to safe, effective, and evidence-based care. And we agree with CMS about the importance of MA plans and providers working closely to adopt best practices that streamline requirements and minimize burdens. MA plans are committed to the development and advancement of such processes and policies and to working with providers to address potential concerns.

However, given the short timeline MA plans will have to implement this policy, we are concerned with the lack of clarity on how to incorporate various elements of the care coordination program (e.g., beneficiary incentive rewards) as they look to the upcoming bid application cycle. In light of the short timeframe between finalizing the rule and the deadline for CY 2020 bid submissions, we expect and would appreciate CMS' prompt release of additional guidance and update of relevant Medicare manual chapters that clarifies the various aspects of implementation to maximize the time plans have to plan, design, and implement prior authorization and step therapy programs and incorporate them into their bid applications for CY 2020.

Additionally, we advise that CMS not impose restrictive requirements onto plans for the "education and information responsibilities in combination with existing regulations on care coordination." Instead, CMS should take the approach it proposes on beneficiary protections – to align policies, procedures, and guidance for Part B drugs with those of Part D drugs. As such, we recommend that CMS not consider any requirements that go beyond those applicable for Part D drugs.