

January XX, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS—4180—P, Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses; Proposed Rule (Vol. 83, No. 231), November 30, 2018.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed regulation to modernize Medicare Part D (Part D) and Medicare Advantage (MA) programs to lower drug prices and reduce out-of-pocket expenses. The AHA has long advocated for increased scrutiny over drug manufacturers' continued efforts to maximize profits at the expense of consumers and taxpayers, and **we continue to commend the Administration for its focus on reining in drug prices for patients and the health care providers who serve them.**

The agency proposes a number of changes to both the MA and Part D programs aimed at increasing plan negotiating power to lower drug prices. Specifically, the rule proposes flexibility around the six protected classes of Part D drugs, as well as changes to the Explanation of Benefits (EOB) and e-prescribing requirements. Additionally, CMS proposes to make permanent the option to utilize step therapy for Part B drugs under MA plans, and seeks comment on the possibility of redefining the term “negotiated price” as it applies to pharmacy concessions.



High drug prices create access barriers for patients and is a growing problem in the Part D program. In 2016, 3.2 million beneficiaries reached the Part D catastrophic phase¹, a significant portion of whom do not receive low-income subsidies to help cover rising costs. A recent analysis by Avalere found that the number of Part D beneficiaries to reach the catastrophic coverage phase who do not qualify for low-income subsidies increased by more than 50 percent from 2013-2016.² In 2016 alone, “more than 800,000 Part D enrollees without low-income subsidies entered the catastrophic coverage phase, compared to approximately 515,000 in 2013.”³ As costs to beneficiaries continue to grow, with a primary driver of increased cost being expensive specialty drugs, Part D plans need additional tools to ensure that beneficiaries can afford their medications.

Our specific comments follow.

FLEXIBILITY FOR PART D PROTECTED CLASS DRUGS

The agency proposes to provide Part D plan sponsors with greater flexibility around the six classes of protected drugs. Under current policy, plans must cover all drugs in the six classes: antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics. The intent of this policy was to prevent plans from designing benefit plans that could discriminate against certain high-cost beneficiaries. As the agency notes in the preamble, the protected class policy is unique to Medicare and does not exist in any other government program or commercially available plan. While legitimate justifications for the policy remain, including preventing plans from discriminating against potentially higher-cost beneficiaries, there are other mechanisms the agency can deploy to monitor patient access to care.

The proposed rule would provide three exceptions to the current rules allowing Part D plans to exclude certain drugs from their formularies with the objective of negotiating lower drug prices, benefitting both beneficiaries and taxpayers. The three newly created exceptions include the utilization of prior authorization and step therapy for Part D drugs; the option to exclude a specific drug from its designated protected class if the current drug does not provide a unique route of administration and is merely a new version of an already existing single-source drug or biologic product; and the option to exclude a specific drug if certain price increase provisions are triggered. CMS specifically seeks comment on several elements of this proposal, including the overall impact of the policy on Part D enrollees, the process for and length of exclusion, and if there are specific patient groups that require additional safeguards. While the protected

¹ <https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-lower-drug-prices-medicare-part-d-and-transformative-updates-existing-model>

² <https://avalere.com/press-releases/more-medicare-part-d-enrollees-are-reaching-catastrophic-coverage>

³ *Id.*

class policy has been an important tool to prevent discrimination, we agree that it is important to reevaluate these requirements in light of changes in the health care industry, and more specifically, unsustainable and continued increases in drug prices.

The agency's proposals will help plans protect beneficiaries from egregious price hikes and high prices for older drugs that have simply been repackaged and patented as a new and improved product. By giving Part D plan sponsors the option to exclude drugs with price increases beyond the rate of inflation, the agency would create a strong incentive for manufacturers to avoid these actions. The second change would address instances where drug manufacturers modify an existing drug slightly and obtain a new patent. When this occurs, and the older formulation is no longer on the market, Part D plans must cover the new, more expensive version of a drug without the new drug proving any advancement in the efficacy of the drug or other benefits. By allowing Part D plans to exclude those newer, more expensive formulations, even if the older formulation is not available, CMS would not only be protecting beneficiaries and taxpayers from unnecessary, excessive costs, but would also be creating a disincentive for drug manufacturers to pursue this tactic.

Increasing the negotiating power of Part D plan sponsors will support plans in achieving lower prices on these drugs. As the agency notes, protected class brand drugs receive fewer rebates at lower discount levels than those drugs not covered under one of the six protected classes. **The AHA supports this policy insofar as the agency conducts rigorous oversight to ensure protection from abuse.** In particular, CMS's proposed three-pronged approach, utilizing prior authorization and step therapy, as well as two potential class exclusion options when applicable, will help modernize the way in which Part D operates.

In considering these proposed changes to Part D, we acknowledge the potential for plan sponsors to exclude drugs on which certain patients rely. Because of this, we urge the agency to monitor beneficiary access to care, as well as to ensure that plans have not designed products that disincentivize enrollment by potentially higher-cost enrollees. Further, while plans are *not required* to exclude those drugs that meet one of the three criteria, there is the likelihood that they will in order to achieve lower drug prices. Therefore, we further urge CMS to include provisions in the final rule that provide for plan coverage of a drug, even if it is excluded, if the prescription is deemed medically necessary for a specific patient. In addition to the assurance of coverage due to medical necessity, we expect the agency will continue to protect patients in need of certain drugs through a robust and timely appeals process.

UTILIZATION OF STEP THERAPY FOR MA PART B DRUGS

The agency proposes to codify an Aug. 7, 2018 change in policy to expand MA plans' existing authority to implement various utilization management tools. Specifically, the change would allow MA plans the option of requiring beneficiaries to try more cost-

effective Part B drug therapies before progressing to more expensive options. Additionally, CMS intends to require MA plans to disclose the possibility of subjecting beneficiaries to step therapy and modifies the appeals process and truncates adjudication timelines to protect those individuals who may need a certain drug due to medical necessity. **The AHA supports efforts to increase bargaining power when negotiating with drug manufacturers, which can lower the overall cost of drugs to enrollees and increase access to critically important medications and trials. However, we again emphasize the importance of strong patient protections to ensure continuity of care, the application of medical necessity, an expedited appeals process, and required review and approval of MA step therapy plans by respective Pharmacy and Therapeutic Committees.**

INCREASED TRANSPARENCY IN DRUG PRICES

E-Prescribing and the Part D Prescription Drug Program. CMS proposes to accelerate the use of electronic Real Time Benefit Tools (RTBTs) by requiring Part D plan sponsors to implement a RTBT to inform prescribers of beneficiary-specific drug coverage and lower-cost therapeutic alternatives available to the enrollee by 2020. **The AHA is supportive of CMS's decision to require Part D plans to use RTBTs.** Providing prescribers and beneficiaries access to information, like a beneficiary's out-of-pocket costs in real time, represents another important step in increasing drug price transparency. **As the agency moves forward with these provisions, we urge action to ensure that selected RTBTs are capable of integrating with the EHR and e-prescribing systems** that prescribers use, without adding burden or disruption to prescribers' work, as this is critical to the overall effectiveness of this proposal.

Changes to Part D EOBs. The agency intends to require sponsors to include information about changes in drug prices and lower-cost therapeutic alternatives in Part D EOBs. These are commonsense changes that will help to provide patients with more information about their prescription drug costs, as well as alternative options that may be available to them. **While we agree that this change will provide important information to beneficiaries, we urge the agency to clarify whether each patient's EOB would provide patient-specific data or not.** In the absence of patient-specific EOBs, we have some concern with the potential for confusion among patients as to which alternative therapies apply to their specific situation, and urge CMS to ensure that plan sponsors be able to help beneficiaries navigate the EOB. We agree with the agency that the frequency at which EOBs are sent to beneficiaries should allow timely, more comprehensive information for patients as they make decisions regarding their prescription drug needs.

Thank you for allowing us to share our comments. Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director, policy, at mhowell@aha.org or (202) 626-2274.

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Sincerely,

/s/

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